Tuberculosis Case Management Guideline

For doctors and other health workers

This version is for countries and contexts with low HIV prevalence.

This deskguide is a decision aid, prepared with the aim of assisting clinicians and health workers to provide quality TB care. However, clinicians should use their clinical judgement, and responsibility for all clinical decisions made remain that of the clinician or other health worker.

This deskguide is the latest version prepared COMDIS partners. This generic version is adapted from the version by the National Tuberculois Programme Nepal, HERD and John Walley, which itself was based on previous versions prepared by the Nuffield LIHS, Leeds, together with other national TB programme COMDIS NGO parters such as ASD Pakistan, GSH Swaziland and the COMDIS China. It has benefited from reference to many WHO TB documents, and is up-dated according to the latest WHO StopTB strategy.

This may be freely downloaded www.comdis.org, and may be adapted according to national TB programme guidelines and country context, any organisation involved in TB care in developing countries. See the adaptation guide.

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History and Examination

Greet and ask what is the problem (Ensure privacy, so feels free to talk),

Chest:

Cough 2 weeks or more without improvement?
Sputum production? Blood present?
Past TB? TB in family?
Asthmatic / any other lung disease? How long?
Smoker? How long?
Shortness of Breath?

Count Respiratory Rate - Is it fast ? (see below)
Listen to Chest? Unilateral wheeze or dullness?

Systemic

Fever? Temperature?
Weight Loss or no weight gain? Record Weight
Diagnosed with heart disease. When? Take blood pressure and pulse.
What tablets are you taking?

Suspect pulmonary TB if:

Cough more than 2 weeks OR,
Cough less than 2 weeks of uncertain duration, PLUS either blood stained sputum, fever at night, weight loss, or previous history of TB in the patient, family or other close contact.

Treat or Refer immediately if patient has one or more of the following:

Impaired consciousness, agitation or lethargy
Difficulty in breathing at rest or cannot talk in full sentences
Pulse >120 in one minute
Blood Pressure < 90 systolic
Crackles or breaths over 30/ minute adult, or over 40/min children 5-13 yrs
Temperature 40 degrees Celsius or more.

Suspect Extra-Pulmonary TB (EPTB) if:

Constitutional TB symptoms and signs of involvement parts of the body other than the lungs such as the lymph nodes, pleura and bones etc.

Classify and manage patients with cough or difficult breathing

First look in the top (pink) row - are there any of the severe signs. If not look in the middle (yellow) row - are signs of pneumonia?. If not look in the bottom (green) row.

SIGNS:	CLASSIFY AS:	TREATMENTS:
One or more of the following signs: • Very fast breathing or • High fever 40ºC or more or • Pulse 120 or more or • Lethargy or • Not able to walk unaided or • Uncomfortable lying down or • Severe chest pain • Systolic BP less than 90	**SEVERE PNEUMONIA OR VERY SEVERE DISEASE**	Position Give first dose IM antibiotics If wheezing present, treat this If known heart disease and uncomfortable lying down, give furosemide **Refer urgently to hospital**
Two of the following signs: • Fast breathing • Night sweats • Chest pain	**PNEUMONIA**	Give appropriate oral antibiotic • If wheezing present, treat • If smoking, counsel to stop smoking • If cough 2weeks or more, send 3 sputums for TB diagnosis • Advise when to return immediately • Follow up in 2 days
• Cough or difficult breathing for more than 2 weeks or • Recurrent episodes of cough or difficult breathing which: o Wake patient at night or early in the morning or o Occur with exercise	**POSSIBLE CHRONIC LUNG OR HEART PROBLEM**	• If cough 2 weeks or more, send 3 sputums for TB diagnosis or send the patient to district hospital for sputum testing. • If sputums sent recently and negative, refer to doctor/ hospital for assessment if a chronic lung problem (e.g. COPD) that has not been diagnosed already • If smoking counsel to stop • If wheezing, treat this • 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

See also WHO IMAI guidelines on www.who.int/healthtopics HIV IMAI acute care http://www.who.int/hiv/pub/imai/en/acutecarerev2_e.pdf, or TB/ Practical Adult Lung “PAL”.

Diagnose cause of cough (also see table above):

Pneumonia if fever and crackles or rapid breathing or pleuritic chest pain

Asthma if attacks of wheeze or night time cough with audible auscultatory wheeze

COPD (Chronic Obstructive Pulmonary Disease/chronic bronchitis) got worse and is/was a smoker and sputum change in volume or colour from yellow or green

Lung Cancer in patient with chronic cough, a history of smoking, especially if over 50 years old and one or more of the following:

- Continuous blood stained sputum or haemoptysis;
- Non specific systematic symptoms like weight loss, arthralgia, tiredness and limb ache without particular cause;
- Enlarged lymph node behind the inner end of the clavicle (common place for secondary tumour)

Tuberculosis *For all patients with cough 2 weeks or more suspect (exclude) TB, and send 3 sputum smears and see page below*

If a smoker *advice to stop, and support them to do so (see PAL guidelines).*

Sending a Patient for Sputum Smears:

Send the patient to diagnostic centre with laboratory request form OR,
Prepare a sputum slide, OR,
Collect sputum specimens and transport as soon as possible to diagnostic centres with laboratory request form.

Steps for taking good sputum samples:

Explain to the Patient about the reasons for sputum collection

Complete TB Laboratory Request Form and Sputum Container Label

Collect the Specimen Correctly: this should be done in a well-ventilated place

1. Breathe deeply in and out and demonstrate a deep cough.
2. Tell the patient he/she must produce sputum, not saliva.
3. Encourage the patient to breathe deeply and then cough
4. Give the patient the container to collect a spot specimen, without the lid. Hold the lid yourself.
5. Ask the patient to breathe deeply and cough.
6. Ask patient to spit into the container without dirtying the outside.
7. Give the patient the lid to fit on tightly. Check the lid is tight.
8. Ask the patient to wash his/her hands and also wash yours.
9. Record on the medical record that the sample has been taken.
10. Store it in a cool place/refrigerator until the sample is transported.
11. Arrange for the sample to be transported to a diagnostic centre as soon as possible so that it is examined within a week after its collection
12. Instruct the patient to collect a second early morning specimen and bring it to the lab.
13. Follow instructions (1 to 8) to collect a third specimen next day.

Diagnosis of tuberculosis

In adults - and in children who can cough up sputum (if not, then refer to a specialist).

At the initial visit (and next morning)

Two or three positive sputum - Record as sputum smear positive pulmonary TB
No sputum positive; give a course of broad spectrum antibiotic e.g.
Cotrimoxazole/ Amoxicillin
If one sputum positive, see below.

At follow-up visit reassess if:

Improved; discharge with advice to return if symptoms recur

Not or only a little improved; request Chest X-ray, another 3 sputum smears and culture if available

Clinical review with X-ray and sputum results:

- *Total of two sputum smears are positive* - sputum smear positive pulmonary TB
- *X-ray findings clinically consistent with TB- sputum smear negative pulmonary TB*
- *No sputum smear positive and X-ray finding not consistent with TB - re-assess and treat for other disease, or refer*

One sputum positive; request chest X-ray, additional 3 sputum smears and culture, if available

Clinical review with X-ray and sputum results:

- *Total of two sputum smears are positive - sputum smear positive pulmonary TB*
- *X-ray findings clinically consistent with TB (but not two positive sputum - sputum smear negative pulmonary TB*
- *Still only one sputum smear positive and X-ray not consistent with TB - Re-assess and treat for other disease, or if not sure refer*

Diagnose Extra-pulmonary tuberculosis when:

- *Positive culture from an extra-pulmonary site or,*
- *Histological, radiological or strong clinical evidence consistent with active TB AND*
- *Medical officer/ physician's decision to treat with a full course of anti-TB therapy.*
- *Lymph nodes enlarged more than 2 cm give two weeks antibiotics, if remain more than 2cm, refer to hospital for aspiration and microscopy.*

Identify Patient Type and Category

Take a Drug History: Ask patient if they ever been treated with TB tablets (Rifampicin makes the urine orange) or injections (streptomycin), and if so for how long?

History of drug intake	Smear result	Type
Never taken TB drugs in past. or Taken TB drugs for less than 4 weeks in past.	Smear positive or negative	New case
Taken full course of TB treatment and declared cured.	Smear positive	Relapse
Taken TB drugs and transferred from another DOTS treatment centre or district.	-	Transferred-in
Smear positive patient had TB drugs 5 months or more. or Smear negative patient taken drugs 2 months or more.	Smear positive	Treatment Failure
Taken TB drugs for one or more months, then interrupted for 2 or more months	Smear positive or negative	Return after default
A patient who remains smear positive after completing a re-treatment (CAT II) regimen	Smear positive	Chronic
A patient who does not fit into the above types	Smear positive or negative	Others

* Other, e.g. treated 1 month, e.g. by private doctor

Record on the TB card and register the type of patient based on case definitions.

Decide Treatment Category:

TB patients are put into one of two treatment categories (CAT I and II) on the basis of smear results, disease classification and type of patient.

Smear Results	Disease Classification	Patient Type	Severity of Disease	Category
Positive	Pulmonary	New (or other*)	-	CAT I
		Re-treatment: - Relapse - Treatment failure - Return after default - Other (Sputum smear positive only)	-	CAT II
		Chronic (CAT II failure)	-	Refer DOTS-Plus Centre
Negative	Pulmonary or Extra-pulmonary	New Other (smear negative)	-	CAT I

Prescribing the Treatment Regimen Correctly

Prescribe weight adjusted regimen of fixed-dose combination drugs.
Fill in the technical part of treatment card,
Inform the patient about TB treatment (see page …)
Help them choose the best treatment supporter (see page …)
Ask which treatment centre is nearest/ most convenient, and say go there to collect and start taking the medicine.
Ask if they have any queries/concerns, respond accordingly.

Category I regimen:

For all new patients (sputum smear-positive, smear negative and extra-pulmonary).

Treatment takes 6 months:

Two months (60 daily doses) of HRZE (Isoniazid, Rifampicin, Pyrazinamide and Ethambutol) AND f*our months* (120 doses) HR (Isoniazid and Rifampicin)
Drugs are fixed dose combination (FDC) throughout. Drugs are given to the patient to keep at a safe place in the home.

Regimen / Patient's Weight	**Intensive phase** (2 months)	**Continuation phase** (4 months)
	2HRZE	4HR
	60 total doses	120 total doses-
	(Isoniazid 75 mg + Rifampicin 150 mg + Pyrazinamide 400 mg + Ethambutol 275 mg)	(Isoniazid 75 mg + Rifampicin 150 mg)
30-37 kg	2	2
38- 54 kg	3	3
55-70 kg	4	4
Over 70 kg	5	5

O.75 g for patients aged over 50 years

If sputum examination result at the end of 2 months is:

Negative - start continuation phase (HR) drugs and have sputum examined again at month 5 and end of treatment.

Positive - extend intensive phase for 1 more month then start the continuation phase; and examine the sputum again at 5 months and end of treatment.

Category II regimen:

For re-treatment cases (sputum smear positive): Relapse, Failure Return after default (and now sputum positive) and “Others” positive.

Treatment takes 8 months:

2 months (60 doses) of HRZE and Streptomycin FOLLOWED BY
1 month (30 doses) of HRZE given AND
5 months (150 doses) HRE

Regimen / Patient’s Weight	**Intensive phase** (3 months)		**Continuation phase** (5 months)
	2(HRZE) S / 1(HRZE)		5(HRE)
	90 total doses plus 60 doses of Streptomycin		150 total doses
	(Isoniazid 75 mg + Rrifampicin 150 mg + Pyrazinamide 400 mg + Ethambutol 275 mg)	Streptomycin (vials, IM) 2 months	(Isoniazide 75 mg + Rifampicin 150mg + Ethambutol 275 mg)
30-37 kg	2	0.5g	2
38-54 kg	3	0.75g	3
55-70 kg	4	1g*	4
Over 70 kg	5	1g*	5

- O.75 g for patients aged over 50 years

If sputum examination result at the end of the intensive phase is:

Negative - start continuation phase (HRE) drugs and have sputum examined again at 5 and end of treatment;

Positive - extend intensive phase for 1 more month then start continuation phase ensuring that sputum is examined again at 5 and end of treatment.

Children 0-8 years

Treatment takes 6 months:
Two months (60 daily doses) of three drugs Isoniazid, Rifampcin and Pyrazinamid (HRZ) and then *Four months* (120 doses) of Isoniazid and Rifampcin (HR)

The drugs are supplied in FDCs (HRZ and HR). Streptomycin is administered separately, if required.

Regimen / Patient's weight	**Intensive phase** 2 months		**Continuation phase** 4 months
	2(HRZ) + S		4(HR)
	60 total doses		120 total doses
	H 30mg R 60mg Z 150mg	SM 1 g TBM*	(Isoniazide 30 mg + Rifampicin 60 mg)
3-7 kg	1	As per body weight	1
8-9 kg	1.5	0.120gm	1.5
10-14 kg	2	0.180 gm	2
15-19 kg	3	0.250 gm	3
20-24 kg	4	0.350 gm	4
25-29 kg	5	0.400 gm	5

***** SM Injection is only for the patients with TB Meningitis TB Miliary and spinal TB with neurological complication. This is use according to the Doctor advice.

Registering the Patient

Register the TB patient (at Treatment centre)

Record full address of patient and contact person details on treatment card.

Identify and record the health facility selected as treatment centre on the treatment card.

Fill in patient card, by transferring data from the treatment card. Record on both cards the next date for sputum examination.

Transfer TB number to the treatment card *(and patient card)*

Educate patient on disease and treatment (use key messages given below)

Identify household contacts for further management.

Ask if he/she has any queries/concerns and respond accordingly.

Refer patient to the nearby Health Institution:

- IF diagnostic centre is chosen as the patient's treatment centre, arrange "Treatment Support" for the patient (page….), and give them a patient card.

- IF patient has chosen another treatment centre, then: give them a patient card and ask the patient to immediately go to the chosen treatment centre.

Educate the Patient using the key messages from the next page.

Educating the Patient

The following messages should be reinforced every time the patient is seen by a health worker.

Key health education messages for the patient about TB:

- Your TB will be cured, but only if you take all the drugs for the full 6 months
- Cough spreads tuberculosis.
- Cover your mouth when you cough.
- Do not spit close to other people.
- TB is not spread sharing dishes, utensils, clothes.

Key health education messages for the patient about treatment

- Your TB will be cured, but only if you take all the drugs for the full 6 months
- Free TB drugs will be provided at (name the treatment centre)
- Show them the tablets and explain the number of each tablet to take every day.
- The following side effects of the TB drugs are serious: If you have any of these symptoms, stop taking the drugs and contact the doctor immediately:
    - yellowish skin or eyes;
    - itching or skin rash;
    - vomiting/confusion;
    - blurred or changed vision;
    - ringing in the ears.
- The following side effects of the TB drugs are minor: If you have any of these symptoms, do not stop taking the drugs but mention them to the doctor the next time you meet:
    - loss of appetite;
    - nausea;
    - abdominal pain;
    - joint pain;
    - burning in the feet, etc.
- Do not get worried if your urine is orange, normal with these drugs.
- If you have problems coming to the clinic to get drugs, discuss with the health worker.
- If you are late collecting your drugs, come as soon as possible.
- Visit Microscopy centre at completion of intensive phase, and bring sputum for examination.
- Your progress will be assessed & further treatment will be advised accordingly.

If the TB patient has a known risk of HIV

If possible give group health education to the new TB patients, include information about TB, adherence and management. Also mention that if anyone has had risk behaviours for HIV (e.g. been a migrant, sex worker, an IV drug user) they should tell the health worker and discuss an HIV test.

If the TB patient is known to have had high risk behaviour for HIV, then counsel them and do an HIV test (unless they opt-out of the test). Counsel them either at the initial or a later consultation. For example patients who have been a migrant worker, or a sex worker, or an IV drug user, or they have had an infection associated with HIV. If any of these, counsel, including saying:

- TB patients can have HIV also.
- TB can be cured in people with HIV, just as in those without HIV
- You can protect yourself and others from HIV by being faithful and using condoms each time you have sex.

We recommend to you to have HIV test. If you are positive, we can refer you for HIV care. This will include tablets (cotrimoxazole) to protect you against infections that are common with HIV and drugs against HIV.

…….

In countries or contexts with significant prevalence of HIV, or with individual patients with HIV:

Some key points:

1. All TB patients should be counselled and tested for HIV, unless they opt-out of the test
2. Educate and counsel on both the TB and HIV, prevention, treatment and adherence issues
3. Start co-trimoxazole preventive treatment for all HIV positive patients
4. During and after TB treatment, continue follow-up care to maintain adherence to preventive behaviour, including condom use and cotrimoxazole, and identify opportunistic infections – and if present do CD4 test
5. When the CD4 is below 250 (or according to your national guidelines) commence anti-retroviral treatment.

See details in the WHO guidelines for TB/HIV, on www.who.int/health_topics tuberculosis, such as:

TB care with TB-HIV co-management, downloadable free:
http://www.who.int/hiv/capacity/TBHIV/en/

Improving the diagnosis and treatment of smear-negative pulmonary and extra-pulmonary tuberculosis among adults and adolescents
http://www.who.int/tb/challenges/hiv/en/

The TB/HIV Clinical Manual (second edition, 2004) downloadable free:
http://www.who.int/tb/publications/who_htm_tb_2004_329/en/index.html

Managing Household Contacts

Screen household close contacts of a sputum smear-positive patient. Close contacts includes family members in the same house or other settings such as hostels, factory, barracks or prison.

Arrange or Visit for screening patient's household contacts.

Refer children to the medical officer/ physician for further assessment according if:

1. 5 years or older with symptoms suggestive of tuberculosis, and
2. Less than 5 years old, regardless of symptoms suggestive of tuberculosis.

Manage household contacts of sputum smear positive cases as follows:

Household Contact	Screening	Management
Adult	Chest symptoms (cough > 2 weeks or other TB symptoms)	Arrange sputum smears
Child	No TB symptoms Have had BCG? (0-5 yrs only)	Reassure Give BCG (if no prior BCG)
	History of cough, or fever, or weight loss	Refer to Physician
Child breast fed by smear positive mother		Treat mother Protect child with INH (5mg/kg) for 6 month Continue breast feeding At completion of 6 months, give BCG if not already given.

Explain Treatment Management

Explain that the follow-up care and supply of drugs will be at their nearest treatment centre or treatment centre. **Say** go straight away to this centre to collect your drugs.

Arrange and send treatment cards and anti-TB drugs to selected treatment centre.

Where diagnosed and again at the treatment centre, explain:

Your TB will be cured, but only if you take all the drugs for the full 6 months.

It is important that you take your drugs regularly.

Taking tablets is a long time - but you must keep taking the tablets so that you get cured.

Almost everyone tires of taking or forgets to take medicine especially when they are feeling well and back to work.

We recommend that we choose someone to be your treatment supporter; who will encourage and remind you to take your tablets and attend appointments.

This is so you get the right pills in the right dose for the right length of time so that you will be cured.

Also, you can tell your treatment supporter if there are any side effects of the medicines, and they can advise you what to do.

You (the patient) keep the strip of tablets in a safe place at home. Take the tablets every day at the same time. Record that you have taken the tablets, putting a tick mark on the patient card [Show where to mark]

Go for a check-up and collect more drugs at the chosen treatment centre

- Every week for the first two months (First 3 months for CAT II)
- Every two weeks in the remaining 4 months (Remaining 5 months for CAT II)

Choose the Best Treatment Supporter

Explain it is for the patient to decide who is the most appropriate treatment supporter.

Help the Patient to select the best treatment supporter. The best person to be a treatment supporter is someone who:

- is **reliable;**
- is **concerned** that you finish the treatment and get well;
- lives **nearby and willing to** meet with you regularly;

Tell that people with TB often choose either:

- Health worker, if the health facilities are nearby and convenient or,
- A community health worker / volunteer (such as FCHV, VHW, MCHW) who lives nearby you, or
- A worker of a community-based organisation or NGO partners or
- A family member.

Ask the patient to bring the chosen supporter to the treatment centre (or treatment centre). So they can be told about TB and what to do as a treatment supporter.

Ask the patient if they have any questions or concerns. **Discuss** these fully with them.

Note:
At follow-up consultations ask whether the treatment support is working well. If not, then discuss again with the patient and choose the best treatment supporter.

Explain the Role of a Treatment Supporter

When the patient comes for the first time with their chosen treatment supporter the health worker should **confirm** her/his acceptance to be a treatment supporter.

Explain the role on the first visit, but also reinforce these points at each visit.
See the treatment supporter and patient together, and then:

Show them the drug strips. Explain how many tablets the patient should take each day. Say the treatment supporter routinely ask to see the drug strips and count the number of daily doses taken since the last time they met – is it the right number?.

Show the treatment supporter where the patient will record having taken the tablets each day on the patient card (or leave blank if not taken). Each time the treatment supporter meets with the patient they look to see the ticks for each day dose taken.

Explain that if a symptom (that may be a side-effect) the patient should go to their treatment centre.

Explain that taking the tablets every day, and for the full course (six months if CAT I, 8 months CAT II) is necessary for the patient to be cured.

Explain they need to go for follow-up and sputum check at the microscopy centre after 2 months, 5 months and at the end of treatment (3, 5 and end of treatment if CAT II).

Explain how to Support Treatment

The following messages should be reinforced every time the treatment supporter and patient are seen by a health worker.

Explain to the treatment supporter and patient. Say:

Most people with TB find it difficult to take treatment for six months or more. Sometimes patients find it difficult to continue, or when they have improved they tire of taking the tablets.

Your role as a treatment supporter is to be there for them, support them, encourage and remind them how important it is to take the drugs regularly. You will help them the tablets should take correctly and remind them to attend all the appointments.

Agree an appropriate time when you can be together when taking tablets. Make this an enjoyable social occasion talking together.

The patient keeps the strips of tablets and takes the tablets every day at the same time (including on the days the treatment supporter is not able to be present).

The patient records with a tick on the patient card when he/she takes the tablets: talk sociably while the patients take their tablets and records with a tick mark on the patient card.

The treatment supporter looks to see that the correct number of tablets has been taken from the strip and that the patient card has been ticked. Complement them when they are doing it right.

If it appears that tablets/ dose have been missed, ask about what happened, why it happened and what can be done in the future. Agree with them about how to avoid missing tablets again.

Do not get angry if they missed treatment, but remind them how tablets should be taken.

Be positive, that they will be cured if they take the tablets correctly and attend the appointments for six months (8 if retreatment).

Continue to look and ask to see that tablets are taken. If not taken, again and encourage them. But if this problem continues, or if the patient disappears, then inform the health worker.

If the patient is to go away for some days remind them to take enough tablets for the time they are away.

Remind them of the date to attend the follow-up appointment and take their all tablets and empty strips with them.

Ask if patient has any complaints indicating side effects.

The following side effects of the TB drugs are **serious**, if any of these symptoms, stop taking the drugs and contact the doctor immediately:

- yellowish skin or eyes
- wide spread itching or skin rash
- vomiting/confusion
- blurred or changed vision
- ringing in the ears etc.

The following side effects of the TB drugs are relatively minor (not serious):

- loss of appetite
- nausea
- abdominal pain
- joint pain
- burning in the feet

If any of these symptoms, do not stop taking the drugs but mention them to the health worker/ doctor the next time you meet. The advice may include:

- If loss of appetite, nausea or abdominal pain, try taking the drugs last thing at night.
- If nausea, another suggestion is to take the drugs after food.
- If joint pain, take aspirin.
- If burning in the feet, mention to the health worker at next visit.

If orange/ red urine, reassure this is normal for the drug.

Follow-up the Patient at the Treatment Centre

Patients visit the health worker at the nearby treatment centre:
If possible with their treatment supporter.

At this visit:

Check the regularity of drug intake by

- looking at patient card
- looking at the pills taken from the strips and
- Asking questions to know if the drugs are taken every day.

If regularly: compliment the patient,

If irregularly: ask why and try to help solve any problems.

Ask if patient has any complaints indicating side effects: **Examine** and **manage** the patient according to the following guidelines:

Side Effect	Management
Minor Side Effects ▪ Anorexia, nausea, abdominal pain	Continue anti-TB drugs and: Give drugs last thing at night
▪ Joint pains	Aspirin
▪ Burning sensation in the feet	Pyridoxine 100 mg daily
▪ Itching of skin	Anti histamine
	If no response refer
Major Side Effects ▪ Skin rash ▪ Deafness ▪ Dizziness (vertigo & nystagmus) ▪ Jaundice ▪ Visual impairment (other causes excluded) ▪ Shock (pale, rapid pulse, low BP) ▪ purpura (dark red spots, do not go change colour on pressure), ▪ Acute renal failure (little urine etc.) ▪ Severe pain and swelling of the joints.	**Stop anti-TB drugs. Refer to a Doctor**

Enter the current and next date of appointment on the treatment card and patient card and inform patient**.**

Follow-up at the Microscopy Centre

The patient goes for a sputum check and examination to the microscopy centre at

- 2 months for CAT 1 (3 months for CAT II),
- 5 months, and the end of treatment

Check the regularity of drug intake by

- looking at patient card
- looking at the pills taken from the strips and
- Asking questions to know if the drugs are taken every day.

  If regularly: compliment the patient,

  If irregularly: ask why and try to help solve any problems.

Ask about and respond to the side effects.

Examine the patient for general health condition including weight.

Review the results of **sputum** examination and **manage** as follows:

Category of Patient	Sputum result at end of 2 (or 3) months	Management
Category I (Smear positive)	Negative at 2 months	Start continuation phase treatment
	Positive at 2 months	Continue intensive phase treatment for 1 more month Then start continuation phase
	Positive at 5 months	Repeat sputum smear to confirm positive If again positive, register as failure and start Category-II
Category I (smear negative pulmonary and EP)	Negative at 2 months	Start continuation phase treatment
	Positive at 2 months	Repeat sputum smear to confirm positive If again positive, register as failure and start Category-II
Category II	Negative at 3 months	Start continuation phase treatment
	Positive at 3 months	Continue intensive phase treatment for 1 month Then start the continuation phase
	Positive at 5 months	Repeat the sputum smear. If confirming positive, then: Continue continuation phase and refer to DOTS-Plus Centre for culture and DST

- **Update** the sputum result and treatment changes and date of next appointment on the treatment card, patient card and register.

Managing Treatment Interruption

Retrieving TB patient

The treatment centre, with help of community members and volunteer treatment supporters will coordinate the efforts to retrieve a patient who delays his/her due contact with health providers.

Identify the absentee patient

- ✓ If patient misses taking tablets, the treatment provider should try to visit the patient and convince/help him/her to continue treatment without interruption.
- ✓ **Treatment supporter** should try to find the patient as soon as they know that the patient isn't taking their treatment or if they are not present where they agreed to meet for supervising taking tablets (within 2 days)
- ✓ If the patient is not found, or if the patient refuses to continue taking treatment, then the treatment supporter must inform the treatment centre straight away
- ✓ If so - or if the patient does not attend to collect their medicine - the **health worker** in treatment centre must retrieve through one or more of:
    - Informing the community health worker/ volunteer of the area
    - Home visiting by staff of the treatment centre, where feasible
    - Writing letter to patient and/or treatment supporter if possible, or
    - Calling the phone (a phone number of the patient, family, friend or treatment supporter should be recorded on the treatment card), or
    - Other locally feasible ways to contact them.

Managing patient with interrupted treatment

Retrieve the past records (treatment card and/or patient card) of the patient, and

1. Look at the category in which patient was registered last time
2. Calculate the length of treatment before interruption
3. Calculate the length of interruption (current date - last due date)
    - ✓ <u>If < 2 weeks</u> – treatment centre continues on existing treatment
    - ✓ <u>If > 2 weeks</u> – patient is sent to microscopy centre where a decision is made by health worker based on guidelines given in the following tables

Treat New Sputum Smear Positive Pulmonary TB Cases who interrupt treatment as follows;
(Category I)

Length of treatment before interruption	Length of interruption	Do a smear?	Result of smear	Register again as	Treatment
Less than 1 month	Less than 2 weeks	No	-	-	Continue on same Category *
	2-8 weeks	No	-	-	Start again on same Category**
	More than 8 weeks	Yes	Positive	Return after default	Start again on Category I **
			Negative	Return after default	Continue on same Category *
More than 1 month	Less than 2 weeks	No	-	-	Continue on same Category *
	2-8 weeks	Yes	Positive	-	One extra month of intensive phase of same category
			Negative	-	Continue on same Category *
	More than 8 weeks	Yes	Positive	Return after default	Start on Category II
			Negative	Return after default	Continue on same Category *
> 2 months	< 2 weeks	no	--	--	Continue on same category *
	2-8 weeks	yes	positive	--***	Start on Category II
			negative	--	Continue on same Category *
	>8 weeks	yes	positive	Returned after default	Start on Category II
			negative	Returned after default	Continue on same Category *

Note:
** A patient must complete all 60 doses of the intensive phase.*

*** A patient who must "start again" will restart from the beginning.*

**** If more than 5 months since the start of treatment, classify as failure.*

Treat Sputum Smear Negative and Extra Pulmonary TB Cases who interrupt treatment as follows; (Category I)

Length of treatment before interruption	Length of interruption	Do a smear?	Result of smear	Register again as	Treatment
Less than 1 month	Less than 2 weeks	no	--	--	Continue on same Category *
	2-8 weeks	no	--	--	Start again on same Category
	More than 8 weeks	yes	positive	Returned after default	Start on Category II
			negative	Returned after default	Continue on same Category *
More than 1 month	Less than 2 weeks	no	--	--	Continue on same Category *
	2-8 weeks	yes	positive	--	Start on Category II***
			negative	--	Continue CAT I
	More than 8 weeks	yes	positive	Returned after default	Start on Category II**
			negative	returned after default	Continue on same Category *
> 2 months	< 2 weeks	no	--	--	Continue on same Category
	2-8 weeks	yes	positive	--***	Start on Category II
			negative	--	Continue CAT I
	>8 weeks	yes	positive	Returned after default	Start on Category II
			negative	Returned after default	Continue on same Category

Note:
** A patient must complete all 60 doses of the intensive phase.*

*** A patient who must "start again" will restart from the beginning.*

**** If more than 5 months since the start of treatment, classify as failure.*

Treat New Sputum Positive Re-treatment TB Cases who interrupt treatment as follows; (Category II)

Length of treatment before interruption	Length of interruption	Do a smear?	Result of smear	Register again as	Treatment
Less than 1 month	Less than 2 weeks	no	-	-	Continue on same category *
	2-8 weeks	no	-	-	Start again on same category **
	More than 8 weeks	yes	positive	Return after default	Start again on same category **
			negative	Return after default	Continue on same category *
More than 1 month	Less than 2 weeks	No	-	-	Continue on same category *
	2-8 weeks	Yes	positive	-	One extra month of intensive phase of same category
			negative	-	Continue on same category *
	More than 8 weeks	Yes	positive	Return after default	Start again on same category ****
			negative	Return after default	Continue on same category *
> 2 months	< 2 weeks	no	--	--	Continue on same category *
	2-8 weeks	yes	positive	--	Start again on same category
			negative	--	Continue on same category *
	>8 weeks	yes	positive	Return after default	Start again on same category
			negative	Return after default	Continue on same category *

Note:
** A patient must complete all 90 daily doses of the intensive phase*

*** A patient who must "start again" will restart from the beginning.*

**** If more than 5 months since the start of treatment, classify as failure.*

***** Send sputum sample or patient to DOTS-Plus centre for DST*

Declaring treatment outcomes

Microscopy centre examines follow up sputum smear and send the results to respective treatment centre regularly. Treatment centre should mention the result under the "Result of sputum examination" section of Tuberculosis Treatment Card and TB register respectively. Treatment outcome of individual patient should declare based on follow up sputum smear results and assessment of their treatment. Outcome result should be written under the "Treatment Outcome" section of the card by putting tick mark and mentioning date as shown below:

Treatment Outcome	
Cured	√ 2064/10/21
Completed	
Treatment Failure	
Died	
Defaulted	
Transfer Out	

Similarly, result of other tests like Mantaux Test, FNAC, Biopsy, AFB Culture and Sensitivity, X-Ray and others can be mentioned in the left-back side of the card under remark section.

Treatment outcome is determined as follow:

<table>
<tr><th rowspan="2">MONTH DRUGS TAKEN</th><th colspan="4">SMEAR RESULTS</th><th rowspan="2">COMMENTS</th><th rowspan="2">OUT-COME</th></tr>
<tr><th>"0" Month</th><th colspan="3">Follow-up</th></tr>
<tr><th></th><th></th><th>2 (3) Month</th><th>5 Month</th><th>6 (8) Month</th><th></th><th></th></tr>
<tr><td rowspan="4">6 Months

(8 CAT II)</td><td rowspan="3">Pos</td><td>Neg</td><td>Neg or Missed</td><td>Neg</td><td>-</td><td rowspan="2">Cured</td></tr>
<tr><td>Pos</td><td>Neg</td><td>Neg</td><td>-</td></tr>
<tr><td>Neg</td><td>Neg or Missed</td><td>Missed</td><td>-</td><td rowspan="2">Completed</td></tr>
<tr><td>Neg</td><td>Neg</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td rowspan="7">Less than 6 Months

(Less than 8 months CAT II)</td><td rowspan="3">Pos</td><td>Neg</td><td>Pos</td><td>-</td><td>-</td><td rowspan="3">Treatment Failure</td></tr>
<tr><td>Pos</td><td>Pos</td><td>-</td><td>-</td></tr>
<tr><td>Neg</td><td>Pos</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td rowspan="4">Pos or Neg</td><td colspan="3" rowspan="4">Smear results during the follow-up are not considered (in these three situations).</td><td>Has not collected drugs for 2 consecutive month</td><td>Defaulted</td></tr>
<tr><td>Died of any reason during the course of treatment</td><td>Died</td></tr>
<tr><td>Transferred to another TB Register</td><td>Transferred Out</td></tr>
</table>

Ensuring Quality

Working together at the health facility:

A monthly TB care review meeting may be held at the diagnostic or treatment centre levels. The participants will include doctors, TB health workers and laboratory technicians (at microscopy centres only). The review could be conducted in a form of participatory discussion to identify problems and take collective decisions.

The monthly **review** may **include** all/any of the following areas:

- Laboratory functioning (identifying initial defaulters)
- Cross check the Laboratory and TB registers to make sure sputum smear positive patients have started treatment
- Categorization and prescription practices
- Contact screening and management
- TB Management/support
- Follow-up of registered TB patients (monitoring the case finding, sputum conversion and treatment outcomes)
- Patient compliance and defaulter tracing
- Record maintenance
- Availability of resources and supply

International Standards for Tuberculosis Care

Tuberculosis Coalition for Technical Assistance (TBCTA), which has different partners including World Health Organization (WHO), has developed an *International Standards for Tuberculosis Care (ISTC)* stating the basic principles of care for persons with, or suspected of having tuberculosis which is same worldwide. The purpose of the *ISTC* is to describe a widely accepted level of care that all practitioners, public and private should seek to achieve in managing patients who have, or are suspected of having, tuberculosis.

ISTC is also endorsed by National Tuberculosis Control Programme and Nepal Medical Association including other medical professional societies on 1 March 2008.

The Nepal Tuberculosis Control Programme guidelines are inline with these standards. It consists of standards for diagnosis, treatment and public health responsibilities - containing 17 standards in total. In brief these are:

Standards for Diagnosis

Standard 1 and 2: All persons with otherwise unexplained productive cough lasting two-three weeks or more should be evaluated for tuberculosis-with 3 sputum specimens (including one morning sample) sent for microscopic examination.

Standard 3: If suspected of having extra Pulmonary TB, specimens from the suspected sites of involvement should be obtained for microscopy and, where facilities are available, for culture and histopathological examination.

Standard 4: All persons with chest radiographic findings suggestive of TB should have sputum specimens submitted for microbiological examination.

Standard 5: The diagnosis of sputum smear-negative pulmonary TB should be based on the following criteria: at least 3 negative sputum smears; chest radiography findings consistent with TB; and lack of response to a trial of broad-spectrum anti microbial agents.

Standard 6: The diagnosis of intrathoracic TB in symptomatic children (with negative sputum smears) should be based on the finding of chest x-ray abnormalities consistent with TB & either a history of exposure to an infectious case or evidence of TB infection; if available including a sputum culture.

Standards for treatment

Standard 7: Practitioners treating TB patient must ensure the assessment the adherence of the treatment until the treatment is completed.

Standard 8: Use an internationally accepted first-line treatment fixed dose combination regimen [HRZE for 2 months & 4 months HR, as with the NTP regimen in this guideline].

Standard 9: To ensure adherence, a patient-centred approach to administration of treatment, based on the patient's needs and mutual respect between the patient & provider, should be developed for all patients. Supervision and support should include patient counselling/education. Measures may include direct observation of medication ingestion (DOT) by an acceptable & accountable treatment supporter.

Standard 10: Monitor patient response to therapy by sputum microscopy at the completion of intensive phase, at 5 months & at end of treatment. Positive smears at the 5th month are failures and have therapy modified appropriately. In patients with EP TB & in children, the response is best assessed clinically.

Standard 11: A written record of all medications given, bacteriologic response, and adverse reactions should be maintained for all patients.

Standard 12: For patients where TB and HIV may co-exist, HIV counselling and testing is indicated as part of their routine management.

Standard 13: Give all patients with TB and HIV infection cotrimoxazole prophylaxis and evaluate for when to start antiretroviral (ARV) therapy,

Standard 14 and 15: Chronic and failure cases should be assessed for possible drug resistance [refer to DOTS Plus centres].

Standards for Public Health Responsibilities

Standard 16: All providers of care for patients with TB should ensure that persons (especially children under 5 years of age) who are in close contact with infectious TB patient are evaluated and managed for latent or active TB.

Standard 17: All providers must report both new & re-treatment TB cases and their treatment outcomes through the National Control TB Programme.

Note: Please refer to ISTC original document for details. www.who.int/tb/publications/2006/istc/en/

Definitions

Type of TB Patient:

New case: If patient has never taken treatment for tuberculosis or has taken anti-tuberculosis drugs for less than four weeks in the past.
Relapse: If patient declared cured or treatment completed in the past, again has a positive sputum smear.
Transferred In: A patient who has been transferred from another DOTS treatment centre or district to continue treatment.
Treatment Failure: If patient while on treatment is sputum smear positive 5 month or later during the course of treatment OR Smear negative patient found smear positive at completion of 2 months treatment.
Return after default: If patient returns to treatment after interrupting treatment for two months or more.
Others: Patients who do not fit in the above mentioned types such as patients known to have taken TB drugs for more than 4 weeks from outside the programme.

Treatment category of TB patient:

Category I: New case of smear positive pulmonary tuberculosis or smear negative pulmonary tuberculosis with extensive parenchymal involvement or seriously ill extra pulmonary tuberculosis.
Category II: Previous treatment for more than [four weeks] in the past, and is found sputum smear positive pulmonary tuberculosis. This category includes: relapse, failure, treatment after default, and others (with smear positive)

Treatment Outcomes:

Cured: Initially sputum smear positive patient who has completed the treatment (6-8 month) and is smear negative in the last month of treatment and on at least one previous occasion.
Completed: Initially sputum smear positive patient who completed the treatment (6-8 months) and had negative sputum smears at the end of intensive phase, but with no sputum examination at the end of treatment OR smear negative patient who received a full course of treatment (6-8 months)
Treatment Failure: Sputum smear positive patient who remained, or became again, smear positive five months or later after commencing treatment OR smear negative found sputum smear positive at the end of 2nd month
Defaulted: A patient who at any time after registration had not collected drugs for consecutive two months or more
Transferred out: A patient transferred from one DOTS treatment centre or district to another DOTS treatment centre or district
Died: Patient who is reported to have died of any cause during the course of treatment (based on information gathered and recorded by a responsible health worker)

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