Tuberculosis Care with TB-HIV Co-management

INTEGRATED MANAGEMENT OF ADOLESCENT AND ADULT ILLNESS (IMAI)



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This is one of six IMAI and IMCI guideline modules relevant for HIV care:

- IMAI Acute Care
- * IMAI Chronic HIV Care with ARV Therapy and Prevention
- IMAI General Principles of Good Chronic Care
- IMAI Palliative Care: Symptom Management and End-of-Life Care
- IMAI TB Care with TB-HIV Co-management
- IMCI Chart Booklet for High HIV Settings

This guideline module is for use in caring for patients with TB disease at first-level health facilities (health centres and the clinical team in district outpatient clinics) in countries with high burden of HIV. It addresses the care of both HIV-positive and HIV-negative patients with TB disease.

It is based on the STB training course and reference booklet *Management of Tuberculosis: Training for Health Facility Staff WHO/CDS/TB/203.a-1* and the following WHO normative guidelines issued in 2006: Antiretroviral therapy for HIV infection in adults and adolescents: Recommendations for a public health approach; Guidance for national tuberculosis programmes on the management of tuberculosis in children; and *Tuberculosis infection control in the era of expanding HIV care and treatment: Addendum to "WHO guidelines for the prevention of tuberculosis in health care facilities in resource-limited settings", 1999.*

It assumes that health workers can consult with or refer to a doctor or medical officer for clinical problems, either on-site (if working in a team in the outpatient department of the district hospital) or by established methods of communication. It also assumes there is a trained district TB coordinator. The IMAI Second-Level Learning Programme addresses TB-HIV co-management including TB-ART co-treatment by the doctor or medical officer. The district TB coordinator can be trained using the TB district coordinator course: *Management of Tuberculosis Training for District TB Coordinators WHO/HTM/TB/2005.a-n.*

The other IMAI guideline modules are cross-referenced in this module and also contain guidelines relevant to TB-HIV care. Training materials for their use are available.

Integrated Management of Adolescent and Adult Illness (IMAI) is a multidepartmental project in WHO producing guidelines and training materials for first-level health facility workers in low-resource settings.

For more information about IMAI, please see http://www.who.int/hiv/capacity/ or contact imaimail@who.int. For more information about global TB/HIV initiatives, see http://www.stoptb.org/wg/tb_hiv/ or http://www.who.int/tb/hiv/en/.

WHO HIV/AIDS Department—IMAI Project

WHO Stop TB Department- TB/HIV and Drug Resistance Unit and Tuberculosis Strategy and Health Systems Unit The management at the first-level facility of **any patient with TB** is addressed by this module. Unless otherwise specified, in this document "TB" refers to TB disease and not TB infection.

The order of the sections of this module corresponds to the order of the steps in the management of a TB patient.

Some parts of this module apply to all patients with TB. These may be HIV-negative or HIV-positive TB patients.

Some parts of this module apply only to patients who have TB and HIV, meaning a patient with TB who tests positive for HIV, or an HIV-positive patient who develops TB.

Throughout this module, the following symbol indicates that a section applies to patients who have both TB and HIV:



If you are managing a TB patient who does not have HIV, you can go through the guideline module and use the sections without the symbol. If you are managing a patient with TB and HIV, you will need to use all of the sections.

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Diagnose TB or HIV

A1 Diagnose TB and determine the disease site

A1.1 Identify TB suspects

In all patients presenting for acute care and during chronic HIV care, it is important to review TB status on each visit

14	F	
H	Þ.	
I.		

Then

Cough > 2 weeks or persistent fever, unexplained	 Send sputum samples. Refer to district doctor/ medical officer if not producing sputum or if nodes are present.
weight loss, severe undernutrition, suspicious lymph nodes (> 2 cm), or night sweats.	 If referral is not possible and the patient is HIV- positive or if there is strong clinical evidence of HIV infection, first-level facility clinician should use pages 9 to 11 to diagnose smear-negative pulmonary TB if not producing sputum and should diagnose suspected extrapulmonary TB.
	Recommend HIV test in all suspected TB patients.

HIV-positive patients are more likely to be very ill when they present with possible TB disease. Consider the clinical condition of the patient (use the *IMAI Acute Care* guideline module). If the patient is severely ill, refer immediately to hospital. Don't wait for sputum results.

If referral is not possible and the serious illness is thought to be caused by extrapulmonary TB, prompt treatment should be initiated and every attempt should be made to confirm the diagnosis to ensure that the patient's illness is being managed appropriately. See *IMAI Acute Care* guideline module for further guidance on when to suspect extrapulmonary TB.

If additional diagnostic tests are unavailable and if referral to a higher level facility for confirmation of the diagnosis is not possible, TB treatment should be started and completed. Empiric trials of treatment with incomplete regimens of anti-TB drugs should not be performed. If a patient is treated with anti-TB drugs, treatment should be with standardized, first-line regimens, and it should be completed. Treatment should only be stopped if there is bacteriological, histological, or strong clinical evidence of an alternative diagnosis.

A1.2 Determine whether the patient has TB disease

TB diagnosis based on sputum smear microscopy examination*

HIV-positive patients are more likely than HIV-negative patients to have extrapulmonary TB or smear-negative pulmonary TB.

lf	Then		
Two (or three) samples are positive	Patient is sputum smear-positive (has infectious pulmonary TB)		
Only one sample is positive in HIV-negative patient	Diagnosis is uncertain . Refer patient to district doctor/ medical officer for further assessment.		
Only one sample is positive in HIV-positive patient	Patient is sputum smear-positive (has infectious pulmonary TB)		
All samples are negative in HIV-negative patient	 Patient may or may not have pulmonary tuberculosis: If patient is no longer coughing and has no other general complaints, no further investigation or treatment is needed. If still coughing and/or having other general complaints (and not seriously ill), treat with a non-specific antibiotic such as cotrimoxazole or amoxicillin. If cough persists and patient is not severely ill, repeat examination of three sputum smears. If sputum negative, refer patient to a doctor/medical officer. 		
All samples are negative in HIV-positive patient	 Patient may or may not have pulmonary tuberculosis: If cough persists, treat with non-specific antibiotic such as cotrimoxazole or amoxicillin and refer for evaluation for possible smear-negative pulmonary TB or other chronic lung/heart problem. 		

* The number of sputum samples examined will depend on national guidelines. For high HIV settings, two sputum samples are recommended, usually one early morning specimen which should be brought to the clinic, and a second "spot" specimen produced at that time.

HIV-positive patients are more likely than HIV-negative patients to have extrapulmonary TB or smear-negative pulmonary TB. If sputum smears are negative and the patient is HIVpositive, refer to a doctor/medical officer for further testing. Where referral is not possible, the first-level facility clinician should make these diagnoses when possible. When it is not possible to confirm the HIV status of the patient (due to lack of HIV test or refusal to be tested) the patient should be considered as if s/he were HIV-positive.

- -

In all patients in HIV prevalent settings (see definition): Do you have cough or difficult breathing?

·		
IF YES, ASK:	LOOK AND LISTEN	Classify
 For how long? 	 Is the patient lethargic? 	in all
 Are you having chest pain? 	Count the breaths in one	with
- If yes, is it new? Severe?	minute—repeat if elevated.	cough
Describe it.	 Look and listen for wheezing. 	
 Have you had night sweats? 	 Determine if the patient is 	
 Do you smoke? 	uncomfortable lying down.	
Are you on treatment for a chronic lung or heart problem or TB2 Determine if	Measure temperature.	
 a chronic lung or heart problem, or TB? Determine if patient diagnosed as asthma, emphysema or chronic bronchitis (COPD), heart failure or TB. Have you ever been treated for TB before? If not, have you had previous episodes of cough or difficult breathing? If recurrent: Do these episodes of cough or difficult breathing wake you up at night or in the early morning? Do these episodes occur with exercise? Are you HIV-positive or do you think you might be? 	If not able to walk unaided or appears ill, also: • Count the pulse. • Measure BP.	

AGE	FAST BREATHING IS:	VERY FAST BREATHING IS:	
5-12 years 30 breaths per minute or r		40 breaths per minute	
13 years or more	20 breaths per minute or more	30 breaths per minute or more	

Use this classification table in all patients with cough or difficult breathing:

SIGNS:	CLASSIFY:	TREATMENTS:
 One or more of the following signs: Very fast breathing High fever (39°C or above) Pulse 120 or more Not able to walk unaided Uncomfortable lying down Severe chest pain 	SEVERE PNEUMONIA OR VERY SEVERE DISEASE	 Position. Give oxygen. Give first dose IM antibiotics. If wheezing present, treat. If severe chest pain in patient 50 years or older, use Quick Check. If known heart disease and uncomfortable lying down, give furosemide. Refer urgently to hospital. If referral is not possible and patient is HIV-positive, see following page. Consider HIV-related illness. If on ARV therapy, this could be a serious drug reaction. See <i>Chronic HIV Care</i> guideline module.
 Two of the following signs: Fast breathing Night sweats Chest pain 	PNEUMONIA	 Give appropriate oral antibiotic Exception: if second/third trimester pregnancy, HIV clinical stage 4, or low CD4 count, give first dose IM antibiotics and refer urgently to hospital. If wheezing present, treat. If smoking, counsel to stop smoking. If on ARV therapy, this could be a serious drug reaction; consult/refer. If cough > 2 weeks or HIV-positive, send sputums for microscopy examination. Advise when to return immediately. Follow up in 2 days.
 Cough or difficult breathing for more than 2 weeks Recurrent episodes of cough or difficult breathing which: Wake patient at night or in the early morning or Occur with exercise. 	CHRONIC LUNG PROBLEM	 Send sputums for microscopy examination. Record in register. If sputums sent recently, check register for result. See TB diagnosis based on sputum smear microscopy examination (p. 9). If smoking, counsel to stop. If wheezing, treat. Advise when to return immediately.
 Insufficient signs for the above classifications 	NO PNEUMONIA COUGH/COLD OR BRONCHITIS	 Advise on symptom control. If smoking, counsel to stop. If wheezing, treat. Advise when to return immediately. If HIV-positive, follow up in 3-5 days.

What to do in HIV-positive patients with SEVERE PNEUMONIA OR VERY SEVERE DISEASE when referral is impossible:

- Send sputum samples for microscopy examination if possible.
- Treat empirically for bacterial pneumonia with IM antibiotics.
- If patient has very fast breathing or is unable to walk unaided, treat empirically for Pneumocystis pneumonia (PCP).
 - Give cotrimoxazole 2 double-strength or 4 single-strength tablets three times a day for 21 days (15mg/kg of TMP component). Give supplemental oxygen if available.
- Assess the patient daily. Consult and discuss case with medical officer if possible (via phone, etc.) and continue to try to refer:
 - Check the patient with pneumonia using the Look and Listen part of the assessment:
 - Is the breathing slower?
 - Is there less fever?
 - Is the pleuritic chest pain less?
 - How long has the patient been coughing?
- After 3-5 days, if breathing rate and fever are the same or worse, start standardized, first-line TB regimen if available, or refer to district hospital. Do not start an incomplete regimen. Once TB treatment is started, treatment should be completed.
- If breathing slower or less fever, start first-line oral antibiotic (for bacterial pneumonia) and finish 7-day course. If PCP treatment started, continue cotrimoxazole for three weeks.

TB diagnosis

Clinicians may diagnose a patient by sputum smear microscopy (as above) or by using chest radiographs, clinical assessment and complementary tests (e.g. culture, other methods). If referral is not possible, the first-level facility clinician should diagnose and manage smear-negative pulmonary and extrapulmonary TB.

Case Diagnosed classification by		Definition used for diagnosis		
Pulmonary TB, sputum	Health worker or clinician	Two or more initial sputum smear examinations positive for Acid-Fast Bacilli (AFB).		
smear- positive (PTB+)	Clinician	 One sputum smear examination positive for AFB and Radiographic abnormalities consistent with active pulmonary TB as determined by a doctor/medical officer OR One sputum smear-positive for AFB and Sputum culture positive for <i>M. tuberculosis</i>. 		
	Clinician	 AHIV- positive or strong clinical evidence of HIV infection and One sputum smear examination positive for AFB 		
Pulmonary TB, sputum smear- negative (PTB–)	Clinician	 Sputum smear examinations negative for AFB and Sputum culture positive for <i>M.tuberculosis</i> OR At least two sputum examinations negative for AFB and Radiographic abnormalities consistent with active TB OR Strong clinical evidence of HIV infection and Decision by a clinician to treat with a full course of anti-TB treatment 		
Extra- pulmonary TB	Clinician	 One specimen from an extrapulmonary site culture-positive for <i>M. tuberculosis</i> or smear- positive for AFB OR HIV-positive and Histological or strong clinical evidence consistent with active extrapulmonary TB OR Strong clinical evidence of HIV infection and A decision by a clinician to treat with a full course of anti-TB treatment. 		

classified as having extrapulmonary TB. Extrapulmonary TB determines the HIV clinical stage. HIV-positive patients with

extrapulmonary TB other than lymphadenopathy are WHO HIV clinical stage 4.

A2 If HIV status is unknown, recommend HIV testing and counselling

A2.1 Recommend HIV testing to all TB patients and all TB suspects

- HIV testing should be recommended in all patients who are TB suspects at the same time the initial sputum sample is sent for sputum smear microscopy examination.
- HIV testing should be recommended in patients who were diagnosed with TB and started on TB treatment and in all new TB patients.
- Record test result

A physician, nurse, ART Aid or other counselor, or other health worker can provide the pre-test information, obtain informed consent, and do the HIV test on-site in the clinic (after a short training). 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 for the pre-test information and counselling in many settings.

Pretest information by the health worker includes three main steps:

- 1. Provide key information on HIV/AIDS and its interaction with TB.
- 2. Provide key information about HIV testing: clinical and prevention benefits, potential risks, procedure to safeguard confidentiality, available services, testing procedures, the rights of the patient to decline testing without affecting the patient's access to services that do not depend upon knowledge of HIV status.
- 3. Confirm willingness of patient to proceed with test and seek informed consent. Additional information should be provided as necessary with referral for additional counselling, as needed.

1. Provide key information on HIV and its treatment

Say: "There is a very important issue that we need to discuss today. People with TB are also very likely to have HIV infection. In fact, HIV infection is the reason many people develop TB in the first place. This is because people with HIV are not able to fight off diseases as well as persons who are not infected.

If you have both TB and HIV, it can be serious and sometimes life-threatening without proper diagnosis and treatment. Treatment for HIV is becoming more available and can help you feel better and live longer.

Also, if we know you have HIV infection, we can treat your TB disease better. If you decide not to be tested for HIV, you will still receive TB treatment.

Explain what HIV/AIDS is and treatments available: "HIV is a virus or a germ that destroys the part of your body needed to defend a person from illness. The HIV test will determine whether you have been infected with the HIV virus. It is a simple blood test that will allow us to make a clearer diagnosis. Following the test, we will be providing counselling services to talk more in-depth about HIV/AIDS. If your test result is positive, we will provide you with information and services to manage your disease. This may include antiretroviral drugs and other medicines to manage the disease. In addition, we will help you with support for prevention and to disclose the result to someone you trust. If it is negative, we will focus on ensuring you have access to services and commodities to help you remain negative.

For these reasons, we recommend that all our TB patients be tested for HIV. Unless you object, you will be tested for HIV today."

2. Explain procedures to safeguard confidentiality

Say: "The results of your HIV test will only be known to you and the medical team that will be treating you. This means the test results are confidential and it is against our facility's policy to share the results with anyone else without your permission. In the event of an HIV-positive test result, you will be supported to disclose to others persons who may be unknowlngly at risk of expsoure to HIV from you.

Ask the patient if they have any other questions.

3. Confirm willingness of patient to proceed with test and seek informed consent

Informed consent means that the individual has been provided essential information about HIV/AIDS and HIV testing, has fully understood it, and based on this has agreed to undergo an HIV test.

Ask: "Are you ready to be tested? Or would you like more time to discuss the implications of a positive or negative test for you?"

If the patient has additional questions, provide additional information (next page). If the patient is unsure or uncomfortable with proceeding with the HIV test, refer him/her to the facility-based counsellor for a full pre-test counselling session.

If the patient is ready, then seek oral consent: "In order to carry out this test, we need your consent."

Remember: It is the patient's right to refuse an HIV test. The patient should still be given appropriate treatment, referral, follow-up, and support.

In patients who consent, explain how the test is done.

Say: *"The test requires that we take your blood from a small prick of your finger.* (explain how the test is performed in your clinic).

Option 1: Blood is tested by provider

Your blood will be tested here in the clinic. You will need to wait about 20-30 minutes while I run the test. As soon as the results are available, we will talk about the test results.

OR

Option 2: Blood is tested in the lab

You will need to go to the lab for the blood test. After the lab takes your blood sample, you will need to wait about 20-30 minutes while the lab runs the test. When the lab returns the results to me, we will talk about the test results.

We will give you the results of your HIV test today before you leave the clinic."

If the patient requires additional information, discuss advantages and importance of knowing HIV status.

Things to say:

- "The testing will allow health care providers to make a proper diagnosis and ensure effective follow-up treatment.
- If you test negative, we can eliminate HIV infection from your diagnosis and provide counselling to help you remain negative.
- You will be provided with treatment and care for managing your disease, including:
 - Cotrimoxazole prophylaxis
 - Regular follow-up and support
 - Treatment for infections
 - *Antiretroviral therapy* (explain availability and when antiretroviral therapy is used. See *Chronic HIV Care with ART and Prevention* guideline module).
- (If a woman) You will be encouraged to get treatment that can prevent transmission from mothers to their infants, and make informed decisions about future pregnancies.
- We will also discuss the psychological and emotional implications of HIV infection with you and support you to disclose your infection to those you decide need to know and to other persons who may be unknowingly at risk of exposure to HIV from you.
- An early diagnosis will help you cope better with the disease and plan better for the future."

A2.2 If patient is HIV-negative, inform and counsel

- Explain the test result.
- Share relief or other reactions with the patient.
- Counsel on the importance of staying negative by correct and consistent use of condoms, and other practices of making sex safer (see section I). Create a risk reduction plan with the patient.
- If recent exposure or high risk, explain that a negative result can mean that she/he is not infected with HIV, or is infected with HIV but has not made antibodies to the virus. A person who has recently been infected may not yet be making antibodies to the virus. The HIV test detects the antibodies to the virus, not the virus itself. In this case, the test would not detect antibodies against HIV in the blood. This time period is often called the "window" period. Repeat HIV testing can be offered after 6-8 weeks.
- Ask the patient if there are any questions.
- Refer, as needed, patient for additional prevention or care services, including peer support and special services for vulnerable populations.

A2.3 If patient is HIV-positive, inform and counsel

- Explain the test result.
- Provide immediate support after diagnosis.
- Provide emotional support.
- Provide time for the result to sink in.
- Empathize.
- Use good listening skills.
- Find out the immediate concerns of the patient and help.
 - Ask: "what do you understand this result to mean?" Correct any misunderstandings of the disease.
 - Provide support.
 - What is the most important thing for you right now? Try to help address this need.
 - Tell them their feelings/reactions are valid and normal.
 - Mobilize resources to help them cope.

- Help the patient solve pressing needs.
- Talk about the immediate future—"what are your plans for the next few days?"
- Advise how to deal with disclosure in the family.
- Stress importance of disclosure and testing partners. Make sure the patient understands that his or her partners may still be HIV-negative, even if in a long-term relationship, and need to be protected from infection (for more information, see *IMAI Acute Care* guideline module, p. 104).
 - "Who do you think you can safely disclose the result to?"
 - "It is important to ensure that the people who know you are HIVinfected can maintain confidentiality. Who needs to know? Who doesn't need to know?"
- Offer to involve a peer who is HIV-positive, has come to terms with his or her infection, and can provide help. (This is the patient's choice.)
- Advise how to involve the partner.
- Encourage and offer HIV testing and counselling of the patient's children. Give information on the benefits of early diagnosis of HIV in infants.
- Make sure the patient knows what psychological and practical social support services are available.
- Explain what treatment is available (see IMAI Acute Care and the Chronic HIV Care with ARV Therapy and Prevention guideline modules).
- Advise on how to prevent spreading the infection.
- Ask patient to come back depending on needs.

More extensive post-test counselling and support sessions can be performed in the clinic at follow-up visits or through other community resources (see *IMAI Acute Care* and the *Chronic HIV Care with ARV Therapy and Prevention* guideline modules, Annex A).

Example script to counsel a patient whose HIV test was negative

Say: Thank you for waiting.

"Your HIV test was negative. The test did not detect HIV in your blood. We believe you are not infected with HIV.

However, there is a very small chance that the test may have missed a recent infection. So I want you to have another test at (name of community VCT centre) in 6 weeks. They can also give you more information about staying uninfected.

In the meantime, HIV infection is common in our community. You need to take steps to assure that you do not become infected in the future.

As you probably know, you can get HIV infection from having sex with someone who is infected.

For this reason, you need to ask your sex partner to be tested.

If your partner does not have HIV, the two of you will need to be faithful and not have sex with any other partners. This will protect both of you from getting HIV.

If your partner does have HIV or you do not know his/her status, or if you have sex with more than one partner, you can protect yourself from HIV by:

- Using condoms properly every time you have sex. We have condoms available in the clinic and you are welcome to take some. The (name of community VCT or other source ...) also has condoms.
- Not having sex until your partner is tested and you find out if he/she has HIV.

Ask the patient if there are any questions.

Here is some information about where your partner can go to be tested, and how you can protect yourself from getting HIV.

I hope you will ask your partner to be tested by the time of our next visit. We will discuss this at your next visit."

A2.4 If patient is HIV-positive, enroll the patient in chronic HIV care

- If you are trained and supported to provide this care, begin doing so, using IMAI Chronic HIV Care with ARV Therapy and Prevention. See section I in this guideline for special considerations.
- If you are not trained or your clinic does not provide chronic HIV care, refer the patient to the chronic HIV care clinic using a *TB/HIV Referral Form* (see C2). Coordinate care of the patient.

Example script to refer a patient for chronic HIV care

Say: "In addition to getting support from family and friends, you need medical care that can help you feel better and live longer even though you have HIV infection.

You need to go to the clinic that provides long-term care and treatment for HIV.

Here is a referral for you to give to the healthcare provider in that clinic that will let him/her know that you are receiving treatment in the TB clinic, and that you have been tested for HIV.

Also, if you/your partner are pregnant or planning to get pregnant, you should tell your healthcare provider at the HIV clinic so that he/she can talk to you about protecting your unborn child from getting HIV.

If you do not want others to know about your HIV status at this time, you should take care to keep your letter in a private place until you give it to the healthcare provider in the HIV clinic.

It is important that you go to this clinic as soon as possible. I hope you will be able to go before our next visit. We'll talk about this at your next visit."

A3 Assess family status including pregnancy, family planning and HIV status of partner(s) and children

Woman of childbearing age? If yes:

- Determine pregnancy status.
- Sexually active?
- Using contraception?
- Breastfeeding?

If pregnant and HIV-positive:

- Consider eligibility for ART.
- Do not use efavirenz in first trimester. If pregnancy status uncertain and she is taking efavirenz, perform pregnancy test.
- Provide or refer for antenatal care and PMTCT interventions: ART or ARV prophylaxis, safer labour and delivery, and safer infant feeding.
- See section 8.6 of Chronic HIV Care.

If not pregnant and HIV-positive:

- If using family planning, ask if she is satisfied or has any problems.
- If not using family planning and wishes to, discuss and offer. See section 11.1 of Chronic HIV Care.

If no pregnancy test is available, how to be reasonably sure a woman is NOT pregnant—Ask her the following auestions:

- Did your last menstrual period start within the past 7 days?
- □ Have you given birth in the last 4 weeks?
- Are you fully or nearly fully breastfeeding
 AND gave birth less than 6 months ago
 AND had no menstrual period since then?
- Have you had a miscarriage or abortion in the past 7 days?
- □ Have you had no sexual intercourse since your last menstrual period?
- Have you been using a reliable contraceptive method consistently and correctly?

If she answers **YES** to any **ONE** of the questions, and has no signs or symptoms of pregnancy, you can be reasonably sure she is NOT pregnant.

This information can affect the choice of TB drug treatment (see B4.2)

If considering pregnancy, counsel on reproductive choices. Use the Reproductive Choices and Family Planning for People Living with HIV flipchart to provide further information.

For all HIV-positive patients, encourage and actively facilitate HIV testing of partner(s) and children

- The patient's partner(s) should be tested as soon as possible to determine if he or she is infected.
- Refer for testing all children, particularly if any symptoms or signs suggestive of HIV infection (see *IMCI Chart Booklet for High HIV Settings* and complementary training course).

Notes:

B Decide on the TB or TB-ART treatment plan

B1 Determine the disease site from the results of sputum smear examination and/or the doctor/medical officer's diagnosis. (see A1.1)

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

- Pulmonary—disease affecting the lungs.
- Extrapulmonary—disease affecting organs other than the lungs.

B2 Determine the type of TB patient

Ask:

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

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

B3 Select the TB treatment category

A doctor/medical officer diagnoses and prescribes treatment for cases in the shaded boxes. Either a health worker or a doctor/medical officer can select the treatment category for the other cases (unshaded). This is based on the disease classification (site), laboratory results, type of patient, HIV status and recommendations in National Guidelines.

Disease Site	Laboratory results	Type of Patient		Recommended treatment category
			New	CAT I
		Previously treated	Relapse	CAT II
	Sputum smear- positive ^a		Treatment after failure	CAT II
Pulmonary			Treatment after default	Usually CAT II
			Chronic or MDR-TB	CAT IV
	Sputum smear- negative ^b			→ CAT I or III °
Extrapulmonary ^b				→ CAT I or III ^c

- a If only one sputum sample is positive, the HIV-positive patient is considered to be smearpositive. The HIV-negative patient should be referred to a clinician for diagnosis.
- Pulmonary sputum smear-negative cases and extrapulmonary cases may rarely be previously treated (treatment after failure, relapse, treatment after default, chronic).
 Diagnosis should be based on bacteriological and pathological evidence.
- c As recommended by WHO, Category III treatment may be the same regimen as for Category I. Each country will decide whether Category I and III are different drug regimens or not. If they are different, the selection of a regimen for a particular patient will depend on the severity of disease.

The HIV status of the TB patient does not affect the selection of the treatment category.

However, HIV-positive patients who are on ART should not be started on TB treatment at the first-level health facility.

If patient is already on ART when a sputum smear for TB is positive or when smear-negative TB is suspected, consult or refer to doctor or medical officer at the district hospital for the treatment plan. This is because there are many possibilities and potential problems which need to be considered: ART treatment failure; TB reinfection or reactivation; active TB becoming manifest as the result of immune reconstitution syndrome; or ART may need to be switched.

Who cannot start TB treatment at first-level health facility?	Any HIV-positive patient with TB who is already on ART. These patients need to be seen by a doctor/ medical officer before starting TB treatment.
	A patient with sputum smear-positive TB who is:
	Treatment after default
	Chronic or XDR/MDR-TB
Who can start TB treatment at first-level	HIV-positive patients not on ART with sputum smear- positive TB who are:
health facility?	• New
	Relapse*
	Treatment after failure*
	Where referral is not possible, also start TB treatment in HIV-positive patients who have or suspected to have :
	Sputum smear-negative TB
	Extrapulmonary TB

* Note: HIV-positive patients with TB have a higher risk of relapse and failure. In an HIVpositive patient that a relapses or fails Category 1 treatment, start Category 2 treatment and consult with the district doctor/medical officer as soon as possible after starting TB treatment. HIV infected patients may have a higher risk of exposure to drug resistant forms of TB, and are likely to have a higher rate of mortality due to drug resistance than TB patients that are not HIV infected. Therefore if a TB patient with HIV has resided in institutions or settings that have had MDR-TB outbreaks or high prevalence of MDR-TB, and depending on national guidelines and availability, it may also be advisable to send a pre-treatment sputum sample for drug susceptibility testing.

B4 Select the anti-TB drug regimen

This should be based on the TB treatment category or the TB or TB-ART treatment regimen advised by the doctor. Take into account pregnancy and contraception status.

B4.1 Select anti-TB drug regimen based on treatment category

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

Those abbreviations are:



Example 1: A commonly used Category 1 regimen is written:



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

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

Example 2: A commonly used Category 2 regimen is written:

2(HRZE)S / 1(HRZE) / 5(HR)3E3

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

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

Category I regimen

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

Category II regimen

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

* 750 mg for patients aged over 60 years

Category III regimen

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

**Regimens in grey with 6 HE daily in the continuation phase may be associated with a higher rate of treatment failure and relapse compared with the 6-month regimen with rifampicin in the continuation phase.

B4.2 Anti-TB drug treatment in special situations

If using oral contraception:

Rifampicin interacts with oral contraceptive medications with a risk of decreased protection against pregnancy. If a woman is taking rifampicin, she should not use pills or implants as the contraceptive effectiveness may be lessened. She may use injectable contraceptives.

If pregnant:

- Most anti-TB drugs are safe for use in pregnancy with the exception of streptomycin. Do not give streptomycin to a pregnant woman as it can cause permanent deafness in the baby. Pregnant women who have TB must be treated, but their drug regimen must not include streptomycin. Use ethambutol instead of streptomycin.
- If pregnant and HIV status not known, offer HIV testing and counselling and explain benefits of knowing HIV status (offer PMTCT interventions see section 8.6 of *Chronic HIV Care with ART and Prevention* guideline module).

If 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. *In the HIV-positive TB patient, decide whether and when to consult or refer for a TB-ART co-treatment plan*

When to start ART and the regimen needs to be decided by a TB-HIV trained doctor or medical officer.

The decision to give ART co-treatment in a TB patient must be made by a TB-HIV trained doctor or medical officer. The health worker at the first-level health facility, however, needs to decide whether and when to consult with or refer the patient to this doctor or medical officer at the district hospital.

For this, use the clinical stage, whether already on ART, and CD4 count (if available). The preferred recommendation for many TB-HIV patients is to start and complete TB treatment, and then start ART. However, if the patient's clinical status is poor (other signs of HIV clinical stage 3 or 4 or CD4 count less than 350/mm3), it may be necessary to refer the patient for ART treatment sooner.

If patient is not on ART, start TB treatment immediately, or if already started, **continue** TB treatment.

Patient clinical status	How to manage—when to consult or refer to doctor or medical officer
Smear-positive pulmonary TB only (no other signs of clinical stage 3 or 4) and patient is gaining weight on treatment.	Start TB treatment. Reassess after intensive phase of TB treatment to determine whether to start ART during TB treatment or after completing it.
Smear-negative pulmonary TB only (no other signs of clinical stage 3 or 4) and patient is gaining weight on treatment.	Start TB treatment. Reassess after intensive phase of TB treatment to determine whether to start ART during TB treatment or after completing it.
Any pulmonary TB and patient has signs of clinical stage 4 or thrush, pyomyositis, recurrent pneumonia, persistent diarrhœa, new prolonged fever, or losing weight on treatment or if no clinical improvement.	Start TB treatment. Refer now to district medical officer for ART co-treatment plan. ART probably needs to be started immediately.
Extrapulmonary TB	Start TB treatment. Refer now to district medical officer for ART co-treatment plan. ART probably needs to be started immediately.

If patient not on ART and CD4 is available:

CD4	How to manage
lf CD4 < 200/mm3	Start TB treatment. Refer now to district medical officer for ART co-treatment plan. This needs to be started as soon as TB treatment is tolerated (between 2 weeks and 2 months).
lf CD4 between 200-350/mm3	Start TB treatment. Refer to district medical officer for ART co-treatment after intensive phase (unless non-TB Stage 3 or 4 conditions are present, in that case refer at once).
lf CD4 > 350/mm3	Start TB treatment. Defer ART until TB treatment is completed unless non-TB Stage 4 conditions are present.

Any HIV-positive patient receiving a TB drug regimen containing isoniazid should also receive pyridoxine 10 mg daily to prevent peripheral neuropathy.

Common TB-ART co-treatment regimens

When to start ART and the regimen needs to be decided by a trained doctor or medical officer.

The health worker at the first-level facility will help manage the patient on TB-ART co-treatment after the medical officer/doctor has decided on the treatment plan.

A patient on TB-ART co-treatment will have higher pill burden and most likely will experience more side effects. Educate the patient on how to manage mild to moderate side effects and report to the health worker immediately for severe ones (see section F).

The following examples include rifampin during the initial and continuation phases of TB treatment. The patient also receives cotrimoxazole and an EFV-based ART regimen if it is started during TB treatment.

There are many pills and several changes in the regimen, which requires careful education of the patient and treatment supporter at each change. The TB treatment is not necessarily in the morning.

ТВ	Initial	Phase	Continuation Phase		
HIV			ART		
	Cotrimoxazole				
	TB initial phase- Until end During until of TB continuation tolerated initial phase phase			After TB treatment completed	
	HRZE (FDC):	HRZE (FDC): 전 전 전 전	HR (FDC, 3 times a week):		
		d4T-3TC (FDC):	d4T-3TC (FDC):	d4T-3TC (FDC):	
	CTX:	CTX	CTX	CTX	
		d4T-3TC (FDC): EFV (separate):	d4T-3TC (FDC): EFV (separate):	d4T-3TC (FDC): EFV (separate):	

Example 1: Start ART as soon as TB treatment is tolerated

Example 2: Start ART after the initial phase of TB treatment

В	Initial Phase	Continuation Phase	
IV	ART		
		Cotrimoxazole	
	During TB initial phase	During continuation phase	After TB treatment completed
	HRZE (FDC):	HR (FDC, 3 times a week):	
		d4T-3TC (FDC):	d4T-3TC (FDC):
	CTX:	CTX	CTX
		d4T-3TC (FDC): EFV (separate):	d4T-3TC (FDC): EFV (separate):

Example 3: Start ART after TB treatment is completed

ТВ	Initial Phase	Continuation Phase]		
HIV				ART	
	Cotrimoxazole				
	During TB initial phase	During continuation phase	After TB treatment completed	From week 3 of ART	
	HRZE (FDC):	HE (FDC):	d4T-3TC-NVP (FDC):	d4T-3TC-NVP (FDC):	
	CTX:	CTX	CTX	СТХ	
			d4T-3TC (FDC):	d4T-3TC-NVP (FDC): 달	

Notes:
C Prepare the patient's TB Treatment Card and, if HIV-positive, the HIV Care/ART Card

C1 Prepare a TB Treatment Card (see Forms)

General patient information:

- Name, sex, age, address (sufficient for defaulter tracing).
- Identification: district TB register number, registration date.
- Health facility: name of health facility responsible for keeping the treatment card.
- Community treatment supporter: name of person responsible for treatment supervision.
- Referral by: tick to indicate who referred the patient for diagnosis/treatment.
- Clinical information:
 - TB disease site and type of patient.
 - Sputum smear microscopy: at start of treatment (month 0) or month during treatment, date sputum was taken, laboratory number, result (standardized grading), patient's weight.
 - TB-HIV, HIV Test: the date and result of the test should be recorded to be sure that patients are aware of their status. This includes previously documented test results. Consistent symbols and abbreviations should be used to record the HIV result, e.g. + positive, – negative, I indeterminate, ND not done/unknown. Plus and minus signs should be circled to make it clear that they represent a result.
 - If TB-HIV, CPT start (cotrimoxazole preventive treatment): the date when the patient was given the first dose of cotrimoxazole should be entered, or P (Previous) if the patient is continuing on CPT that commenced before TB diagnosis. If the patient is not eligible, this should be stated in the CPT box along with the reason.
 - If TB-HIV, ART start: the date when the patient was first started on ART should be recorded.

- TB treatment category.
- Regimen. Record the drug regimen for the initial phase on the front of the *TB Treatment Card*. Record the drug regimen for the continuation phase on the back. Under the drug combination, record the number of tablets, or g if streptomycin.
- On back of card:
 - X-ray: result at start of treatment (if negative sputum smear microscopy).
 - HIV care, Pre ART Register Number: All HIV-positive TB patients should be referred and/or registered for HIV care. The patient's HIV care registration number should be recorded here.
 - HIV care, CD4 result: If CD4 is used to determine whether a TB patient is eligible to start ART, the result of the most recent test should be recorded on the patient card.
 - HIV care, ART eligibility, Date eligibility assessed and ART Register Number: A patient's ART eligibility should be assessed and recorded (yes, no, unknown). The date patient was first assessed for eligibility should also be recorded, along with the ART register number if the patient has started ART.

C2 In the HIV-positive TB patient, update the HIV Care/ART card or prepare a referral form to HIV Care If HIV Care is available in your clinic, prepare the HIV Care/ART Card. See Chronic HIV Care with ART and Prevention for instructions.

If you need to refer the patient to another facility for HIV care, fill out a TB-HIV referral form. See form on the next page.

Every time the patient visits the facility you need to:

- Update the TB Treatment Card;
- Update the HIV Care/ART Card; and
- Update the Pre-ART or ART register, depending on whether or not the patient is on ART.

Example: TB/HIV REFERRAL FORM

Patient name	tient name Date:			
Patient TB Register number				
Referred from				
	(Name of TB treatment clinic/health facility)			
Name of referral clinician: _				
Referred to				
(1	Name of HIV care clinic/h	ealth facility, VCT, PMTCT)		
Cotrimoxazole started: yes	no Date start	ed:		
Current TB medications: (Ch started:/	eck all that apply)	Date TB treatment		
isonaizid	pyrazinamide	streptomycin		
rifampicin		other:		
Note from HIV Care Clinic/Fa		acility		
(Name of clinic:)			
Name of clinician:		Date:		
Cotrimoxazole started: yes	no Date start	ed:		
Antiretrovial medications pr	rescribed:			
zidovudine (AZT or ZDV) _	didanosine (ddl)	nelfinavir (NFV)		
stavudine (d4T)	abacavir (ABC)	saquinavir/ritonavir (SQV/r)		
lamivudine (3TC)	tenofovir (TDF)			
nevirapine (NVP)	Indinavir/ritonavi	r (IDV/r)		
efavirenz (EFV)lopinavir/ritonavir (LPV/r)				
Notes to TB clinician:				
Signed:				

Provide basic information about TB or TB-HIV to patient, family and treatment supporters

D1 Inform 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 tuberculosis.

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 to be? What do you think may have caused your illness?	What is TB? 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?	TB can be cured TB can be cured with the correct drug treatment. The patient must take all of the recommended drugs for the entire treatment time in order to be cured.	
Do you know that TB can be completely cured?	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?	How TB spreads TB spreads 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?	 How to prevent TB from spreading 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, using a fan. Use UV lights. There is no need to eat a special diet or to sterilize dishes or household items. 	

How many	Who else should be examined or tested for TB?	
people live with you? What ages? Does anyone else in your household have cough? Who has cough?	All children aged under 5 years 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 measures or referral to a clinician. Other household members should be tested for TB if they have cough.	
Can you explain why it is important that somebody else observes you taking your pills?	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 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. If you do not take all of the drugs, you will continue to spread TB to others in your 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. If you must travel, or if you plan to move, tell the health worker so that arrangements can be made to continue treatment without interruption.	
How long should you take the drugs for? How frequent and where are your visits?	 Explain for the specific patient: Duration of treatment Frequency of visits for taking treatment Where to go for treatment (<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. 	
What should you expect when taking the drugs? What should you do next?	 (If the patient is taking rifampicin) Urine may turn orange/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. Treatment should not interfere with normal life and work. 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. Remind the patient to bring family and other close contacts for TB testing as needed. 	
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.		

In the HIV-positive patient, also inform about HIV and prepare for self-management and positive prevention

Counsel on how HIV is transmitted and not transmitted

HIV is a virus that destroys parts of the body's immune system (body defence). A person infected with HIV may not feel sick at first, but slowly the body's immune system is destroyed. She/he becomes ill and is unable to fight infection. Once a person is infected with HIV, he/she can give the virus to others even if she/he has no symptoms yet.

HIV can be transmitted through:

- Exchange of HIV-infected body fluids such as semen, vaginal fluid or blood during unprotected sexual intercourse.
- HIV-infected blood transfusions.
- Injecting drug use.
- Sharing of instruments for tattoo, scarification or circumcision.
- From an infected mother to her child during:
 - Pregnancy
 - Labour and delivery
 - Postpartum through breastfeeding

HIV cannot be transmitted through hugging or kissing, or mosquito bites.

* Explain available treatment and care for HIV including:

- Cotrimoxazole prophylaxis.
- Regular follow-up and support.
- Treatment for infections.
- ARV therapy. (Explain availability and when it is used. See *Chronic HIV Care with ART and Prevention*).
- · Interventions to prevent transmission from mothers to their infants
- Counselling to make informed decisions about future pregnancies and family planning advice.
- Support and counselling.
- Support for disclosure.

Give post-test counselling and support

Advise on basic and positive prevention (see section I and section 11 of *Chronic HIV Care*).

Support disclosure of HIV-positive status

- Discuss advantages of disclosure.
- Ask the patient if they have disclosed their result or are willing to disclose the result to anyone.
- Discuss concerns about disclosure to partner, children and other family members, friends.
- Assess readiness to disclose HIV status and to whom. Assess social network (start with least risky).
- Assess social support and needs. See Annex A.4 in *IMAI Chronic HIV Care with ARV Therapy and Prevention*.
- Provide skills for disclosure (role play and rehearsal can help).
- Help the patient make a plan for disclosure.
- Encourage attendance of the partner to consider testing; explore barriers to this.
- Reassure that you will keep the result confidential.
- If domestic violence is a risk, create a plan for a safe environment.
- If the patient does not want to disclose the result, reassure that the results will remain confidential.
- Explore the difficulties and barriers to disclosure. Address fears and lack of skills (help provide skills).
- Continue to motivate. Address the possibility of harm to others.
- Offer another appointment and more help as needed (such as peer counsellors).

Especially for women, discuss benefits and possible disadvantages of disclosure of a positive result, and involving and testing partners.

- Men are generally the decision makers in the family and communities. Involving them will:
 - Have greater impact on increasing acceptance of condom use and practicing safer sex to avoid infection.
 - Help avoid unwanted pregnancy.
 - Help to decrease the risk of suspicion and violence.
 - Help to increase support to their partners.
 - Motivate them to get tested.
- Disadvantages of involving and testing the partner: danger of blame, violence and abandonment.

Health worker should try to counsel couples together, when possible.



Notes:

Give preventive therapy

E1 For all HIV-positive TB patients, offer cotrimoxazole prophylaxis (to prevent other infections)

Advise patient on advantage of cotrimoxazole prophylaxis.

Initiate

Ask about previous history of sulpha allergy (to cotrimoxazole/Septrin[®], Bactrim[®], Septra[®], S-P/Fansidar[®] etc.).

Dispense

- If also on directly observed TB treatment, give cotrimoxazole at same time.
- If not on directly observed TB treatment, dispense a month's supply. Schedule follow-up visit 2 days before the supply runs out.
- Give one double-strength (960mg) or two single-strength (480mg) tablets daily.

Monitor

- Ask about symptoms.
- Check for rash and pallor.
- Assess adherence, ask if they have taken all doses; count pills left in bottle. Record on card.

Response to side effects of cotrimoxazole

Nausea	Continue cotrimoxazole and take with food. If severe or persistent vomiting, consult or refer.
Rash	If generalized rash or fixed drug reaction or peeling or eye or mouth involvement, stop the cotrimoxazole and refer urgently to hospital. (see <i>IMAI Acute Care</i> , p 43).
Pallor or haemoglobin < 8gm or bleeding gums	Stop the cotrimoxazole. Call for advice or refer.
New jaundice	Stop the cotrimoxazole. Call for advice or refer.

Cotrimoxazole prophylaxis in children

The interpretation of HIV antibody test in children < 18 months is different. Maternal HIV antibodies can be passed to the child and last for up to 18 months, so a positive HIV antibody test can indicate HIV exposure or HIV infection.

But young children have immature immune systems and thus are susceptible to opportunistic infections. So it is important to start cotrimoxazole prophylaxis in children who are potentially HIV-infected at 6 weeks of age.

See Section 12 of *Chronic HIV Care with ART and Prevention* for more information on how to diagnose HIV in infants, and how and when to start cotrimoxazole in children.

E2 For household contacts of TB patients, consider isoniazid preventive therapy (to prevent TB)

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 others in the household who have cough for more than 2 or 3 weeks
- Any person in the household who is HIV-positive

Of these contacts, children less than 5 years and HIV-positive adult contacts should be started on isoniazid preventive therapy if active TB disease has been excluded.

Isoniazid preventive therapy for TB contacts aged less than 5 years

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

Note: If your country also recommends preventive therapy with isoniazid for older household contacts (school-age children and/or adults), give it to these contacts also. Give 5 mg/kg isoniazid daily for at least 6 months, up to a maximum dose of 300 mg.

Isoniazid preventive therapy in HIV-positive TB contacts

Isoniazid preventive therapy reduces the chance that an HIV-positive contact of a TB patient will develop TB disease. However, it is very difficult to rule out TB disease in an HIV-positive patient. Depending on country guidelines, an HIV-positive TB contact may need to be evaluated by a doctor/medical officer in order to rule out active TB disease. Isoniazid preventive therapy **must not be given** to any child or adult who has active TB disease.

Response to side effects of isoniazid

Minor side effects

Anorexia, nausea, abdominal	Continue isoniazid and:
pain	Give isoniazid at bedtime
 Joint pains 	Give aspirin
 Burning sensation in the feet 	Increase pyridoxine 100 mg daily

Major side effects

•	
New itching of skin or skin rash	
 Dizziness (vertigo and nystagmus) 	
Jaundice	STOP isoniazid
Vomiting	Refer the patient urgently to a
Confusion	clinician.
Convulsion	

E3 For household contacts of TB patients who are aged less than 2 years, give BCG immunization if needed

Immunization with BCG can reduce the chance of developing severe TB (ie disseminated TB and TB meningitis), by 50–80%.

- After a course of preventive therapy:
 - 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.
 - Give one dose of BCG vaccine to children aged less than 2 years who have not already had BCG immunization.
 - Use sterile procedures to administer BCG as with any vaccine.
 - A child who is receiving preventive therapy with isoniazid should first complete the course of isoniazid and then receive BCG immunization.

F Prepare the TB or TB-HIV patient for adherence

F1 Determine where the patient will receive directly observed treatment (DOT)

Discuss with each new patient:

- The specific treatment needed (daily directly observed treatment for 2 or 3 months in the initial phase).
- Whether the patient can come to the health facility each day. Note: If the patient's treatment regimen includes a streptomycin injection, a trained health worker must observe the treatment and give the injections. A trained health worker and the supplies for giving sterile injections are usually available only at a health facility.
 - If the patient will come to the health facility each day, a health worker at the health facility will directly observe treatment.
 - If it is not convenient for the patient to come to the health facility each day, explain to the patient that a community TB treatment supporter, that is, a person from outside the health facility, may provide directly observed treatment.
 - Explain that a community TB treatment supporter may observe treatment in the community including the patient's home or workplace.
 - This treatment supporter will keep the patient's drugs, observe as the patient swallows the treatment each day, and mark the necessary records (see section B.5).
 - If the patient needs a community TB treatment supporter, discuss possible locations and individuals.

F2 Prepare for adherence

F2.1 Prepare the patient for self-management

- Patient self-management is important even in patients receiving directly observed therapy.
- Use the 5 A's to prepare patients for adherence: Assess, Advise, Agree, Assist and Arrange.
- Explain the importance of self-management with the IMAI Flipchart for Patient Education.

F2.2 Select a treatment supporter

The treatment supporter should be someone who:

- ✓ Is chosen by or acceptable to the patient
- ✓ Is a respected and trusted person in the community
- ✓ Has accepted the patient's illness
- ✓ Is committed to support the patient for a long time
- ✓ Has gained the patient's trust over time
- ✓ Is available to be educated
- ✓ Is available often especially in the first months of therapy
- ✔ Is somebody who will treat all information as confidential

Different types of treatment supporters and their proximity to the patient

A treatment supporter may be a community member very close to the patient, such as a family member or friend. Or the treatment supporter could be someone who already has an established relationship with the health services—already paid for or have responsibility for health-related activities.



Essential tasks of a treatment supporter

- Peer support—Talk with the patient about the patient's life, how the patient is feeling and any concerns or problems that the patient may be experiencing. Reinforce key messages on prevention.
- Be a patient advocate—Be able to identify any problems that the patient is having and should notify the health facility immediately (For example: health problems, problems taking medications, housing problems, no food available, problems in with family members or partners).
- Patient counselling and education—Explain the importance of adherence and regular visits to the health facility; provide information about prevention, treatment, positive living.
- Monitor for symptoms of new side effects/opportunistic infections and refer to the health facility when needed—This should be not only for patients but also family members of the patient and even other community members encountered by the treatment supporter.
- Adherence support—should be tailored to the individual patient's circumstances and be based on the patient's needs and mutual respect between the patient and the provider. Measures may include direct observation of ingestion (directly observed therapy—DOT) of both TB and ARV medication.

Directly Observed Therapy

- Agree on a time and place to meet the patient. Do not make the patient wait.
- Give the patient the 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.
- Record on the 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.
- Encourage the patient to continue coming for 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 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.

F2.3 Train and supervise treatment supporters

How to prepare the treatment supporter:

- Have a meeting with the supporter before getting commitment to explain what is required (commitment, confidentiality, medical knowledge and in some cases emergency resource needs such as help with household, children which can arise while on treatment, etc).
- Educate on what "being confidential" means.
- For patients on ART, educate the patient and treatment supporter together with Flipchart for Patient Education, Patient Treatment Card and Patient Self-Management and Caregiver Booklet.
- For patient on TB treatment, use the TB Treatment Supporter material (see next page).
- Educate on how to remind the patient to take the medicine (and to work out with the patient on how best to do this).
- Be present at the follow-up appointments.
- If patient is not able to keep track, help remember all important test results and clinic history over time.
- Accompany patient to support group meetings if possible.
- Educate to prevent his/her own burn-out (see Chronic HIV Care with ART and Prevention, Annex B.5).
- Prepare to provide psychosocial support.

What you can do in addition:

- Hold treatment supporter meetings at facilities every two weeks to deal with issues they might have (burn out, patient not adherent, barriers to treatment and adherence, etc.).
- Establish a warm line or other quick way of consultation if urgent problems with patients arise.
- Organize a pool of treatment supporters for those who may not be able to disclose to someone they know.
- Mobilize communities to know who to contact for treatment support and to enlist people to be treatment supporters.

See section 8.9 of *Chronic HIV Care with ART and Prevention* for adherence preparation, support and monitoring of patients on ART.

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 to others when someone with TB coughs or sneezes.
- TB can be stopped from spreading by treating and curing persons who have it.
- People with TB have many different symptoms. The major symptom of TB in the lungs is coughing for more than 2-3 weeks.
- 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 by:
 - Taking regular treatment to become cured of TB.
 - Covering the mouth and nose when coughing or sneezing.
 - 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.
- Possible minor side-effects are:
 - 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/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.
- For a daily regimen, it is customary to give 6 doses per week or if using FDC in blister pack, 7 days per week.
- 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.

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

See: A Guide for Tuberculosis Treatment Supporters WHO/CDS/TB/2003.300 and Module E: Identify and Supervise Community TB Treatment Supporters WHO/CDS/TB/2003.314e

F2.4 Extra or special adherence support

For patients dealing with:

- Complex medical problems
 - Initial weeks of combined TB- ART treatment
 - Second-line ART regimens
 - MDRTB
 - Patients experiencing adverse effects of treatment
 - Co-morbidities (additional disease)
- Difficult social situations
 - Children or adolescents with poor understanding of their disease
 - Patients who live far away from the health facility
 - Alcohol or drug use
 - Psychiatric or neurological problems
 - Orphans or vulnerable children

Additional adherence support is often needed during TB-ART co-treatment because of the extra pill burden and more adverse effects. Immune reconstitution syndrome (worsening of TB signs and symptoms) might happen, and this can be uncomfortable and confusing for the patient.

- Family: Chronic HIV care should be family-centred and care for all members together, paying attention to prevention of the spread of TB and HIV.
- Community: Trained TB community treatment supporters can be trained to support the patient on ART as well.
- Good coordination between TB and HIV programme: Share treatment supporters.
- Specific counselling on benefits of ART and adherence barriers: Explain the benefits of ART, advise and refer to community-based organizations if they can provide additional adherence support (see next page).

Adherence support should not just focus on medical issues since there are many other issues that affect adherence. Additional adherence support may include the following:

- Food supplementation—monthly food stipend of beans and rice or other sources of protein.
- Transportation costs for health centre visits—monthly visits to the health clinic can be a financial burden to individuals and can deter them from coming to see the doctor or nurse.
- Additional education—about TB, HIV and the importance of taking medications regularly and having monthly clinic visits.
- Peer support groups—People facing similar life situations, especially adverse or unpleasant situations, often find comfort, support and strength in being together with others who are in the same or similar situations. These may be peer-led groups or therapeutic groups led by a professional or paraprofessional (see IMAI Therapeutic Support Groups Training Course Facilitator Manual).

G Support the TB or TB-HIV patient throughout the entire period of TB treatment

G1 Support or directly observe TB treatment and record on the TB Treatment Card

- Directly observe the patient's intake of anti-TB drugs, either daily or 3 times per week, according to the recommended schedule.
 - At every appointment you must watch the patient actually swallow the dose. You must <u>see</u> the patient swallow the drugs. When health workers hand the drugs to patients but do not watch patients swallow them, patients may take some but not all of the drugs, sell some of the drugs, save them for later, etc.
 - When giving directly observed treatment, make it quick and easy for the TB patient. Do not make TB patients wait in a queue at the health facility. Arrange for TB patients to see the appropriate health worker without waiting, perhaps by coming to a side or back entrance. There they can take the day's dose of anti-TB drugs quickly and be on their way. Any delays discourage TB patients and are not acceptable.
 - When a drug schedule calls for directly observed daily administration, it is customary to skip giving drugs for one day on the weekend. Skipping one day per week is allowed and will not affect the effectiveness of the regimen. Be sure that the patient knows on which days to come for treatment.

How to directly observe TB treatment

- 1. Take out the patient's *TB Treatment Card*.
- 2. Pour a glass of water for the patient. (if the patient gets nausea, suggest taking the drugs with food or gruel).
- 3. Open the patient's box of drugs. Take out all the drugs that the patient should take today.
- 4. Put the tablets into the patient's hand and then watch the patient swallow the tablets one at a time. If it is difficult to swallow them one after the other, the patient may pause briefly. The drugs must be taken together to make sure that they work together.
- 5. If the patient's regimen includes streptomycin, give the injection after the patient has swallowed all the tablets. Use a sterile needle and syringe. Check the *TB Treatment Card* for the correct dose of streptomycin.
- 6. Record the treatment on the *TB Treatment Card*.
- Record each treatment on the TB Treatment Card:
 - Daily observed administration of drugs. One box is checked for each day the treatment is administered. If the provider directly observes the intake of drugs, the box is ticked off. If drugs are given for several days without direct supervision, the day the drug is taken under direct supervision is marked with an X, and a horizontal line is drawn through the days for which the drugs are given. If health staff gives drugs to a treatment supporter for several days, the dates when the supporter receives the drugs are noted in the column on the right. The supporter may also keep a copy of the *TB Treatment Card*. If a community TB treatment supporter is directly observing treatment, the tick marks from the treatment supporter is resupplied with drugs.
 - After facility visits, weight, laboratory and X-ray monitoring can be recorded on the treatment card in the monthly drug administration section in the last column.
 - Transfer. Before and during treatment, a patient itinerary is recorded in this table.
 - Outcome of treatment. At the appropriate time, record the treatment outcome.

G2 Recognize and manage side-effects or other problems

Ask how the patient is feeling and listen carefully to identify any complaints that may indicate side-effects.

G2.1 Recognize and manage side-effects in patients receiving TB treatment only

Loss of appetite, nausea, abdominal pain	Give isoniazid at bedtime or take with food or gruel
Joint pains	Aspirin
Burning sensation in feet	Pyridoxine 100 mg daily. If not response use amitryptiline (see p. 82, <i>IMAI Acute Care</i> guideline)
Orange/red urine	Reassure patient that this is expected (with rifampicin)

Minor side-effects

Major side-effects

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

- ^a Itching of skin is extremely serious if the patient is taking thioacetazone (not recommended by WHO).
- 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.
 Repeated vomiting should be observed. Refer a repeatedly vomiting patient to a clinician.

Reminder: Use the **IMAI Acute Care** guideline module to respond to new signs or symptoms. If at any time you observe that a patient's condition has significantly worsened, refer the patient to a doctor or hospital for further assessment and treatment.

G2.2 Recognize and manage side-effects in patients receiving TB-ART co-treatment

Signs or symptoms:	Response	
Anorexia, nausea, abdominal pain	Take drugs with food (except for DDI or IDV). If on zidovudine, reassure that this is, usually self-limited. Treat symptomatically. If on INH, give it at bedtime.	
Joint pains	Give aspirin, paracetamol, or NSAIDS	
Burning sensation in feet	Potential added toxicity if INH added to DDI or stavudine. Give pyridoxine 100 mg daily. If no response use amitryptiline (see p. 82, <i>IMAI Acute Care</i>) or call for advice.	
Orange/red urine	Reassure patient that this is expected (with rifampicin).	
Headache	Give paracetamol, aspirin or NSAID. Assess for meningitis (see <i>IMAI Acute Care</i>). In on AZT or EFV, reassure that this is common and usually self-limited. If persists more than two weeks or worsens, call for advice or refer.	
Diarrhoea	Re-hydrate. Follow diarrhoea guidelines in <i>IMAI Acute</i> <i>Care</i> . Reassure patient that if due to ARV will improve in a few weeks. Follow-up in 2 weeks. If not improved, call for advice or refer.	
Fatigue	Consider anaemia especially if on AZT. Check haemoglobin. Fatigue commonly last 4 to 6 weeks especially when starting AZT. If severe or longer than this, call for advice or refer.	
Anxiety, nightmares	This may be due to efairenz. Give at night; counsel and support (usually lasts<3 weeks). Call for advice or refer if severe depression or suicidal or psychosis. Initial difficult time can be managed with amitryptiline at night.	
Blue/Black nails	Reassure. It is normal with AZT (zidovudine).	
Changes in fat distribution	Discuss carefully with your patient—can she/he accept it?	
Itching of skin, skin rash	If generalized or peeling, stop TB and ART drugs and refer.	
	If on nevirapine or abacavir, assess carefully. Is it dry or wet lesion? Call for advice.	

G2.2 Recognize and manage side-effects in patients receiving TB-ART co-treatment (*continued*)

Deafness (confirm that this is not due to ear wax)	Stop TB drugs and refer.	
Signs or symptoms:	Response	
Dizziness, lack of balance	Stop TB drugs and refer.	
Jaundice (yellow skin or eyes)	Send for ALT test and stop TB and ART drugs. 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	Stop TB drugs and refer.	
Psychosis, depression	Call for advice or refer if severe depression or suicidal or psychosis. Initial difficult time can be managed with amitriptyline at bedtime.	
Fever	Check for common causes of fever (see <i>IMAI Acute</i> <i>Care</i>). This could be a side effect, an opportunistic infection or other new infection or immune reconstitution syndrome. Call for advice or refer.	
Yellow eyes (jaundice), abdominal or flank pain	Stop TB and ART drugs. Call for advice or refer. (abdominal pain may be pancreatitis from DDI or d4T). Stop TB and ART drugs and check ALT if available. Call for advice or refer.	
Pallor: anaemia	If possible measure haemoglobin and exclude OI. Refer/consult (and stop AZT/substituted4T) if severe pallor or symptoms of anaemia or very low haemoglobin (<8 g/dL; <7 g/dL in pregnant women).	
Cough or difficult breathing	This could be immune reconstitution syndrome or an OI (see <i>IMAI Acute Care</i>). Call for advice.	
Lymphadenopathy	This could be immune reconstitution syndrome. Call for advice.	

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Possible causes for signs and symptoms for a HIV-positive TB patient

	Opportunistic infections	Immune reconstitution syndrome (IRIS) ART side effects Opportunistic infections from failure of therapy Other (for example, CD4 still not high enough to protect the national
Common infections and other acute and chronic problems (not related to HIV)	Common infections and other acute and chronic problems (not related to HIV)	the patient) Common infections and other acute and chronic problems (not related to HIV)
HIV-positive or negative patient	HIV-positive patient with immunosuppression, before ART	HIV-positive patient on ART

G2.4 Immune reconstitution syndrome (IRIS)

- IRIS appears when starting ART as new signs and symptoms of an opportunistic infection that was "hidden" because of severe immunosuppression.
- Typical manifestations of immune reconstitution syndrome are herpes zoster or tuberculosis occurring shortly after the initiation of ART.
- IRIS is a sign that the immune system is starting to work again, and it does not mean that the ART is not working.
- Call for advice or refer for management.

G3 Continue providing information about TB

- If a TB patient has still not had an HIV test, encourage testing.
- Continue providing 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.

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:	Respond as directed:	
Be alert for side-effects: Ask general questions to identify side-effects: • How are you feeling? • Have you had any problems? Listen and look for major side- effects:	 Respond as directed: If minor side-effects, give reassurance and advice: If anorexia, nausea, abdominal pain, take drugs with food or gruel. If joint pains, take aspirin. 	
 Itching of skin, skin rash Deafness Dizziness, lack of balance Jaundice (yellow skin or eyes) Vomiting repeatedly Difficulty with vision 	 If burning sensation in feet, take 100 mg pyridoxine daily. If orange/red urine, this is normal and expected. If major side-effects, stop anti-TB drugs and refer urgently to a clinician.^a 	
As needed, remind patient of one or more relevant messages (on right):		
If the patient has not yet brought household contacts for examination or testing	All children aged under 5 years living in the household should be examined for symptoms of TB. Other household members with cough should be tested.	
If the patient is unfamiliar with the drugs, or a change occurs in the regimen	Describe the type, colour, and amount of drugs to be taken. Describe how often drugs should be taken and for how long.	
	(If preassembled drug boxes are used) 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.	
If the patient feels better	Even after you feel better, you must continue taking drugs for the entire treatment period.	
If the patient may be planning to travel or move	If you plan to travel or move from the area, please inform me. We can make arrangements so that you will not miss any treatments.	

If the patient has missed a dose	To be cured, you must take all of the recommended drugs together, for the entire time. If you do not take all of the drugs, you will continue to spread TB to others.
If the patient complains about continuing treatment	Taking only some of the drugs, or taking them irregularly, is dangerous and can make the disease impossible to cure.

^a If the patient must be referred or hospitalized, explain that it is necessary to continue TB treatment after receiving referral care. The patient should return to the health facility to continue treatment.

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.	
After 2 (and/or 3) months initial treatment	If the laboratory sees TB germs in sputum, you may need longer treatment in the initial phase. If the laboratory cannot see TB germs, you are ready for the next phase of treatment.	
During continuation phase	If no TB germs are seen, you will continue the same treatment. If TB germs are seen, the treatment must be changed.	
Just before end of treatment	If no TB germs are found at this examination, you are considered cured.	
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.

G4 Monthly, review community TB treatment supporter's copy of the TB Treatment Card and provide the next month's supply of TB drugs

Check the TB Treatment Card that is kept by the treatment supporter.

For patients who receive directly observed treatment from a community TB treatment supporter (instead of coming to the health facility each day), each month check the *TB Treatment Card* that is kept by the treatment supporter. When the community TB treatment supporter visits the health facility to collect the next month's supply of drugs, review the supporter's copy of the *TB Treatment Card* and discuss any problems.

- Copy onto the original *TB Treatment Card* (kept at the health facility) the days that the patient took the treatment.
- Record on the front of the TB Treatment Card the drugs that you provide to the supporter for the next month.

This shows that 28 days	brugs given to supporter, dat		
of Category I drugs were given to the treatment supporter.	l – 28	5 April	
	l – 28	7 May	

Drugs given to supporter, date

If possible, interview the patient periodically to assess the community TB treatment supporter's work.

Ask questions about the drugs the patient is receiving and the relationship with the community treatment supporter. Assess whether treatment is correct and the relationship with the community TB treatment supporter is positive and supportive.

G5

Provide combined TB-ART DOT if necessary

Daily DOT is the preferred method to ensure full adherence to TB treatment and should be organized in such a way that it is accessible and attractive for the patient, e.g. by using a treatment supporter in the home or near the house or workplace. If the TB patient is also on ART, the daily observation of TB treatment should ideally be combined with the morning dose of ART. Since ART is a life-long therapy daily, DOT may not be sustainable after the end of TB treatment; therefore a flexible patient-specific approach needs to be developed that ensures the maximum possible adherence. The patient receiving ART can be observed by the treatment supporter once a week, several times a week, daily or twice daily, depending on the needs of the patient. All types of treatment supporters, even family members, can be trained to provide DOT for both TB treatment and ART given proper training (see below).

A treatment supporter that directly observes combined TB-ART can provide TB drugs and one dose of ART together. If there are other doses of ART that are not observed, the treatment supporter should remind the patient to take the other doses, lay out the pills, or help in any way that is effective for that patient. On the following day, the treatment supporter should also check whether the patient took the other ART doses.

G6 Ensure continuation of TB treatment

- G6.1 Coordinate medical referrals and transfer of a TB patient who is moving to another area and ensure that the TB patient continues treatment
- Use the form on the next page 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: one to send with the patient, one to keep at the health facility, and one for the District TB Coordinator.
- This form may also be used by clinicians to refer patients to your health facility to register and begin treatment.
- If patient is also on ART, follow the procedures for Transfer Out with records.

Tuberculosis Treatment Referral/Transfer

(Complete top	o part in triplicate)			
Tick for this referral or transfer: \Box Referral ¹ or [☐ Transfer ² Da	te of referral	/ transfer	
ame/address of referring/transferring facility				
From sending facility:	Se	Sending BMU		
To receiving facility:		Receiving BMU		
Name of patient		_ Age	Sex: 🗆 N	1 🗆 F
Address of patient (if moving, future address):				
Diagnosis:				
(For Transfer) BMU TB Register No.	Date TB tre	atment starte	ed:	
		Γ		
*CAT I, II, III Drugs patient is receiving	Other (CPT, A	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				
	, aag ei zeiere			
For use by facility receiving	j referred / transf	ferred patier	nt	
BMU Facility				
BMU TB Register No Name of pati				
The above patient reported at this facility on				
Name / signature of person receiving the patient				

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

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

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

Note: A facility referring or transferring large numbers of patients such as large hospitals may use separate forms for referral and transfer and may have a specific register for referrals.

G6.2 Arrange for TB patients to continue treatment when travelling

- Review travel plans: During regular treatment visits, ask patients to be sure to inform you if they will travel, so that arrangements can be made to continue treatment without interruption.
- If a patient will travel out of the area, or will be unable to have treatment directly observed for one or more days, provide instructions and drugs for a short period of self-administration. If necessary, you may provide drugs for up to 2 weeks.
- If the patient's drugs are not pre-packaged, prepare a separate packet of drugs for each day that the patient will be absent. Give the patient careful instructions, orally and in writing, about how to take the drugs. Point out the number and colour of the drugs in each day's packet. Tell the patient to:
 - Take the drugs at the same time each day.
 - Take pills with water.
 - Take all of the drugs for the day together.
- Ask checking questions to make sure that the patient understands when and how to take the drugs.
- On the patient's TB Treatment Card, mark a tick when you observe treatment; then draw a line through the days on which the patient will self-administer the drugs.

G6.3 Conduct a home visit to a patient who misses a dose or fails to collect drugs for self-administration

ASK

- Why did you miss your appointment?
- What problems caused you to miss?

LISTEN carefully to find out whether there have been difficulties

- Attitudes of the health facility staff who observe treatment
- Waiting time at the health facility
- Transportation
- Work or family commitments
- Side-effects of treatment
- 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.	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 (see side- effects table on page 20).
Patient had difficulty swallowing because of pain (this could be oral thrush).	Use <i>IMAI Acute Care</i> or <i>IMAI Palliative Care</i> to classify and provide treatment or to refer patient as necessary.
Patient cannot leave small children at home and is tired of bringing them to the health facility.	Suggest that a family member or neighbour watch the children. Remind family members/ neighbours that the patient must continue treatment to protect their health, particularly the health of the children.
	If possible, identify a community TB treatment supporter closer to the patient's home.

MOTIVATE the patient with statements such as the following:

- TB can be cured if you keep coming for the medicine, and then you will not have to worry about it any more.
- 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 doses one day at a time. Do not give an extra dose on any day

RECORD a zero (0) on the *TB Treatment Card* for each day missed. Add a comment on the action taken, for example, "home visit, treatment resumed."
G6.4 Trace patient after interruption of TB treatment: summary of actions after interruption of TB treatment

Interruption for less than 1 month

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

Interruption for 1 up to 2 months

First:	Then, take action base	d on results of s	putum examination:
 Trace patient Solve the cause of 	If all smears are negative, or patient has extrapulmonary TB	Continue treatr compensate fo	ment and prolong it to r missed doses
 interruption Collect 3 sputum samples 	If one or more smears positive, and	Patient has been treated for less than 5 months	Continue treatment and prolong it to compensate for missed doses
While waiting for results, continue treatment		Patient has been treated for 5 months or more	If patient was on: Cat I – Start Cat II Cat II – Refer (may evolve to chronic)

Interruption for 2 months or more (default)

Fi	rst:	Then, take action base	d on results of s	putum examination:
•	Collect 3 sputum samples	If all smears are negative, or patient has extrapulmonary TB		es on individual o restart or continue o further treatment
•	Solve the cause of interruption,	If one or more smears positive, and	Patient was previously on Cat I	Start Cat II
•	if possible Do not give treatment while waiting for results		Patient was previously on Cat II	Refer (may evolve to chronic)

Notes:

Monitor TB or TB-ART co-treatment

H1 Monitor progress of TB treatment with sputum examinations and weight

H1.1 Determine when the patient is due for follow-up sputum examinations

Schedule for follow-up sputum examinations (for pulmonary TB cases only)

				Month	s of tre	atment			
Treatment category	1	2	3	4	5	6	7	8	9
Category I new smear-positive pulmonary	_	•	 		•	• • • • •		*	
Category II previously treated smear- positive pulmonary			•	1	•			•	
Category III smear-negative pulmonary		-	1						

Initial phase of treatment

..... Continuation phase of treatment (directly observed)

H------ Alternative continuation phase of treatment (HE self-administered)

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

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

H1.2 Collect two sputum samples for follow-up examination

- Fill out Request for Sputum Examination (see Forms)
- Send the sputum samples to the laboratory

H1.3 Record results of sputum examination and weight on TB Treatment Card

- Record the results of the follow-up examination on the patient's *TB Treatment Card*. Write in the month of treatment, and the result. Record the result as "neg" or if positive, record the highest grading.
- The laboratory technician will record the examination results on the bottom half of the Request for Sputum Examination form and return it to the health facility.

- One or two positive sputum smears mean that the patient is still sputum smear-positive.
- If both smear specimens are negative, the patient is sputum smear-negative.

H1.4 Based on sputum results, decide on appropriate action needed and implement the treatment decision

If sputum examination result is negative

Begin or complete continuation phase of treatment.

If the sputum examination result is positive

- At end of initial phase of treatment (Category I or II):
 - Extend the initial phase of treatment by 1 extra month.
 - Review whether treatment has been irregular. If so, discuss with patient the importance of regular treatment and adherence.
 - Adjust the schedule for follow-up sputum examination as shown below.
- At 5 months or later:
 - Consider the case a treatment failure.
 - Close the *TB Treatment Card* (Outcome = Treatment failure) and open a new *TB Treatment Card* (Type of patient = Treatment after failure).
 - Begin Category II treatment (or Category IV if proven multidrug-resistant).
- At end of initial phase of treatment for a smear-negative pulmonary case (Category III):
 - Open a new *TB Treatment Card* (Type of patient = Other) and begin Category II treatment.

Adjusted schedule for subsequent follow-up sputum examinations (after extra month of initial-phase drugs given)

				Month	s of tre	atment			
Treatment category	1	2	3	4	5	6	7	8	9
Category I with extra month of initial-phase drugs		•	•	 	•		•		*
Category II with extra month of initial-phase drugs	-		•		1				•

If patient develops new signs or symptoms

- Use *IMAI Acute Care* to assess, classify and treat. Refer as indicated.
- If TB-HIV patient not yet on ART is not gaining weight or develops other signs of HIV clinical stage 3 or 4, refer to medical officer/clinician for consideration to start ART.

Notes:

Determine TB treatment outcome

At end of treatment, record treatment outcome on the *TB Treatment Card*:

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

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

Treatment	out	come	Date of de	cision	
Cured Defaulted		Completed Transferred or	Died 🛛	Failed 🗆	
Dellauttea		indifficinca of			

Treatment outcome	Definition
Cure	Sputum smear microscopy positive patient who was sputum negative in the last month of treatment and on at least one previous occasion.
Treatment completed	Patient who has completed treatment but who does not meet the criteria to be classified as a cure or a failure
Treatment failure	New patient who is sputum smear microscopy positive at 5 months or later during treatment, or who is switched to Category IV treatment because sputum turned out to be MDRTB. Previously-treated patient who is sputum smear microscopy positive at the end of his re-treatment or who is switched to Category IV treatment because sputum turned out to be MDRTB.
Died	Patient who dies from any cause during the course of treatment.
Default	Patient whose treatment was interrupted for 2 consecutive months or more
Transfer out	Patient who has been transferred to a health facility in another BMU and for whom treatment outcome is not known.

⁺ Also sputum smear-negative patients who become sputum smear-positive at 2 months.

- A patient who has stopped coming for treatment and cannot be located or cannot be convinced to resume treatment is classified as a "Default" after 2 months of missed treatment. Do not mark this treatment outcome on a patient's card until a patient has missed treatment for 2 months.
- When you transfer a patient to another facility to continue treatment, record the date and mark the outcome "Transfer out" on the back of the *TB Treatment Card*. If the transfer is confirmed, inquire later about the treatment outcome. When the patient's outcome is reported from the other health facility, record the final treatment outcome and the date of that outcome on the card. Only if you cannot determine another outcome, leave the outcome "Transfer out" with the date of the transfer.
- If a patient was a transfer from another health facility (type of patient was "Transfer in"), remember to report the patient's treatment outcome to the originating health facility.
- In smear-negative pulmonary and extrapulmonary TB patients, "Cure" and "Treatment failure"¹ are not possible outcomes because these outcomes are based on whether or not a patient has sputum conversion (positive to negative) in follow-up sputum smear examinations. However, the other outcomes are possible: "Treatment completed," "Died," "Default," and "Transfer out."
- When a patient does not complete treatment, return all drugs remaining in the patient's drug box to the drug supply room.
- Some patients do not complete treatment because they die or stop coming for treatment and cannot be located.
- When treatment is completed, discharge the patient.

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

In an HIV-positive TB patient, monitor HIV clinical status and provide HIV care throughout the entire period of TB treatment

If trained and supported to do so, follow the chronic HIV care sequence of care in HIV-positive TB patients (shown on the next two pages). If HIV care with ART will be provided in another clinic, coordinate care with that clinic.

- 1. Triage.
- 2. Education and support.
- 3. Assess: Clinical review of symptoms and signs, medication use, side effects, complications; then do clinical staging.
 - Pay particular attention to TB-related signs and side effects (section G2).
 - Repeat clinical staging—If the patient has new signs of clinical stage 4 or is losing weight, use section B4 of these guidelines.
 - If patient is on ART, respond to new signs or symptoms using *IMAI Acute Care* and the table on side-effects in section G2.
- 4. Assess family status.
- 5. Review TB status: use these guidelines until TB treatment is finished.
- 6. Provide clinical care—bearing in mind TB-HIV co-management.
- 7. Prophylaxis.
 - Patients on TB treatment should not be receiving INH prophylaxis.
 - Provide cotrimoxazole prophylaxis according to Section E1.
 - Provide fluconazole prophylaxis if this is in the patient's treatment plan.

continued on page 84

Sequence of care after positive



If health worker visit needed:



TB A Determine: • Disease site • Type of TB • TB treatment category • TB-ART co-treatment plan (by MD/MO/ AMO) • Family status and HIV status of partner(s) and children B Decide TB or TB-ART treatment plan C Prepare TB Treatment Card D Educate on TB & HIV

- E Give preventive therapy
 - Cotrimoxazole
 - INH to household contacts
 - BCG if <2 years

F Prepare for and support adherence

- Prepare patient for self-management
- Select, prepare, supervise treatment suporter
- Other types of adherence support

G Support the patient throughout TB treatment

- Support or directly observe treatment
- Manage side-effects
- Continue education on TB and HIV

H Monitor TB treatment

Determine TB treatment outcome



8. ARV therapy.

- TB patients need to have an ART co-treatment plan from a doctor or medical officer to start ART.
- Some other opportunistic infections need to be treated before starting ART and mental health/substance use problems need to be stabilized. Use sections 8.2 and 8.3 of *Chronic HIV Care*.
- Provide the patient and treatment supporter with the appropriate education card for their current regimen.
- Adherence preparation, support and monitoring using the 5 A's (Assess, Advise, Agree, Assist and Arrange) to develop a partnership with the patient and to develop self-management skills are particularly important in TB-HIV patients.
- 9. Manage other chronic problems—persistent diarrhoea, fever, weight loss, injecting drug use and drug substitution therapy.
- 10. Dispense medications, schedule follow-up, record data.
 - Coordinate dispensing of ART with TB medications if you are managing both (see section B6).
 - Update the HIV Care/ART Card.
 - Conduct home visits and trace patients who fail follow-up.
 - Link to community care.
- 11. Prevention for PLHIV.
 - All patients should receive ongoing interventions to help them prevent transmission to others, to prevent mother-to-child transmission, to make reproductive choices and receive appropriate family planning interventions, support for disclosure, etc.
 - All patients should receiving ongoing support for positive living to help them protect themselves from other infections, nutrition support, physical activity, and advice to avoid harmful or ineffective expensive treatments or food supplements.

Assure continuity of HIV care with ART after TB treatment is finished. The patient will need a new *Patient Treatment Card* and may need changes in the approach to adherence support.

Special considerations in children

K1 When to suspect TB infection in children

TB diagnosis in young children is not always straightforward, as adequate sputum samples are not easy to obtain. Children less than 5 years who have a history of close contact with a TB patient and symptoms of TB (cough, fever, weight loss or failure to thrive) should be referred to a doctor or medical officer for evaluation.

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

- Chronic symptoms suggestive of TB
 - Cough
 - Fever
 - Weight loss or failure to thrive
- Physical signs highly suggestive of TB*:
 - Gibbus, especially of recent onset (resulting from vertebral TB) or
 - Non-painful enlarged cervical lymphadenopathy with fistula formation
- A positive tuberculin skin test:
 - >= 5 mm in high-risk children (HIV-infected or severely malnourished) or
 - >=10 mm in all other children
- Chest x-ray suggestive of TB.

* Other physical signs of extrapulmonary TB (such as pleural effusion, distended abdomen with ascites, or subacute meningitis) will require further investigation by a doctor or medical officer.

All children diagnosed with TB should be tested for HIV if this has not already been done.

K2 TB drug dosing in children

The drug dosages in mg/kg of body weight are the same for children as for adults.

Drug	Recommended dose in mg/kg	body weight (range)
	Daily	Three times weekly
isoniazid	5 (4-6), maximum 300 daily	10
rifampicin	10 (8-12), maximum 600 daily	10 (8-12), maximum 600 daily
pyrazinamide	25 (20-30)	35 (30-40)
ethambutol*	children 20 (15-25)*	30 (25-35)
	adults 15 (15-20)	
streptomycin	15 (12-18)	15 (12-18)

* The recommended daily dose of ethambutol is higher in children (20 mg/kg) than in adults (15mg/kg), because the pharmacokinetics are different (peak serum ethambutol concentrations are lower in children than in adults receiving the same mg/kg dose).

К3

ART in HIV-infected children with TB

In HIV-infected children with confirmed or presumptive TB disease, initiation of TB treatment is the priority. However, the optimal timing for initiation of ART during TB treatment is not known. The decision on when to start ART after starting TB treatment involves a balance between the child's age, pill burden, potential drug interactions, overlapping toxicities and possible immune reconstitution syndrome versus the risk of further progression of immune suppression with its associated increase in mortality and morbidity. Many clinicians will start ART 4-8 weeks after starting anti-TB treatment.

TB infection control

L1 How TB is spread

TB is caused by Mycobacterium tuberculosis (*M. tb*). People who have TB disease in their lungs or larynx (throat) can release tiny particles containing *M. tb* into the air by coughing or sneezing. These particles are called droplet nuclei. They are invisible to the naked eye because they are only about one-millionth of a meter long. Droplet nuclei can remain airborne in room air for many hours, until they are removed by natural or mechanical ventilation.

For TB to spread, there must be a source that produces *M. tb* (person with TB disease) and others to inhale droplet nuclei containing *M. tb*. Anyone who shares air with a person with TB disease of the lungs or larynx in an infectious stage is at risk. When another person inhales one or more of the droplet nuclei he or she can become infected with TB, or, in other words, develop TB infection.

L2 When is TB disease infectious?

TB can be infectious when it occurs in the lungs or larynx.

In general, a person with TB disease of the lungs or larynx should be considered infectious until the person:

- Has had three consecutive negative sputum smears on two different days; or
- Has completed at least two weeks of anti-TB therapy, preferably with direct observation by a TB treatment supervisor; and
- Has improvement in symptoms.

A TB suspect should be considered infectious until a diagnostic evaluation is completed.

L3 The TB infection control plan for all health facilities should include:

- Screen all clients to identify persons with cough > 2 weeks as soon as possible after arrival at the facility.
- Ask patients to cover their mouths when they cough if possible.
- Provide face masks or tissues to persons with symptoms of TB disease ("TB suspects");

Face masks do help prevent the spread of *M. tb* from the patient wearing them to others, by capturing the large wet particles near the mouth and nose. Thus face masks could be provided to persons who have a positive symptom screen, to wear until they leave the facility. Cloth masks can be sterilized and reused. Paper tissues provided to these persons, with instructions to cover their mouth and nose when coughing or sneezing, are less costly and also less likely to identify people as TB suspects with attendant risk of stigma. However, they are less likely to be used effectively.

Suggested clinic operating procedure: Clients with a positive screen should immediately be handed tissues (or scraps of cloth) and instructed to cover their mouth and nose when they cough or sneeze. Alternatively clients should be given a face mask and asked to wear it while in the facility.

Place TB suspects in a separate well-ventilated waiting area or outside.

Suggested clinic operating procedure: A staff person should direct or escort the TB suspect to a separate waiting area. Clients need to be assured of their place in the queue for registration and/or services (this special waiting area should have the highest natural ventilation possible).

Expedite TB suspects' receipt of services in the facility.

Suggested clinic operating procedure: TB suspects should be moved to the front of the queue for whatever services they are accessing, e.g. HIV testing and counselling or VCT, medication refills, medical evaluation. This reduces the duration of potential exposure in the facility and may be an incentive to disclose information during screening.

- Ensure rapid investigation of TB suspects or referring TB suspects to TB diagnostic services if not available on site.
- Use and maintain environmental control measures (see next section).
- Screen staff for symptoms of TB disease (see section A).
- Provide voluntary, confidential HIV counselling and testing for staff with appropriate access to treatment.
- Train and educate all staff on TB, TB control and the TB infection control plan. Advise against wearing face masks (see section J5).
- Monitor the implementation of the TB infection control plan.

L4 Environmental control measures

Environmental controls are the second line of defence for preventing the spread of TB in HIV care settings. If the work practice controls are inadequate, environmental controls will not eliminate the risk of spread of TB.

Environmental control measures include:

Ventilation (natural and mechanical)

Controlled natural ventilation can reduce the risk of spreading TB. Ventilation is the movement of air in a building and replacement of air in a building with air from outside. When fresh air enters a room it dilutes the concentration of particles, such as droplet nuclei containing *M.tb*, in room air.

- **Open doors and windows** to bring in air from the outside; 'controlled' implies that checks are in place to make sure that doors and windows are maintained in the position that enhances ventilation. Design waiting areas and examination rooms so that they have maximum natural ventilation can help reduce the spread of TB.
- In warm climates, use an open-air shelter with a roof to protect patients from sun and rain.
- Fans may also assist in this process and distribute the air.
- Always collect sputums for TB outside (open environment) and away from other people, not in small rooms such as toilets or other enclosed areas.

* Filtration and ultraviolet germicidal irradiation

These environmental control measures are more technologically complex and expensive, and thus more appropriate for referral hospitals, to supplement ventilation. The primary way **to prevent transmission of TB to health workers** and others at the health facility is for TB patients to take their drugs regularly. They will then become non-infectious in a week or two. Good ventilation of the place where treatment is provided is also very important.

Personal respiratory protection (respirators) are not a priority intervention. Respirators can protect health care workers from inhaling *M. tb* only if appropriate work practice and environmental controls are in place; i.e. they are a last line of defence. They are expensive to purchase and require specialized equipment to determine the appropriate fit. Frequently, they are unavailable in resource-limited settings. Their use should be restricted to specific high risk areas in hospitals and referral centres, such as rooms where spirometry or bronchoscopy are performed or specialized treatment centres for persons with multi-drug resistant TB.

Respirators are different from face masks, such as surgical masks made of cloth or paper. Face masks do not protect those wearing them from inhaling *M. tb.* In fact, the use of these masks may contribute to a false sense of security. **There is no role for health care workers or staff to use face masks for protection from TB.**

Prevention for PLHIV

M1 Prevent sexual transmission of HIV

(Use the IMAI Flipchart for Patient Education to support providing this information and for more detail.)

Warn about the risks of unprotected sex and make an individual risk reduction plan

- Educate on risk of HIV infection to sexual partners.
- Help patient assess current risk of transmission and make an individual risk reduction plan.
- Explain that it is possible to be re-infected with another strain of HIV or to get a sexually transmitted infection (STI).
- Explain that sexual activity need not be avoided, but precautions are necessary.



Counsel on consistent and correct use of condoms during every sexual encounter.

- Educate that it is essential to consistently use condoms even if already infected with HIV or if both partners are HIV-positive.
- Use condoms for vaginal, anal and oral intercourse.
- Demonstrate how to use both male and female condoms.
 - Use model to demonstrate correct use.
 - Educate to put condom on before penetrative sex, not just before ejaculation.
 - Request client to demonstrate correct use of condoms.
- Educate on advantages/disadvantages of both male and female condoms.
- Advise to use water-based lubricants.



Discuss potential barriers to consistent and correct use of condoms

- Explore options to overcome barriers.
- Provide techniques/skills for negotiating condom use according to the needs expressed by clients.
- Role-play condom negotiation with client.

Provide condoms and discuss how client will assure a regular supply of condoms

Counsel on safer sex and reducing risk of transmission

- Counsel on partner reduction while emphasizing consistent condom usage during all sexual encounters.
- Counsel on less risky sex—choose sexual activities that do not allow semen, fluid from the vagina, or blood to enter the mouth, anus or vagina of the partner.
- Educate on symptoms of STIs with clients and counsel them to receive prompt treatment if they suspect a STI.
- Dispel any prevailing myths on cleansing of HIV infection through sexual intercourse with minors or others. Discuss any other local myths that may impact on positive prevention, for example, belief that condoms transmit HIV.
- For adult men, emphasize not having sex with teenagers or girls (or boys).
- Emphasize that even if a client is on ART, HIV transmission can still occur.
- Respond to concerns about sexual function. Encourage questions from clients. Emphasize that normal sexual activity can continue, with above stated precautions.



Stay faithful to your partner.



Limit number of sexual partners. 4 Always use condoms.



Do not have sex with young girls. It does not cure HIV. It makes things worse by spreading infection to the young generation.

Explore other forms of sexual pleasure.



Discuss disclosure (see Annex A.5 of *Chronic HIV Care*) and encourage partner testing.

- Discuss barriers and explore benefits of disclosure.
- Develop strategy for disclosure if client is ready.
- Refer to PLWHA support groups or others for additional support, if required.
- Strongly encourage and facilitate partner testing (record result on HIV Care/ART Card).
- Discuss testing of children.
- Provide ongoing counselling for discordant couples.

M2 Counsel on family planning and childbearing

If woman of childbearing age or any man, counsel on reproductive choice and family planning. (use the *Reproductive Choice and Family Planning for People Living with HIV Flipchart* to support providing this information and for more detail).

If considering pregnancy:

- Advise on the risks associated with pregnancy:
 - Infections such as malaria, TB, pneumonia are more dangerous in pregnancy.
 - Greater risk of postpartum complications.
- Pregnancy does not cause faster progression of HIV/AIDS for the woman.
- Discuss risks for the baby. Possible transmission from HIV-positive woman to her baby during pregnancy, delivery or breastfeeding. Also increased risk of miscarriage, stillbirth, and low birth weight.
- Discuss PMTCT interventions.
- Could infect uninfected partner.
- If man is not infected with HIV, discuss artificial insemination. If not possible, advise having sex without condoms only at fertile time of month.
- If pregnancy not desired; discuss family planning.
- Encourage condom use in all to protect from STIs, infection from another strain of HIV, and also to prevent transmission to sexual partners.
- Condoms are also an effective method of contraception when used correctly and consistently (offering dual protection from both pregnancy and STIs/HIV). However, if a woman desires further pregnancy protection, she may wish to use condoms with another contraceptive method.

Risk of mother-to-child transmission of HIV

Out of 20 babies born to women with HIV, without treatment (risk of transmission can be lowered with treatment).

Not infected	13
Infected during pregnancy and delivery	4
Infected during breastfeeding	3



Breastfeeding

Example of patient treatment card for TB-ART Treatment

d4T - 3TC - EFV stavudine lamivudine efavirenz

ART	Week 1-2	Week 3-8 (2 months)	Month 2-6	Month 7 and on
		d4T-3TC (FDC) combined tablet	d4T-3TC (FDC) combined tablet	d4T-3TC (FDC) combined tablet
ART	RHZE 4 separate tablets	RHZE 4 separate tablets	RHZE 4 separate tablets	
ARI -		d4T-3TC (FDC) EFV (separate)	d4T-3TC (FDC) EFV (separate)	d4T-3TC (FDC) EFV (separate)

Remember that

- If you miss doses (even 3 doses in a month) DRUG RESISTANCE can develop. This is bad for you and your community.
- If you stop you will become ill within months or a year.
- Drugs **MUST NOT** be shared with family and friends.
- If you find it difficult taking your pills regularly, DISCUSS with health workers. ASK for support from your treatment supporter, family or friends.

It is common to have side effects. They usually go away in 2 weeks.

lf you have:	Do the following:
Nausea	Take pills with food.
Diarrhoea	Keep drinking and eating.
EFV can cause brain effects such as sleepiness, dizziness, bad dreams, or problems with sleep or memory	These side effects usually go away. Taking the efavirenz at night is important.
Muscle pain, fatigue	These will go away.
Orange/red urine	This is normal.

If nausea or diarrhoea persist or get worse, or you have any of the following, report to the health worker **AT THE NEXT VISIT.**

- Tingling, numb or painful feet or legs or hands.
- Arms, legs, buttock, and cheeks become THIN.
- Breasts, belly, back of neck become FAT.

SEEK CARE URGENTLY if:

- Severe abdominal pain.
- Yellow eyes.
- Skin rash.
- Fatigue AND shortness of breath.



Revised TB Recording and Reporting Forms and Registers

For country adaptation

						F	ube.	rculo	Tuberculosis Treatment Card	Trea	Itme	ut C	ard				В	MU T	BMU TB Register No.	gister	No.				
Name:													ł	ā	Disease site (check one)	e sit	e (ch	sck or	e)						
Sex: 🗆 M 🔤 F	Ő	ate c	f reg	Date of registration:	ion:										🗌 Pulmonary 🛛 🗆 Extrapulmonary, specify	onary		Extra	bullme	onary	, spe	cify_			L
Age:	Ĩ	ealth	Health facility:	ا نځ										Ļ	Type of patient (check one)	f pat	ient	(checl	< one)						
Address:															. ≪ Ne≪			Trea	Treatment after default	after	- defa	ult			
													Ι		☐ Kelapse ☐ Transfer in	ose sfer ir		Othe	I reatment after failure Other, specify	atter	tallu	อ			
Name / address of community treatment supporter (if applicable)	sommur	litv tr	eatr	ient s	oddns	orter	(if ap	plice	able)										-						ıΓ
		.			:								I		Spi	utur	l sm	ear n	Sputum smear microscopy	scol	Ś		Ne Ne	Weight	
I. INITIAL PHASE - prescribed regimen and dosages	- prescrit	ped re	egime	sn and	dos:	ages	Å	err	Referral by					2	Month		Date		Lab No.		Result		¥)	(kg)	
								Self-	☐ Self-referral	ਯ					0										
CAT (I, II , III):								Com	Community member	ty me	smbe	L				_				_					
Number of tablets per dose and dosage of S:	dose ar			j.				Publ	Public facility	ility/	in or o	der 1													
(RHZE) (RHZE)		n N N	2995	5 5				Othe	C Other, specify	scify		Ē										\square			
													I						TB/HIV	≧					
																			Date	e			Result*	lt*	
Cotrimoxazole				ARV						ō	Other			Ī	HIV test										
														5	CPT start	t									
														ЧA	ART start	t									
								1					1	* (Pos	(Pos) Positive; (Neg) Negative; (I) Indeterminate; (ND) Not Done/unknown	; (Neg) I	legative;	(I) Indett	erminate;	ND) NC	ot Done/	unknown			
Tick appropriate box after the drugs have been administered	ox after	the	drug	s ha	ve b	een a	Idmi	niste	ered																
Daily supply: enter 🗠 . Periodic supply: enter X on day when drugs are collected and draw a horizontal line (riodic supp	oly: en	er Xo	n day	when o	drugs a	re coll	ected	and di	aw a	horizo	ntal lin	 		 through the number of days supplied. Ø = drugs not taken 	uguo-	the nu	nber o	f days	suppli	ed. Ø	= druc	s not ta	aken	Γ
Month 1 2	3 4	2	9	7 8	6	10	7	12	13	4	15 1	16 17	18	19	20	3	52	23 24	1 25	26	27	28	29	30 31	_
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						_	_	_													-	-			-

Number of tablets per dose				<u> </u>	(RH)			(RHE)	<u></u>			Other													
Daily supply: enter Rev Periodic supply, enter X on day when drugs are collected and draw a horizontal line	supply,	enter	X on c	lay wh	ien dri	ugs are	e colle	cted a	nd dra	awah	orizon	tal lin) e	ו ר	●) thi	uguo.	the nu	mber	•) through the number of days supplied. \emptyset = drugs not taken	/s sup	plied.	0 = Ø	ngs n	ot tak	en
Month 1 2 3 4	ഹ	e	4	œ	6	6	1	12 13	3 14	1 15	16	17	18	19	20	51	23	53	24	25 2	26 27	7 28	53	8	31
				\uparrow	+	+	+	_	_	_						+	+	+	+	+	_	+	_		
							_	_										-	+	-	_	_			
-										ļſ				1											-
X-ray (at start)	Ī	HIV care	e								Ũ	omn	Comments:												
Date:	Pre	Pre ART Register No.	Rec	gister	No.																				
Results (-), (+), ND	딩	CD4 result	Ħ								I														
	AR	ART eligibility (Y/N/Unknown)	gibility	V CVV	I/Unkn	(umo					I														
	Da	Date eligibility assessed	gibilit	y ass	sesse	q																			
	AR	ART Register No.	giste	r No.																					
											I														
Treatment outcome	I																								
	1																								
□ Treatment completed	1																								
Treatment failure	1																								
□ Transfer out																									
Name and address of contact person:	tact	- au																							

II. CONTINUATION PHASE

Name and address of contact person:

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Unit TB
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8	τo			
Type of patient ³				
pat	D			
e of	ш			
Type	R			
Ľ	z			
	Site P / EP			
	Treatment category			
	Date Treatment treatment category started			
	Health facility ¹			
Address				
	əgA			
	M/F Sex			
Name				
	BMU TB No.			
	Date of registration			

Footnotes appearing on first page of the register only.

providers formally engaged in any of the following TB control functions (DOTS): referring TB suspects/cases, laboratory diagnosis, TB treatment and patient 1 Facility where patient's treatment card is kept. In case several copies are kept, the most peripheral facility should be entered. Use standardized type of health facilities according to block 2 of the Yearly Report on Programme Management in BMU. Health facility is defined as any health institution with health care support during treatment.

2 Enter the treatment category:

CAT I: New case of sputum smear microscopy (+), severe sputum smear microscopy (-)PTB & EPTB e.g. 2(RHZE)/4(RH)

CAT II: Re-treatment e.g. 2(RHZE)S/1(RHZE/)5(RHE) CAT III: New sputum smear microscopy negative PTB and EPTB

CAT III: New sputum smear microscopy negative PTB and EPTB e.g. 2(RHZE)/4(RH)

3 Tick only one column:

N=New – A patient who has never had treatment for TB or who has taken antituberculosis drugs for less than 1 month.

R=Relapse – A patient previously treated for TB, declared cured or treatment completed, and who is diagnosed with bacteriological (+) TB (sputum smear microscopy or culture).

F=Treatment after failure – A patient who is started on a re-treatment regimen after having failed previous treatment.

D=Treatment after default – A patient who returns to treatment, positive bacteriologically, following interruption of treatment for 2 or more consecutive months.

T=Transfer in – A patient who has been transferred from another TB register to continue treatment. This group is excluded from the *Quarterly Reports on TB Case Registration and on Treatment Outcome.* **O=Other previously treated**– All cases that do not fit the above definitions. This group includes sputum smear microscopy positive cases with unknown history or unknown outcome of previously treated sputum smear microscopy negative, previously treated for and chronic case (i.e. a patient who is sputum smear microscopy positive at the end of a re-treatment regimen)

Remarks					
tivities	CPT Y/N Start date				
TB/HIV activities	ART Y/N Start date				
		Transfer			
е		Default			
e & dat	ne5	Died			
Treatment outcome & date	Outcome ⁵	Treatment Failure			
atment		Treatment Complete			
Tre		Cure			
	Date				
	End of treatment	Date/ Lab. No.			
		Sputum smear micros- copy result			
mination	5 months	Date/ Lab. No.			
d other exa		Sputum smear micros- copy result			
oscopy and	2 or 3 months ¹	Date/ Lab. No.			
Results of sputum smear microscopy and other examination		Sputum smear micros- copy result			
	Before treatment	X-ray Result ⁴			
		HIV result ³ Date			
		Date/ Lab. No,			
		Sputum smear micros- copy result ²			

Basic Management Unit TB Register- Right side of the register book

Footnotes appearing on first page of the register only

1 CAT I patients have follow-up sputum smear microscopy examination at 2 months; CAT II patients have follow-up sputum smear microscopy examination at 3 months. CAT I patients with initial phase of treatment extended to 3 months have follow-up sputum examinations at 2 AND 3 months with results registered in the same box

3 (Pos): Positive; (Neg): Negative; (I): Indeterminate; (ND): Not Done / unknown. Documented evidence of HIV test performed during or before TB treatment is 2 (ND): Not done; (NEG): 0 AFB/100 fields; (1-9): exact number if 1 to 9 AFB/100 fields; (+): 10-99 AFB/100 fields; (++): 1-10 AFB/ field; (+++): > 10 AFB/ field

reported here. Measures to improve confidentiality should accompany recording of HIV status in the TB patient record or registers 4 (Pos): Suggestive of TB, (Neg): Not suggestive of TB; (ND): Not Done.

5 Tick only one column for each patient:

reatment because sputum turned out to be MDRTB. Previously-treated patient who is sputum smear microscopy positive at the end of his re-treatment or Treatment failure: New patient who is sputum smear microscopy positive at 5 months or later during treatment, or who is switched to Category IV Cure: Sputum smear microscopy positive patient who was sputum negative in the last month of treatment and on at least one previous occasion. Treatment completed: Patient who has completed treatment but who does not meet the criteria to be classified as a cure or a failure. who is switched to Category IV treatment because sputum turned out to be MDRTB. Died: Patient who dies from any cause during the course of treatment.

Default: Patient whose treatment was interrupted for 2 consecutive months or more.

ransfer out: Patient who has been transferred to a health facility in another BMU and for whom treatment outcome is not known.

Request for Sputum Smear Microscopy Examination

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

Referring facility1	Date			
Name of patient	Age Sex: 🗆 M 🗆 F			
Complete address				
Reason for sputum smear microscopy examination:				
OR Group Number of month of treatment: BMU TB Register No. ²				
Name and signature of person requesting examination				
1. Including all public and private health facility/providers 2. Be sure to enter the patient's BMU TB Register No. for follow-up of p	atients on chemotherapy			

RESULTS (to be completed in the laboratory)

Laboratory Serial No.

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

3. To be completed by the person collecting the sputum

4. Blood-stained, muco-purulent, saliva

Examined by _____

Date Signature

Abbreviations

3TC	lamivudine
ABC	Abacavir
AIDS	Acquired Immunodeficiency Syndrome
ALT	Alanine Aminotransferase (a liver function test)
ARV	Antiretroviral (drugs)
ART	Antiretroviral Therapy
AZT	azidothymidine—chemical name for the generic zidovudine (also called ZDV)
CD4	Count of the lymphocytes with a CD4 surface marker per cubic millimetre
	of blood (mm³)
d4T	stavudine
ddl	didanosine
EFV	efavirenz
FDC	Fixed drug combination
Н	Isoniazid (INH)
HIV	Human Immunodeficiency Virus
IDV/r	ldinavir/retonavir
IMAI	Integrated Management of Adolescent and Adult Illness
IMCI	Integrated Management of Childhood Illness
INH	Isoniazid
LPV/r	Lopinavir/retonavir
MDR	Multiple drug resistant (TB)
NFV	nelfinavir
NVP	nevirapine
OI	Opportunistic Infection
PLHA	Person living with HIV/AIDS, now referred to as PLHIV
PLHIV	Person living with HIV
PMTCT	Prevention of Mother to Child Transmission (of HIV)
PEP	Post-Exposure Prophylaxis
Rx	Treatment
SQV/r	Saquinavir/retonavir
ТВ	Tuberculosis
TDB	tenofovir
TLC	Total Lymphocyte Count
XDR	Extensive drug resistant (TB)
ZDV	zidovudine, AZT

