Final Draft

How to Provide Patient Centred TB Treatment

A guide for health workers

July 5, 2005

1 Introduction

Tuberculosis (TB) is a major public health problem in the United Republic of Tanzania. The new case-load has increased almost six times from 11,753 cases in 1983 to 64,665 in 2003 (NTLP annual report, 2003) largely fuelled by the spread of HIV/AIDS. This has dramatically increased the workload of health care providers and is also putting increasing pressure on already over-stretched health facilities.

TB treatment is long (lasting 6 to 8 months) and demanding as patients need to come to the health facility everyday for directly observed treatment (DOT) for the first two months. DOT is a core element of TB treatment as it helps to ensure that patients take the right number of tablets every day as directed, for the full course of treatment. This is crucial for the cure of patients, to prevent the development of drug resistance and to protect communities.

There is however growing recognition that DOT puts too much demand on patients and therefore should be adapted to the needs of patients and to the working conditions of health care workers to minimize disruption of the services. Patient Centred Treatment (PCT) has been developed in response to these needs in order to make it easier for patients to complete their treatment without compromising on the principles of DOT. The planned changes in TB treatment make patient centred treatment feasible and timely.

1.1 Key changes in TB treatment

1.1.1 Introduction of fixed dose combination (FDCs) in blister packs.

Currently, Tanzania is using single and two fixed-dose combination drugs to treat TB patients. The drugs used for the intensive phase of treatment (i. e. Rifampicin, Isoniazid, Pyrazinamide, Ethambutol) will be made available in a single tablet as a fixed dose combination (FDCs). FDCs have major advantages over the drugs currently in use. They are easier for health workers and patients to use. Fewer errors occur in counting and dosage and patients need to swallow fewer tablets. The blister packs also simplify logistics, protect the drugs from heat, moisture and dirt and are easy to store.

1.1.2 Use of rifampicin based regimen for the full duration of treatment.

Tanzania plans to change the treatment in the continuation phase from Ethambutol-Isoniazid (EH) to Rifampicin-Isoniazid (RH) in line with the current WHO recommendations for resource poor countries with generalised epidemics of HIV/AIDS.

The rifampicin-based regimen in the continuation phase is more effective and also shortens the total duration of treatment from eight-months to six-months. However, this change brings a new challenge as DOT is needed throughout the treatment and not just the two-month intensive phase. New supervision models are urgently needed.

1.2 What is Patient Centred Treatment?

Patient Centred TB Treatment (PCT) means that TB **patients are given an opportunity to choose where their daily treatment is supervised and by whom**. This means that, patients can choose to come to the health facility for their daily DOT or they can take their treatment at home with a treatment supporter of their own choice. The supporter needs to collect drugs at weekly intervals from the health facility, to ensure that the patient takes the drugs as prescribed and to keep record of the daily intake of drugs.

As patients will be able to choose the DOT option which suits them best in view of the constraints they face in daily life, it should help them adhere to treatment and be cured of TB. It should also reduce the burden at health facilities.

1.2.1 Why provide Patient Centred Treatment?

Patient Centred Treatment is a needs' based strategy informed by the views of patients, health workers and communities. The National TB Leprosy Programme (NTLP) carried out a study to ascertain the need for and feasibility of providing patient centred treatment in three districts in collaboration with the Ifakara Health Research and Development Centre, the National Institute for Medical Research and the Novartis Foundation for Sustainable Development.

The study findings highlighted that a majority of patients found daily health facility based DOT to be a strain because of their poor physical condition, the distance involved, daily walking, lack of funds to pay for travel or simply the need to rest. Many patients requested for drugs to be made available at closer health facilities or to be taken at home. The other group of patients articulated the need for daily contact with health services.

Most patients and health workers welcomed the possibility of allowing patients to choose where their daily treatment is supervised and by whom. When offered a choice, more than half the patients opted for home based DOT and the rest for health facility based DOT. It is clear that one supervision model does not suit all patients.

Patients would typically choose a family member or spouse to be their supporter as they can provide them with holistic support without a financial incentive. The good health of the individual is considered to be enough "payback". This overcomes one of the key constraints with community based DOT of providing incentives to supervisors which may not be sustainable on a large scale.

Patients opting for home-based DOT will continue to have regular contact with the health services, though not on a daily basis. As the burden of supervising the daily drug intake for some patients will be reduced, health workers will have more time to counsel patients.

1.3 Objectives of this guide

This guide on providing patient centred treatment complements the fifth edition of the Manual of the NTLP which provides the technical information for the correct diagnosis and management of TB. It should be used together with the NTLP manual.

This guide has been written to enable the health worker to understand the key elements of TB treatment and how to provide patient centred treatment. It takes a step-by-step approach and should also serve as a reference.

2 Overview of the key steps to provide Patient Centred Treatment

Inform patients that they will be cured

Inform patients about TB, its treatment (including side-effects) and the importance of completing a full course of treatment.

Explain DOT – Directly Observed Treatment

Explain that someone needs to watch the patient take their treatment everyday to ensure that the patient takes the right drugs, in the right doses, for the full duration of treatment.

Explain the choices for DOT

Inform patients that they can take their drugs at the health facility under the supervision of a health worker or at home under the supervision of a supporter of their choice.

Give patients the time to decide

Let patients discuss where they want to take their treatment with their family.

Start health facility DOT until the patient chooses

Start treatment at the health facility until the patient chooses otherwise.
Explain possible drug side effects
Prepare the patient's TB treatment card and identity card.

Key steps to provide home based DOT

Identify a supporter

Ask the patient to identify a treatment supporter who will:

- Remind and watch the patient take their drugs everyday
- Mark the treatment card after the drugs are taken
- Collect drugs every week from the health facility
- Inform the health worker of any problems encountered
- Accompany the patient to the health facility when needed

Orient the supporter

Carefully explain the tasks above to the supporter.
Demonstrate how to provide DOT and how to mark the treatment card.
Explain possible side-effect and what needs to be done.
Make sure that the supporter fully understand the tasks.
Check that the supporter can carry out the tasks.

Provide enough drugs to last until the next visit.

Cut up the blister pack to prepare daily blister strips, which contain the exact number of tablets that a patient needs to take each day.
Explain how many tablets the patient should take each day.
Agree on the date of the next visit and note this on the treatment card.
Ask patients to bring back the empty blister packs and treatment card during each visit to the health facility.

Keep regular contact with the patient and supporter

Ask the supporter to return every week to collect more drugs.
Ask the patient to come to the health facility at least once every two weeks.

What to do during the visit of supporter / patient to health facility?

Take the time to talk to the supporter and patient on each visit.
Help them to resolve any problems that they have encountered
Check the daily treatment record when re-supplying drugs.
Check that the record corresponds to the empty blister packs.
Discuss any problems in filling out the treatment card.
Copy the daily drug intake entries onto the TB treatment card.
Provide the supporter with drugs for the next week.

When to start the continuation phase?

Patients (except those who are sputum smear positive), start continuation phase after they complete the two month intensive phase of treatment.

Sputum smear positive patients need to have a follow up sputum exam after the completion of the intensive phase of treatment (2/3 months),

- if the result is positive, extend the intensive phase for an additional month.
- If the result is negative, start the continuation phase of treatment.

How to provide treatment in the continuation phase?

Show patients the new drugs to be taken, tell them how many tablets they need to take and for how long.
Explain that daily DOT is needed in the continuation phase as well.
Offer patients on health facility based DOT the possibility of home based DOT with a supporter of their choice.
If they choose home based DOT, follow the steps mentioned above.
The supporter needs to collect the drugs once every two weeks.
Follow the same procedure mentioned above for home based DOT.

When is treatment completed?

Patients (except those who are sputum smear positive) will complete treatment after taking the drugs as directed for 4 months under DOT

Smear positive patients need to have further follow-up sputum examinations at the end of the fifth and sixth month to determine if they have completed treatment.

What to do at the end of treatment?

Congratulate the patient and the supporter.
Record the treatment outcome on the treatment card.

3 Inform patients and their families about TB

At the time of diagnosis, you should provide patients and their families with basic information about TB, how it is spread and above all reassurance that TB can be cured. You should also explain the treatment, the need for DOT and the importance of complying and completing treatment.

Communicate with patients and their families in supportive manner as this is a critical part of treatment. Speak clearly using words that patients can understand. Encourage them to ask questions. Listen carefully to their concerns. Try to understand their needs and help them to solve their problems.

3.1 TB is caused by a germ

TB is an illness caused by a germ called *mycobacterium tuberculosis*, which is breathed into the lungs mainly through the air.
TB germs can settle anywhere in the body but most often in the lungs.
When TB damages the lungs, a person coughs up sputum and cannot breathe easily.
Without correct and early treatment, a person can die from TB.

3.2 TB is curable

Patients will be cured of TB if they take all their drugs as directed for the full duration of treatment.
TB drugs are provided free of charge.
Patients cannot spread the disease about 2 weeks after taking treatment regularly.
Most patients will start feeling better within weeks however, they must continue the treatment for the full 6-8 months. Otherwise they could fall ill again with TB.
Smear positive patients need to submit sputum specimens during their treatment to monitor the progress.

3.3 TB patients can lead a normal life

Patients can lead a normal life during their treatment.
They can work as soon as they feel better, e.g. have sex, go to school, etc.
Treatment should not interfere with normal life and work.
Patients do not need a special diet but should eat well in order to regain the weight that they have lost.
They do not need special utensils.
They do not need to sleep in a separate room or bed. However, smear positive patients should be advised to use a separate bed for the first two weeks of treatment, if the situation at home allows this.
It is important that patients do not smoke or take alcohol for the entire period of treatment.

3.4 Explain the relationship between TB and HIV AIDS

Not all TB patients are infected with HIV AIDS.
An HIV-infected person is much more likely to develop TB.
TB can be cured in HIV-infected persons, but the chance of relapse is higher.
Inform patients that they can have access to diagnostic counselling and testing to check their HIV status.
There are benefits for patients to know their HIV status.

- It helps them to plan for the care of their family and children.
- It enables the health worker to plan better management for the patient including accessing anti-retroviral drugs (ARVs).
- It helps to prevent, diagnose and treat complications.

3.5 Patients can spread TB, but they can also prevent the spread of TB

TB spreads to others when someone with TB coughs or sneezes, spraying TB germs into the air. Others may breathe in these germs and become infected.
Patients can prevent the spread of TB by:

- Taking their treatment regularly.
- Covering the mouth and nose when coughing or sneezing.
- Opening windows and doors to allow fresh air to flow through the home.

3.6 Children under 5 living in the patient's household should have a check-up

Examine all children aged under 5 years living in the patient's household or having daily contact with the patient for TB symptoms as they are at risk of severe forms of the disease.
Test other household members only if they have a cough.

3.7 Explain the possible drug side-effects and what needs to be done

Inform patients about possible drug side-effects so that they can recognize the symptoms early and report to the health facility and do not simply discontinue treatment.

3.7.1 Most patients complete treatment without significant side-effects

Inform patients that most TB patients complete their treatment without any significant drug side-effects. However, few patients do experience side-effects and should report to the health facility in such cases.

3.7.2 Possible minor side-effects

Inform the patients that their urine may turn orange/red. Reassure them that this is normal for the drug and that they should not worry.
If they feel like vomiting (nausea) or have abdominal pain, they should take their drugs with some food or gruel.
If they have pain in their joints or burning sensation in the feet, give them analgesics and make sure that they continue treatment.

3.7.3 Possible major side-effects

If patients suffer from itching of skin, skin rash, deafness, dizziness with a lack of balance, jaundice, vomiting repeatedly or difficulty with vision, they should stop the drugs immediately and they should return to the health facility.

3.8 Continue to provide information throughout the treatment

Do not try to give too much information in one visit.
At each visit choose a few appropriate messages to reinforce or to teach.
Messages about side effects are important and should be given early in treatment. The patient may need to be reassured to continue taking the drugs.
As the patient feels better you may need to stress the importance of continuing treatment and dangers of stopping.
Encourage patients to ask questions and clear any doubts.
Give the supporter and patient the leaflet on TB and its treatment. Go through it carefully with them.
Ask the supporter to discuss the leaflet with the patient at home.

4 Explain DOT and its importance

4.1 What is DOT?

Directly observed treatment (DOT) means that an observer watches the patient swallowing their tablets everyday for the full 6 to 8 months.
This ensures that a patient takes the right drugs, in the right doses, at the right intervals.

4.2 Why DOT is crucial?

Patients must take the full treatment to be cured and to prevent the development of drug resistance.
If patients don't take the drugs as directed, or stop before completing the full treatment, they will not get cured, and may even die.
The disease will be prolonged and more difficult to treat in the future.
Patients may skip doses when they start to feel better or to discontinue treatment if the drugs lead to side-effects.
With DOT, patients are watched taking their medicine – no missed doses, no drug interruptions.

5 Explain the choices – daily DOT at the health facility or at home

5.1 Explain the choices available for daily DOT

Patients can either

- come to the health facility everyday to take their drugs under the supervision of a health worker or
- they can take their drugs at home under the daily supervision of a person of their own choice.

Patients will get the same drugs in either place and can visit health facility and meet the health worker whenever they need to do so.
Note: This choice can only be offered to Category I and III patients (i.e. new TB patients). Category II patients (i.e. previously treated TB patients) can only be offered this choice after they complete the first two months of the initial phase of treatment which include the daily Streptomycin injection.

5.2 Give patients the time to think about the options

Do not rush patients into making a decision. Let them take as many days, within a two week period, as they need before making up their minds. Suggest that they should feel free to discuss this matter again with you, together with their family. It is important that patients understand that the choice is theirs.

6 Prepare the patient's TB treatment card

The TB Treatment Card is the record of the patient's diagnosis and treatment.
Fill out the TB Treatment Card completely and accurately.
Be sure to write the patient's complete physical address so that you can visit the patient if necessary.
Also record the **name** and **full physical address** of a contact person and **ten-cell leader** or other influential person in the area who will know how to find the patient if not at home.
Record the results of the sputum examination and the patient's weight.

7 Start treatment at the health facility until the patient chooses otherwise

7.1 Choose the appropriate treatment category for the patient

Consider the disease site, the type of patient, and laboratory results to choose the correct category of treatment (Category I, II, III, or IV – see Table 1).
Record treatment regimen and dosage for both phases on the treatment card.

7.2 Make it quick and easy for a patient to get DOT

Provide each dose under DOT.
Do not make the patient wait in the queue at the health facility.
Arrange for them to see the appropriate health worker without waiting.
Any delays in the queue discourage patients and it is not acceptable.

7.3 Keep the treatment card up-to-date throughout the treatment.

Tick each dose given on the treatment card.
Keep record of any side-effects that might occur.

Table 1 TB Treatment regimens

Category I and III regimen: 2RHZE / 4RH; Duration of treatment: 6 months

New sputum smear positive pulmonary TB (PTB)
New patients with severe forms of extra-pulmonary TB (EPTB)
New sputum smear negative and EPTB (less severe forms)

Patient's weight (pre-treatment)	Initial phase (2 months)	Continuation phase (4 months)
	RHZE: 150 mg + 75 mg + 400 mg + 275 mg	RH: 150 mg + 75 mg
	Daily DOT (56 doses) Number of tablets per dose	Daily DOT (112 doses) Number of tablets per dose
30-39 kg	2	2
40-54 kg	3	3
55-70 kg	4	4
>70 kg	5	5

R – rifampicin; H- isoniazid; Z – pyrazinamide; E – ethambutol
Maximum recommended daily dosage of rifampicin is FDCs is 750 mg.

Category II: 2S(RHZE) /1(RHZE) / 5(RH)$_3$3E$_3$; Duration of treatment: 8 months

Previously treated sputum smear positive PTB (relapse, treatment failure and sputum smear positive return after default)

Patient weight (pre-treatment)	Initial phase (3 months)		Continuation phase (5 months)
	Daily DOT (84 doses)		Thrice weekly DOT (60 doses)
	2 months: (RHZE)S*: R 150 mg + H 75 mg + Z 400 mg + E 275 mg + S vial 1 g.	1 month: RHZE: R 150 mg + H 75 mg + Z 400 mg + E 275 mg	(RH)E: R 150 mg + H 150 mg + E 400 mg
30-39 kg	2 + .5 vial 1 g. S	2	RH: 2 + E: 2
40-54 kg	3 + .75 vial 1 g. S	3	RH: 3 + E: 2
55-70 kg	4 + 1 vial 1 g** S	4	RH: 4 + E: 3
>70 kg	5 + 1 vial 1 g** S	5	RH: 5 + E: 3

Maximum recommended daily dosage of rifampicin is FDCs is 750 mg.
*S -Streptomycin should not be given to pregnant women as it can cause permanent deafness in the baby.
**Maximum dosage for patients older than 50 years is 750mg streptomycin

8 How to provide home-based treatment

8.1 Ask the patient to identify a treatment supporter

8.1.1 Role of the treatment supporter

The treatment supporter should support the patient to complete a full course of treatment. In particular, the supporter should:
- Remind /encourage the patient to take their drugs everyday
- Watch the patient take their drugs everyday
- Mark the treatment card after the drugs are taken
- Vouch for the drug intake to the health worker
- Collect drugs every week from the health facility
- Inform the health worker of any problems encountered
- Accompany the patient to the health facility when needed
- Make sure the patient goes for the follow-up sputum exam

8.1.2 Anyone can be a treatment supporter – it's up to the patient to decide

Inform the patient that he/she is free to choose anyone to support and supervise his or her treatment – spouse, family member, relative, neighbour, health worker, community worker.
It does not matter if the supporter and/or patient cannot read or write.

It is crucial that the treatment supporter:
- Is willing and able to carry out the tasks
- Is interested in the well-being of the patient
- Lives close to the patient so that it is easy to provide DOT.

8.2 Orient the supporter and patient

Provide good orientation to the supporter and patient as this is crucial to ensure that the patient successfully completes his/her treatment. Encourage the supporter and patient to ask questions.

8.2.1 Make sure that you have enough time

Make sure that you have at least half an hour to orient the supporter properly. Although this take time but you will find that a good supporter will reduce your workload as well.

8.2.2 Make sure that the supporter can carry out the tasks

Explain the tasks the supporter will have to carry out (see point 8.1.1)
Check if the supporter understood your instructions. If necessary, repeat them.
Ask the supporter if he/she will be able to carry out these tasks.
If not, discuss possible solutions with the patient and supporter until an appropriate supporter has been found.
Thank the supporter for taking on this important role.
Explain that it is crucial that the supporter takes this responsibility seriously.
Inform the supporter that there will be no monetary incentives given to supervise patient treatment.
Encourage the supporter to ask questions.

8.2.3 Record the details of the supporter on the treatment card

Ask and record the name and full address of the supporter as well as the relationship with the patient. You should be able to contact the supporter at this address if necessary. Ask for the name of the street leader or ten cell leader. Record this on the treatment card.

8.2.4 Explain about the disease and the need for DOT in simple words.

See point 3 and 4.2

8.2.5 Explain the treatment carefully

The treatment will last for 6 to 8 months and needs to be supervised everyday for the full period.
Inform them about the number of tablets the patient needs to take everyday. Show the tablets.
All the tablets should be taken at the same time before a meal early in the morning. They cannot take one tablet in the morning and another later in the day.
The supporter must watch the patient swallow all the tablets everyday and mark the treatment card accordingly.
If the patient feels like vomiting (nausea), after taking the drugs, he/she should take some food with the drugs.
Ask the supporter and patient to repeat how many tablets have to be taken and when they should be taken to make sure that they have fully understood this.
Encourage them to ask questions.

8.2.6 Demonstrate how to supervise treatment and practice with the supporter

Take out the patient's TB treatment card.
Pour a glass of water for the patient. If the patient feels like vomiting, suggest that they take the drugs with food or gruel.
Take out the tablets that the patient should take that day.
Put the first tablet in the patient's hand and watch the patient swallow the tablet.
Ask the supporter to give the next tablet and watch the patient swallow that tablet. Ask the supporter to continue until the patient finishes all the tablets for that day.
If it is difficult to swallow the tablets one after the other, ask the supporter to let the patient pause briefly.
Explain that the tablets must be taken at the same time to make sure that they work together.
Show the supporter how to record the treatment on the TB treatment card with a simple tick on the day.
Ask the supporter and the patient if he/she has any questions.

8.3 Explain how to fill out the treatment card

8.3.1 Make a copy of the patient's treatment card for the supporter

Copy all the information from the patient's TB treatment card (name, address, laboratory results, drug regimen, etc.) to another TB treatment card.
Give the duplicate card to the treatment supporter.
Keep the original card at the health facility.

8.3.2 Explain the importance of the treatment card

The treatment card is proof of the drugs taken each day. This must be filled out on a daily basis.
Explain that everyday after the supporter observes the patient swallowing all the tablets, he/she needs to mark a tick on the treatment card.
Explain that the treatment card will prove to you (the health worker) that the patient has taken the treatment as directed.

8.3.3 Show how to mark the treatment card

Carefully explain how to mark the treatment card.
The first day will already be ticked, as the patient should have taken the first dose at the health facility.
Draw an arrow to show in which direction the next ticks should be made.
The supporter should tick the next box to the right of that filled out after watching the patient swallow all the tablets the next day. And the following on the day after. And so on.
Ask the supporter to show where he/she would tick the next day. Correct if necessary.
If the patient misses treatment on any day, that date should be left blank.
When the patient starts treatment again the correct box should be ticked i.e. leaving the number of boxes blank for the days that the patient did not take treatment.

8.3.4 Supporters who cannot read/write can maintain the treatment record

Even if the supporter cannot read or write, he/she may be able to understand how to correctly fill out the treatment card. It may however take more time to explain. It is important that you take the time to explain this in simple terms and repeat it if necessary.

If you think that the supporter has not fully understood this and will not be able to fill the card out correctly, ask if someone in the household can read and write. If so, the supporter should bring that person to the health facility so that they learn how to fill out the card.

8.3.4.1 If the supporter cannot maintain the treatment record

If the supporter is not able to maintain the treatment record and no one in the household / neighbourhood can do so, then,
The supporter should vouch for the drug intake when he/she goes to collect the drugs for the next week.
The health worker should mark the treatment card based on the word of the supporter and patient.
The empty blister strips and improvement in physical condition of the patient will also support the regular drug intake.

8.3.5 Never give a double dose

If the patient misses a dose, give the missed dose on return.
Do not give a double dose on any day. Continue according to the schedule.
The duration of treatment will be extended by the number of days missed.
Leave the missed day blank on the patient treatment card.

9 Explain possible drug side effects

Drug side-effects can lead to patients discontinuing their treatment. It is important that patient know what to expect and what they should do in such an event (see Table 2). The patient may need to be reassured in order to continue taking the drugs.

Table 2: Side-effects and their management

Minor side-effects	Management
Loss of appetite (anorexia), nausea, abdominal pain	Take drugs with food or gruel
Joint pains	Aspirin
Burning sensation in feet	Pyridoxine 100 mg daily
Orange/red urine	Reassure patient that this is expected (with rifampicin)
Major side-effects	
Itching of skin, skin rash	Stop anti-TB drugs. Refer the patient urgently to a clinician.
Deafness (confirm that this is not due to ear wax)	
Dizziness, lack of balance	
Jaundice (yellow skin or eyes)	
Vomiting repeatedly[a]	
Difficulty with vision	

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

10 Provide enough drugs to last until next visit

Cut the blister strips up to prepare daily blister strips, which contain the exact number of tablets that a patient needs to take each day.

Explain again how many tablets the patient should take each day.

Show that you are providing enough drugs for 1 week. This will be 7 doses – one for each day.

Give the drugs to the treatment supporter.

If the patient comes without the supporter, give the drugs to the patient and ask him/ her to give them to the supporter.

Record the date and the drugs given on both copies of the treatment card (the record to be kept at the health facility and the patient’s record).

Remind the supporter to watch the patient swallowing the drugs and to record this on the treatment card.

Ask the supporter to keep the drugs in a cool, dry place, safe from children.

11 Agree on date of next visit to health facility

11.1 Discuss if there is a health facility closer to their home.

If so, check if the drugs and support can be provided from that health facility.

If so, transfer the treatment record to that health facility.

Give patients and supporters clear instructions if they need to collect their drugs from a different facility.

Ask them to repeat where they should go to make sure that there is no misunderstanding.

11.2 Ask the supporter to return every week to collect more drugs

Check if the supporter can return in a week. If this will be difficult, agree on when they should come back.
Make sure that they have enough drugs to last until they return.
The patient and/or supporter should bring the empty blister strips and treatment card each time they return to the health facility.

11.3 Ask the patient to come to the health facility at least once every two weeks

It is important to have regular contact with the patient (see **Table 3**).
Ask the patient to come with the supporter at least once every week during the first 2-months intensive phase and once every two weeks during the 4- months continuation phase.
This will give you an opportunity to see if the patient ‘s health is improving and to discuss any problems which may have arisen directly with the patient.
If at any time you observe that a patient’s condition has significantly worsened, refer the patient to a clinician for further assessment and treatment.

Table 3 Contact with health services for those opting for home-based treatment

	Intensive phase	Continuation phase
DOT	Daily	Daily
Frequency of drug collection by supporter	Once a week	Once every two weeks
Frequency of patient visit to health facility	Once every two weeks minimum	Once every two weeks minimum
Filling out treatment records	Daily	Daily

12 What to do when patient and supporter come to health facility

12.1 Take the time to talk to the patient and supporter on each visit

Ask whether there were any problems with the treatment in the last week.
If the patient has had side-effects, ask the treatment supporter or the patient to describe them to you. Listen carefully to be certain that the treatment supporter has advised the patient correctly and give additional information if needed. If necessary, refer the patient to a clinical officer.
Make a note of these problems on the treatment card kept at the health facility.

Discuss with the patient whether the supporter is providing and observing treatment in a timely and supportive way. This may need to be done privately, (health staff and a patient) otherwise the patient may not be free to explain clearly if there were any problems with the supporter.

Ask the treatment supporter and patient if they have any questions / concerns.

Acknowledge the important role played by the supporter and thank him /her.

12.2 Check the daily treatment record

Check the treatment card filled out by the supporter to see whether the patient is taking the drugs on schedule and the supporter is marking the card correctly.
If there are missed days, ask why.
Discuss possible ways to solve the problem.

Check whether the empty blister strips match the record on the treatment card.
If the treatment supporter is marking the card incorrectly, discuss this.
Show how to record correctly.
If there is no improvement in the marking of the card in time, look for other solutions (see point 8.3.4.1).
Throw away the empty blister strips after you have checked if they match the record on the treatment card.

12.3 Copy the entries onto the TB treatment card

Copy the ticks from the patient's treatment card to the original TB treatment card kept at the health facility. Copy the ticks accurately so that the duplicate card and the original card both show the dates on which treatment was given.

12.4 Provide the supporter with drugs for the next week

Prepare the weekly supply of drugs (see point 10).
Ask the supporter and/or patient to explain how they will take the drugs.
Correct any mistakes.
Always record the drugs provided to the treatment supporter on both the original treatment card and the treatment supporter's copy.
Always agree on the day of the next visit and make sure that the patient has enough drugs until then.
Write the date for the next visit on the patient treatment card so that they have a written record to refer to.

13 Monitor progress of treatment by follow-up sputum examination

Periodic follow-up sputum examinations are vital to determine the patient's progress, to make decisions about care and to establish the treatment outcome.

Follow-up sputum check is only needed in sputum smear positive cases.

13.1 Inform the supporter / patient when a follow-up sputum examination is due

Check the patient's treatment card to see whether the sputum examination is due (see Table **4**). Inform the patient / supporter accordingly.
Provide the supporter or patient with a sputum container during their visit prior to the date of the sputum examination so that sputum is produced at home early in the morning.
One early morning sputum specimen is required for a follow-up sputum examination.
Register all sputum results with date and laboratory number in the district TB register.

Table **4** Schedule for follow-up sputum examinations for smear positive pulmonary TB

	Category I patients	**Category II patients**
At the end of ...	**2nd month** **5th month** **6th month**	**3rd month** **5th month** **8th month**

13.2 Explain and demonstrate the steps to collect sputum

Explain that the sputum examination will show if the TB germs have been killed.
Show how to open and close the container.
Demonstrate the steps to collect sputum
Breathe deeply and demonstrate a deep cough.
The patient must produce sputum, not only saliva.
Explain that the patient should cough deeply to produce sputum and spit it carefully into the container.
Give a labelled sputum container to the patient / supporter to take home.
Ask the patient to collect one early morning sputum specimen and to bring it to the health facility.

13.3 Ask the patient to return to discuss the results of follow-up examination

Tell the patient and supporter when to return to the health facility to learn the results of the sputum examination.
Weigh the patient and record the weight on the TB treatment card.
Record the results of the sputum exam on the TB treatment card.

14 Decide on follow-up treatment

A patient should have a clinical examination at this occasion either by a medical doctor, clinical officer, experienced health worker, or district TB leprosy cooridinator.
The results of the follow-up sputum examination will determine if the patient can start the continuation phase of treatment (see Table 5).

Table 5: Follow up action based on smear results for sputum smear positive cases

Smear results	Action
Negative	Start continuation phase
Positive at end of 2nd / 3rd month (initial phase)	Extend continuation phase RHZE by 1 month Check early morning sputum at end of 3rd month (Category I)/ 4th month (Category II)
Positive at end of 3rd / 4th month	Start continuation phase RH (Category I) / RH (Category II) Send sputum sample to the TB reference laboratory for susceptibility testing Change treatment if necessary (refer NTLP manual)
Negative at end of 5th and 6th /8th month	Patient cured bacteriologically
Positive at end of 6th / 8th month	Treatment failure (refer NTLP manual)

14.1 Extend the intensive phase for additional month, if necessary

If the follow-up sputum examination is positive, the patient needs to continue the initial phase of treatment for an additional month:
Explain to the patient and treatment supporter that the sputum examination found that the TB bacilli are still present. The patient needs one more month of the initial phase drugs.
Discuss with the patient and supporter to confirm if the treatment has been done under direct supervision and regularly. If not, try to solve the problem.
Ask the treatment supporter to continue DOT and record this on the patient's treatment card each day.
Inform the patient that he/she will need to go for another sputum examination at the end of the month.

15 Start the continuation phase of treatment

If the follow-up sputum smear is negative, sputum smear positive patients can start the continuation phase, .
All other patients can start the continuation phase once they have taken all the required doses of the initial phase of treatment.
Congratulate the patient and the supporter on the successful completion of the initial phase of treatment.

15.1 Explain the treatment for the continuation phase

Show the patient and supporter the new drugs that have to be taken.
Explain how long this treatment phase will last and the number of drugs to be taken.
Inform the patient and supporter that the drugs need to be taken everyday under supervision as before.
Explain that the patient must finish all doses to be cured of TB even if he /she is feeling better. If not, he /she could fall ill with TB again.

15.2 How to manage the continuation phase for patients on home-based DOT

Give the treatment supporter 2 weeks' supply of drugs.
Remind the supporter that he/she will have to watch the patient swallow their treatment every day.
Show the treatment supporter how to mark the back of the card each time treatment is observed.
Ask questions to be sure that the treatment supporter knows the correct dose and frequency.
Ask the patient and the supporter to come back in 2 weeks to collect more drugs.
Continue to check the daily treatment records to ensure that the patient is taking all the doses as prescribed
Continue to check that the daily treatment records are correctly filled out
Encourage the patient and supporter to continue the treatment.

15.3 How to manage the continuation phase for health facility based DOT

Offer the patient the choice of:
coming daily to the health facility to take their drugs under supervision or
taking their treatment at home under the supervision of a supporter of their choice
If the patient chooses health facility DOT, continue with daily health facility based DOT.
Make sure that the patient does not have to wait for his/ her treatment.
Record the daily drug intake on the patient card.

If the patient chooses home based DOT ask him/her to identify a treatment supporter (see point 8.1)
Orient the supporter (see point 8.2)
Give the treatment supporter 2 weeks' supply of drugs.
Show the treatment supporter how to mark the card each time treatment is observed.
Remind the supporter that he/she will have to watch the patient swallow each tablet.

Ask questions to be sure that the treatment supporter knows the correct dose and frequency.
Inform the supporter / patient when a follow-up sputum examination is due (smear positive patients only).

16 When is the treatment completed

For smear positive patients: when the sputum smear at the 5th and 6th month is negative
For all other patients: when the patient has taken the correct number of doses of the continuation phase drugs (4 months for category I and III, 5 months for category II).
If the patient has missed some doses along the way, the duration of treatment extends until all the doses are taken, which may be some days or weeks longer.

17 What to do at the end of treatment

17.1 Congratulate the patient and supporter.

Congratulate the patient and the supporter on the successful completion of the treatment.
Reassure the patient that he/she is cured.

17.2 Ask the patient and supporters to be advocates for TB

Patients and supporters are great advocates for TB.
Ask them to:

- spread the word that TB can be cured
- dispel fears of TB
- encourage people with a cough for more than 3 weeks to seek diagnosis
- encourage patients to comply with treatment
- encourage patients to lead normal lives.

17.3 Record the treatment outcome

Record the treatment outcome at the end of treatment based on the definitions (see Table 6).

Table 6: Definition of treatment outcome

Outcome	Definition
Cured	Sputum smear positive who is smear negative at end of treatment and at least one previous occasion
Treatment completed	A patient who has completed treatment but for whom smear results are not available at the end of treatment
Failure	A patient who remains or becomes smear positive at 5 months or later
Died	A patient who dies for any reason during TB treatment
Defaulter	A patient who interrupts treatment for two consecutive months or more
Transferred out	A patient who has been transferred to another region and whose treatment result is not known.

18 What to do in case any of the following happen

18.1 The next supply of drugs is not collected

Inform the person in-charge of the health facility promptly and agree on who should make a home visit to the patient / supporter to find out about the problem.
Discuss possible solutions to the problems faced with the patient and supporter.
Make sure that the patient receives the treatment as soon as possible.
If necessary, the patient may have to come to the health facility for daily treatment.

18.2 The patient does not come for a check-up as scheduled

A patient should come to the health facility once a week during the intensive phase and once every two weeks during the continuation phase.
Discuss this issue with the treatment supporter when he/she comes to collect the drugs and try to find a solution.
If the patient still does not come to the health facility, inform the person in-charge of the health facility promptly and agree on who should make a home visit to the patient / supporter to find out about the problem.
Discuss possible solutions to the problems faced with the patient and supporter.

18.3 The supporter or patient will be away for a few days

Ask the supporter / patient to suggest what arrangements could be made to continue DOT if either of them will be away for a few days.
If the suggestion is acceptable, follow up as required.
If no one can provide DOT, give the patient enough drugs to self-administer for a maximum of 1 week. The patient should keep the empty blister strips and mark the treatment record.

18.4 The patient would like to change the supporter

The patient is free to change the supporter but he/she must bring the new supporter to the health facility to be oriented.
Discuss and make note of the reason for the change in supporter on the treatment card.
Train the new supporter immediately.
Make sure that the supporter fully understands the tasks to be performed.
Record the name, address, and relationship of the new supporter on the patient treatment card.

18.5 The patient would like to change to health facility based DOT

The patient is free to change where he / she takes treatment.
Discuss and make note of the reason for the change on the treatment record.
Explain to the patient that they need to come daily to the health facility for treatment.
Make sure that the patient gets treatment without delay at the health facility.

18.6 The patient would like to change to home based DOT

The patient is free to change where he / she takes treatment.
Discuss and make note of the reason for the change on the treatment record.
Ask the patient to identify a supporter who will supervise their daily drug intake at home.
Record the name, address, and relationship of the supporter on the patient treatment card. (See point 8.2.3)
Orient the supporter.