STANDARD OPERATING PROCEDURE (SOP) ON PROVIDING DIRECTLY OBSERVED THERAPY (DOT) FOR TUBERCULOSIS

Department of Pharmacology
Faculty of Medicine
UWUSL 2026

1) Title

Providing Directly Observed Therapy (DOT) for Tuberculosis

2) Issued by

Department of Pharmacology
Faculty of Medicine
Uva Wellassa University

3) Purpose

To establish a standardized procedure for the delivering Directly Observed Therapy (DOT) to patients receiving anti-tuberculosis treatment, ensuring that the prescribed medicines are taken with the correct drugs, doses, intervals and duration, while supporting adherence and monitoring for adverse effects.

4) Scope

This SOP applies to trained DOT providers responsible for directly observing anti-tuberculosis treatment in the community or health-care setting under the supervision and coordination of the District Chest Clinic (DCC)/District TB control services.

5) Definitions

1) **DOT** (Directly Observed Therapy): A supportive mechanism in which treatment intake is directly observed to ensure that the patient takes the prescribed treatment as directed.
2) **DOT provider:** A trained and responsible person who observes treatment intake, supports adherence, monitors for adverse effects and maintains required records. This includes Health care workers :– curative, preventive in both state and private sector, Religious Leaders ,Community Leaders , Heads of Institutions , NGOs / CBOs ,Cured TB patients , Any person of responsibility.
3) **DCC**: District Chest Clinic or the designated TB service responsible for clinical oversight and programme records.
4) **Treatment interruption**: one or more prescribed doses not taken as planned; all interruptions must be documented and communicated according to local programme procedures.
5) **Adverse event**: an unwanted or harmful symptom, sign or laboratory abnormality that may occur during treatment and requires assessment according to severity.

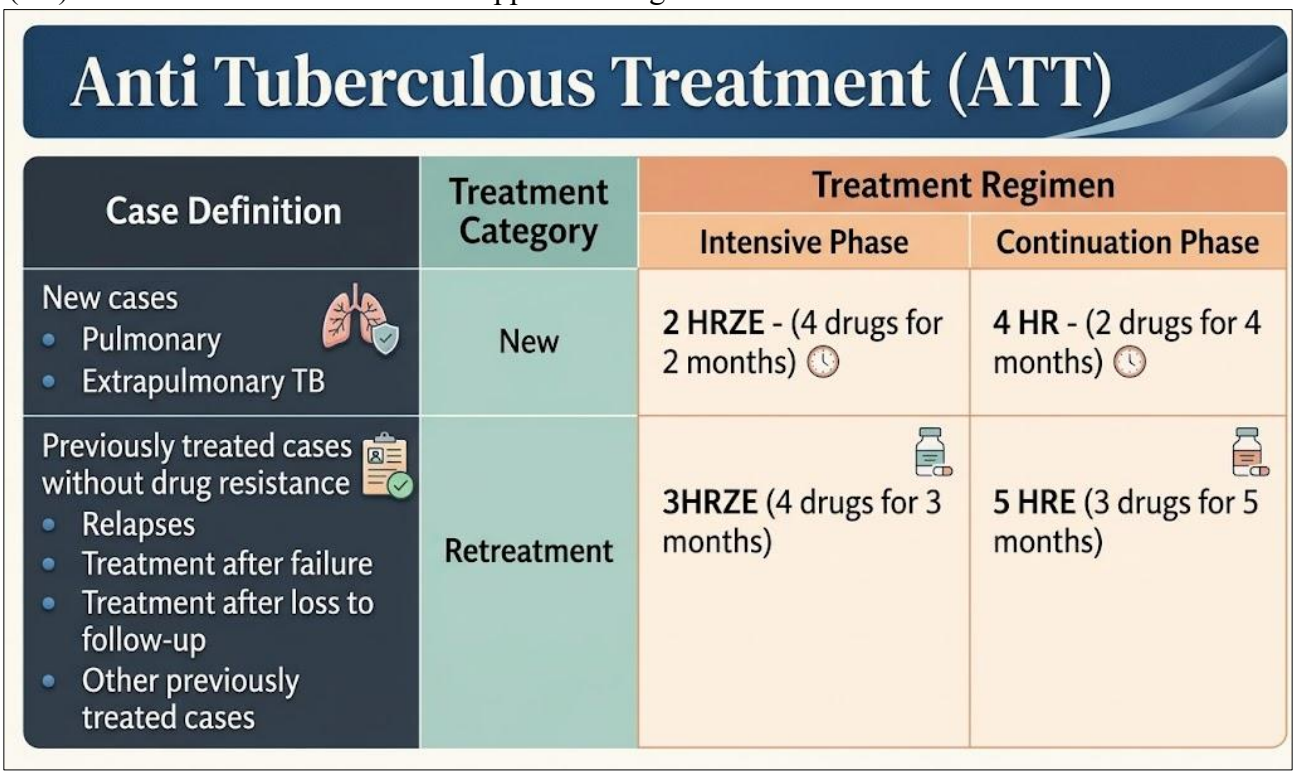
6) Responsibilities of a DOT provider

1) Deliver the prescribed anti-TB medication to the patient.
2) Ensure the patient swallows the prescribed medicines in the provider's presence.
3) Check for possible adverse effects and identify problems requiring referral.
4) Maintain the TB treatment card (TB 01), DOT card and DOT register accurately.
5) Answer patient questions and provide health education.
6) Give priority to a TB patient in a busy health-care setting so that the patient is not unnecessarily kept waiting.
7) Follow up patients who miss a treatment dose.
8) Notify the District Chest Clinic of adverse effects, clinical problems or missed DOT visits.

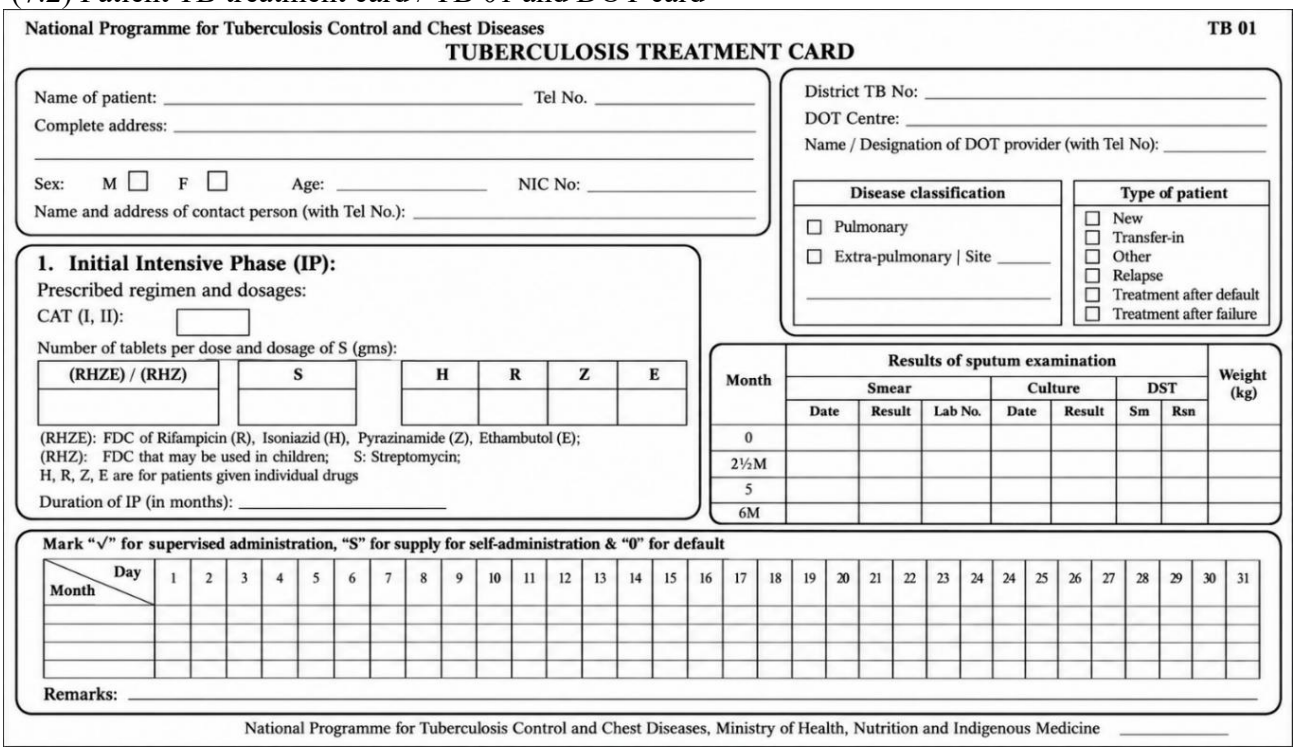
9) Ensure that household and other close contacts are appropriately screened through the relevant TB services.
10) Maintain confidentiality, avoid discrimination and communicate respectfully.
11) Know the contact details of the relevant District Chest Clinic/DTCO or Medical Officer.

7) Materials / Information Required

(7.1).Prescribed anti-TB medicines supplied through the DCC.



(7.2) Patient TB treatment card / TB 01 and DOT card



National Programme for Tuberculosis Control and Chest Diseases — **TB 01**

TUBERCULOSIS TREATMENT CARD

Name of patient: _____ Tel No. _____

Complete address: _____

_____

Sex: M ☐ F ☐ Age: _____ NIC No: _____

Name and address of contact person (with Tel No.): _____

District TB No: _____

DOT Centre: _____

Name / Designation of DOT provider (with Tel No): _____

Disease classification	Type of patient
☐ Pulmonary	☐ New
☐ Extra-pulmonary | Site _____	☐ Transfer-in
	☐ Other
	☐ Relapse
	☐ Treatment after default
	☐ Treatment after failure

1. Initial Intensive Phase (IP):

Prescribed regimen and dosages:

CAT (I, II): ☐

Number of tablets per dose and dosage of S (gms):

(RHZE) / (RHZ)	S	H	R	Z	E

(RHZE): FDC of Rifampicin (R), Isoniazid (H), Pyrazinamide (Z), Ethambutol (E);
(RHZ): FDC that may be used in children; S: Streptomycin;
H, R, Z, E are for patients given individual drugs

Duration of IP (in months): _____

Month	Results of sputum examination							Weight (kg)
	Smear			Culture		DST		
	Date	Result	Lab No.	Date	Result	Sm	Rsn	
0								
2½M								
5								
6M								

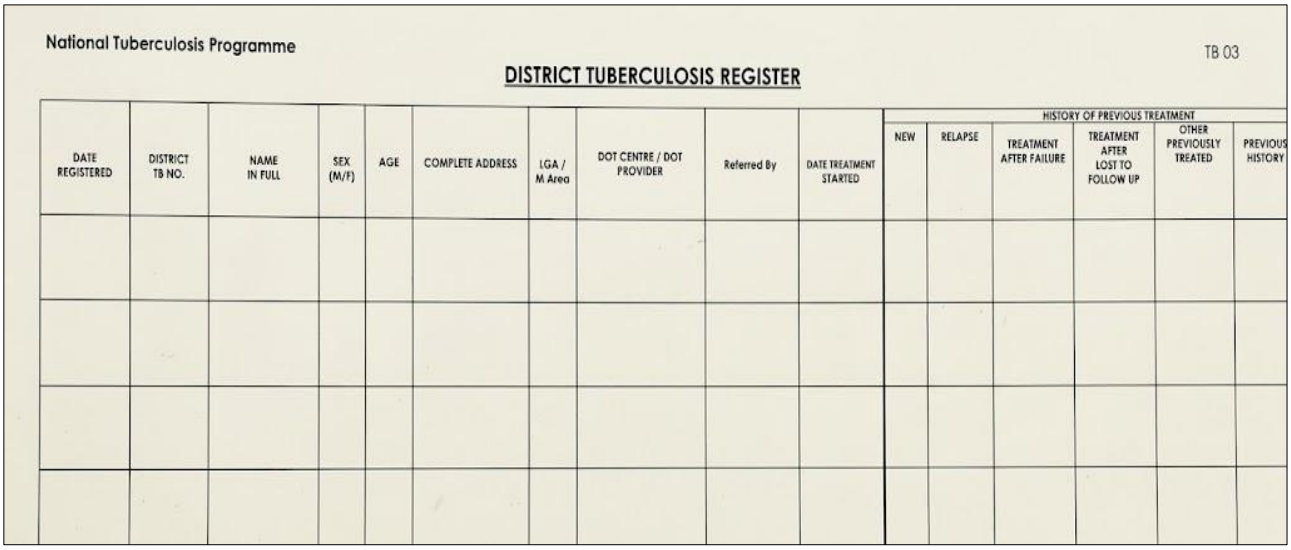
Mark "√" for supervised administration, "S" for supply for self-administration & "0" for default

Month \ Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	24	25	26	27	28	29	30	31

Remarks: _____

National Programme for Tuberculosis Control and Chest Diseases, Ministry of Health, Nutrition and Indigenous Medicine _____

(7.3) DOT register.



National Tuberculosis Programme — TB 03

DISTRICT TUBERCULOSIS REGISTER

DATE REGISTERED	DISTRICT TB NO.	NAME IN FULL	SEX (M/F)	AGE	COMPLETE ADDRESS	LGA / M Area	DOT CENTRE / DOT PROVIDER	Referred By	DATE TREATMENT STARTED	HISTORY OF PREVIOUS TREATMENT					
										NEW	RELAPSE	TREATMENT AFTER FAILURE	TREATMENT AFTER LOST TO FOLLOW UP	OTHER PREVIOUSLY TREATED	PREVIOUS HISTORY

National Tuberculosis Programme

TB 03

DISTRICT TUBERCULOSIS REGISTER

Site of Disease (S)		Treatment Category		HIV Testing Dime (Y/N)	Smear [S], Culture [C], on MTB/RIF [X] Test Results &										TREATMENT OUTCOMES AND DATE OUTCOME REPORTED						REMARKS
PTB	EPTB	NEW TREATMENT REGIMEN with first unit drugs	RE-TREATMENT REGIMEN with first-line drugs		AT THE TIME OF DIAGNOSIS			MONTHS 1/2/3/4			MONTH 5		END OF TREATMENT		Cured	Treatment Completed	Treatment Failure	Died		Lost to Follow-up	Not Evaluated	
					S	C	X	S	X		S	C	S	C				Confirmed- AS NOT NOT TO TB	All-Other Deaths			
					Date			Date			Date		Date									

(7.4) Appropriate secure drug-storage facility.



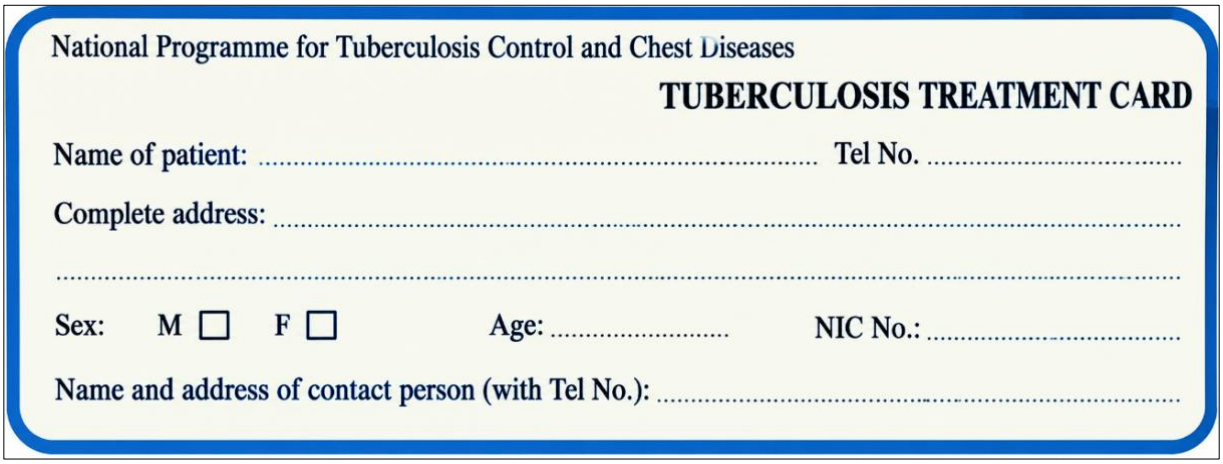
(7.5) Contact details of the DCC, District Tuberculosis Control Officer (DTCO) and relevant Medical Officer.

(7.6) Writing materials and any locally approved reporting/referral forms.

8) Procedure

(8.1) Verify the Patient and Treatment

(8.1.1) Confirm the patient's identity using the available patient information and treatment records.



National Programme for Tuberculosis Control and Chest Diseases

TUBERCULOSIS TREATMENT CARD

Name of patient: ..... Tel No. .....

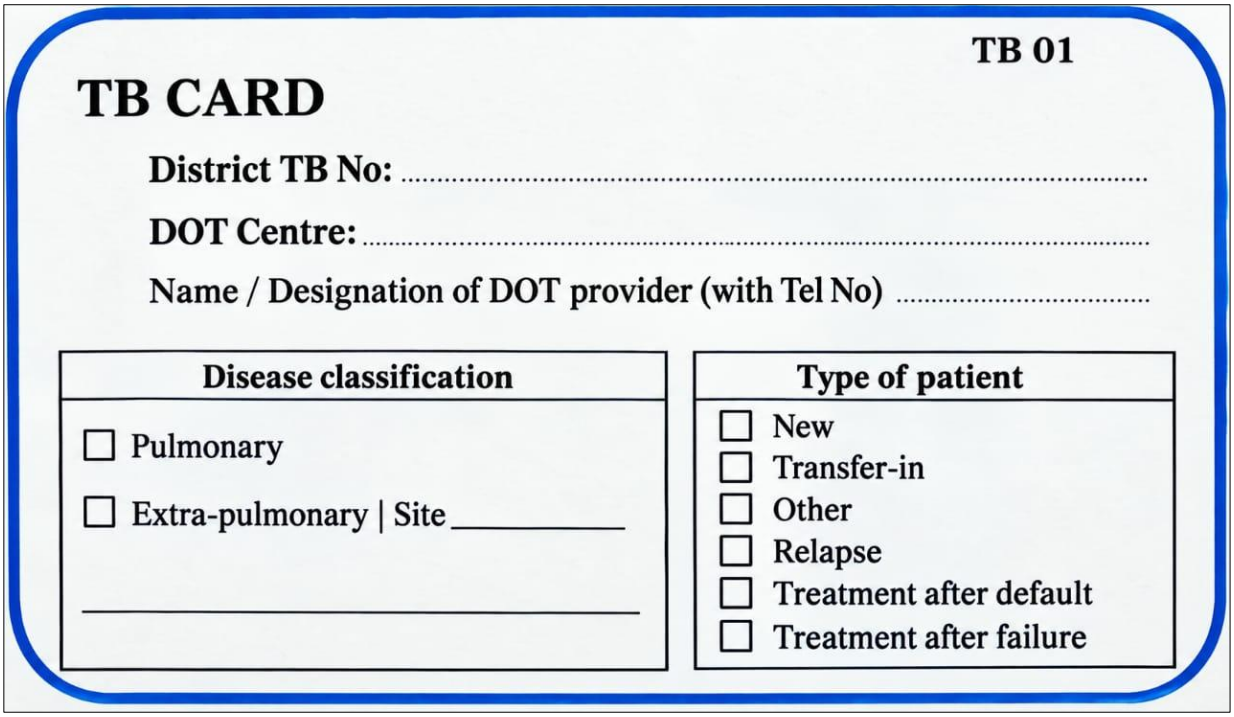
Complete address: .....

.....

Sex: M ☐ F ☐ Age: ..... NIC No.: .....

Name and address of contact person (with Tel No.): .....

(8.1.2) Check the District TB number and patient category.



TB 01

TB CARD

District TB No: .....

DOT Centre: .....

Name / Designation of DOT provider (with Tel No) .....

Disease classification	Type of patient
☐ Pulmonary	☐ New
☐ Extra-pulmonary | Site _____	☐ Transfer-in
_____	☐ Other
	☐ Relapse
	☐ Treatment after default
	☐ Treatment after failure

(8.1.3) Confirm the prescribed drugs and dosage from the treatment card.

I. Initial Intensive Phase (IP):

Prescribed regimen and dosages

CAT (I, II): ☐

Number of tablets per dose and dosage of S (gms):

(RHZE) / (RHZ)	S	H	R	Z	E

(RHZE): FDC of Rifampicin (R), Isoniazid (H), Pyrazinamide (Z), Ethambutol (E);
(RHZ): FDC that may be used in children; S: Streptomycin;
H, R, Z, E are for patients given individual drugs

Duration of IP (in months): _____

(8.1.4) Check the expected treatment date/visit information.

Mark '√' for supervised administration, 'S' for supply for self-administration & '0' for default

Month \ Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	27	28	29	30	31

Remarks _____

(8.1.5) Ensure that the correct patient's medicines are being administered.

(8.2) Provide the Daily DOT

(8.2.1) Receive the patient in a respectful and confidential manner.

(8.2.2) Provide the prescribed dose at the scheduled treatment time.



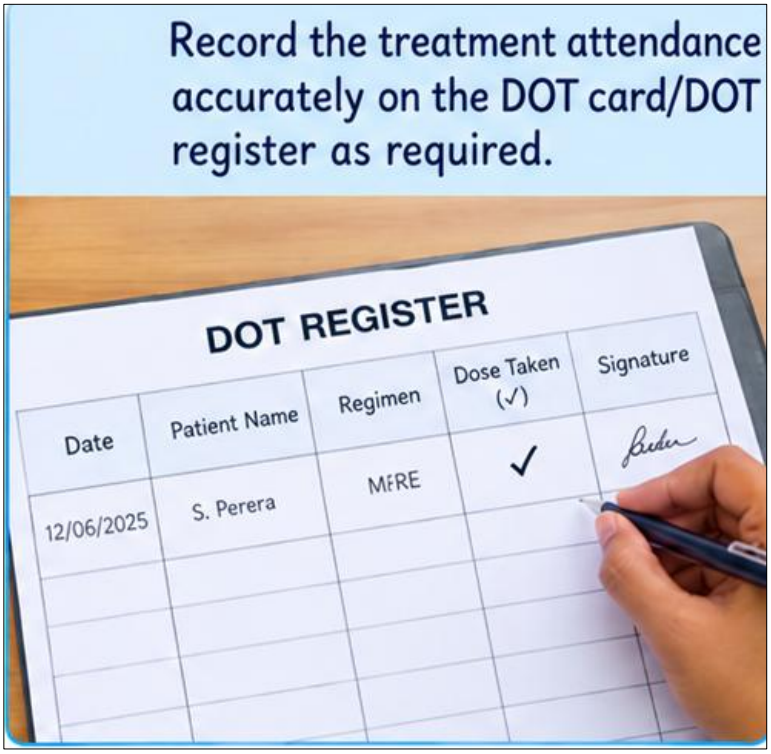
(8.2.3) Observe the patient taking/swallowing the medicines.



(8.2.4) Confirm that the dose has been taken before recording the attendance.



(8.2.5) Record the treatment attendance accurately on the DOT card/DOT register as required.



(8.2.6) Ask briefly about new symptoms or possible adverse effects.



(8.2.7) Provide appropriate reassurance and health education.



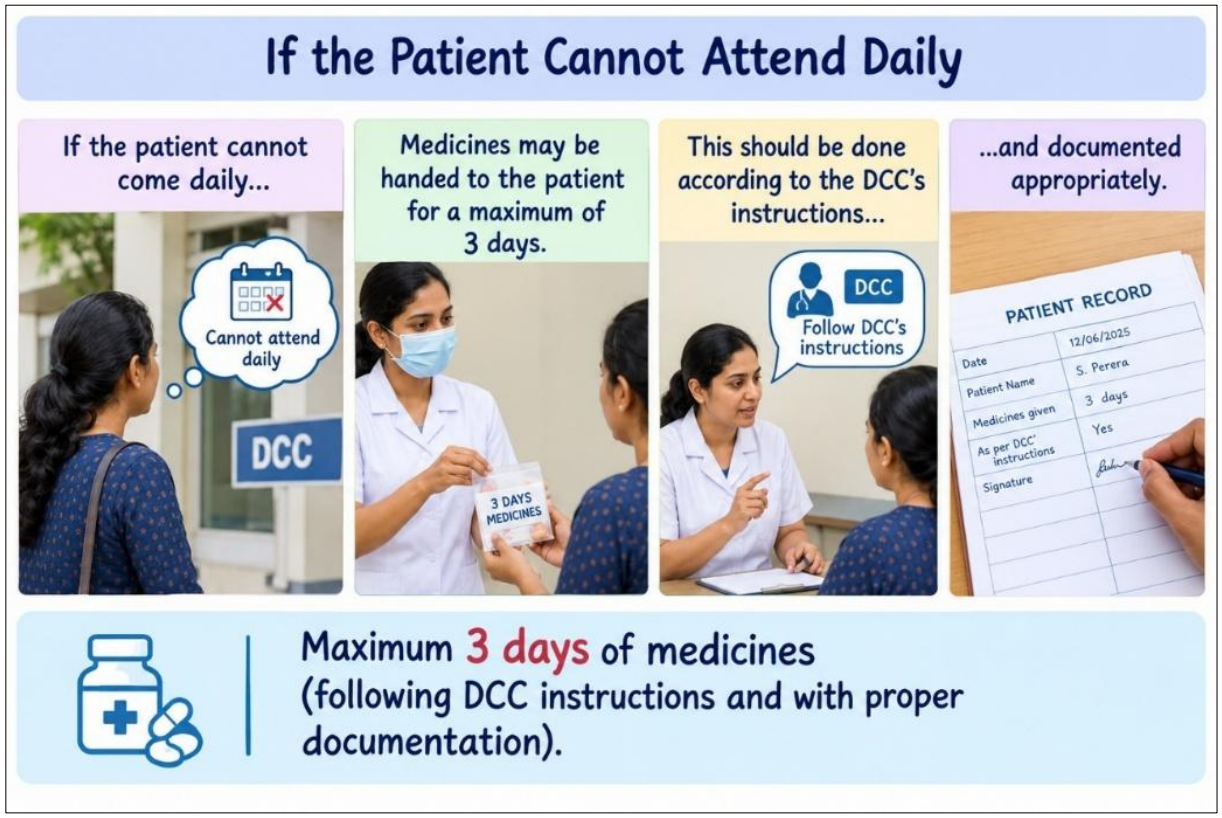
(8.2.8) Arrange referral/contact with the DCC when indicated.



NPTCCD guidance states that during the **intensive phase DOT is daily**; during the **continuation phase it is at least weekly**. Previously treated patients are described as receiving daily DOT throughout treatment. Follow the treatment plan issued by the DCC for the individual patient.

(8.3) If the Patient Cannot Attend Daily

According to the NPTCCD training material, if a patient cannot come daily, medicines may be handed to the patient for a maximum of 3 days. This should be done according to the DCC's instructions and documented appropriately

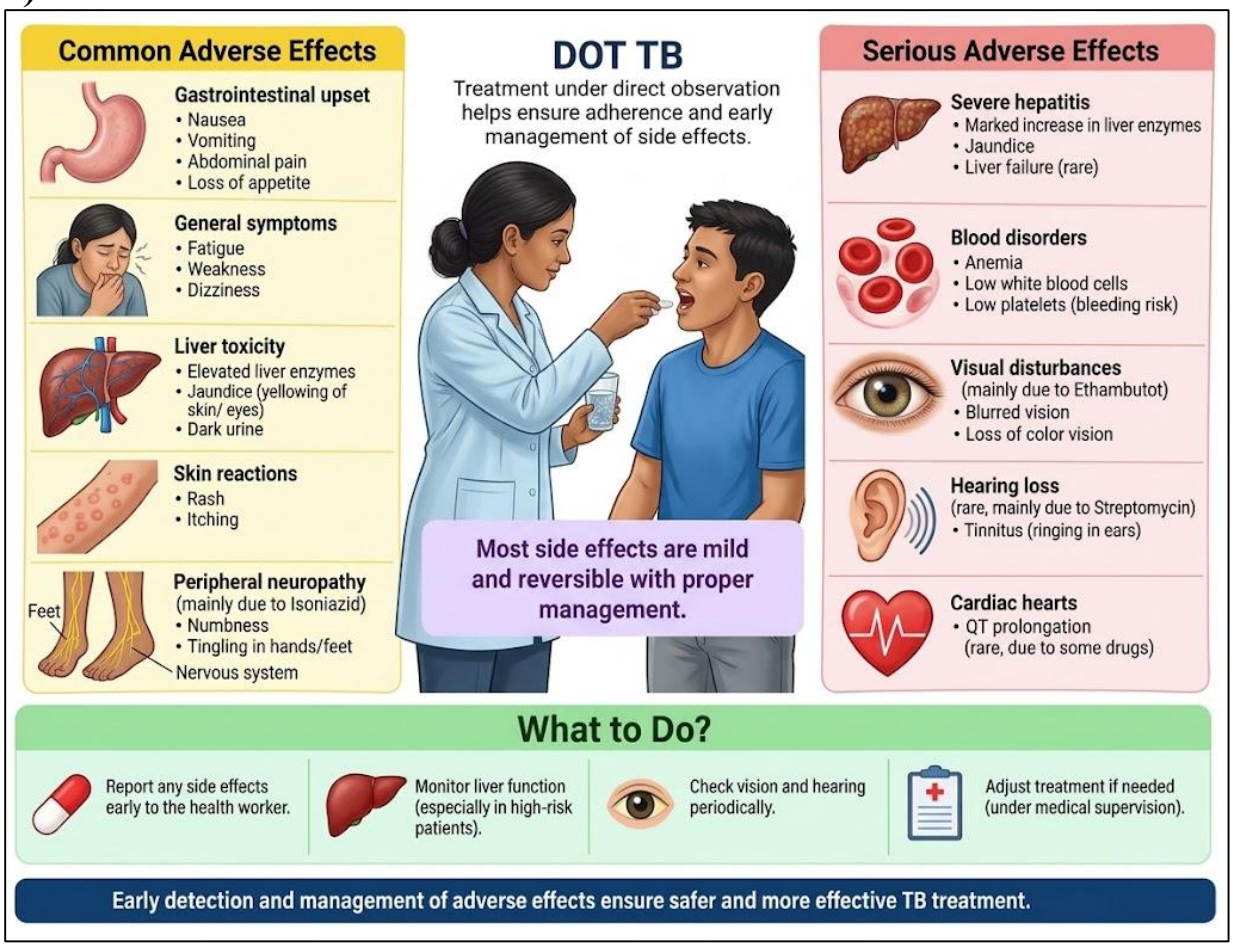


(8.4) Monitoring During Treatment

(8.4.1) Confirm treatment intake and adherence at each DOT encounter.
(8.4.2) Ask about symptoms suggestive of adverse reactions.
(8.4.3) Encourage a balanced diet; the NPTCCD material gives additional meals and adding eggs and milk where possible as examples.
(8.4.4) Provide supportive, non-judgmental counselling.
(8.4.5) Protect patient confidentiality and avoid discrimination.
(8.4.6) Be consistent and punctual and maintain good rapport with the patient.



9) Adverse Effects and Referrals



Minor effects described in the NPTCCD material include pink or yellow-coloured urine, joint pains and mild itching. Major effects requiring attention include persistent nausea/vomiting or yellow eyes/urine, itching with rashes, changes in vision, tinnitus, vertigo or gait-related problems.

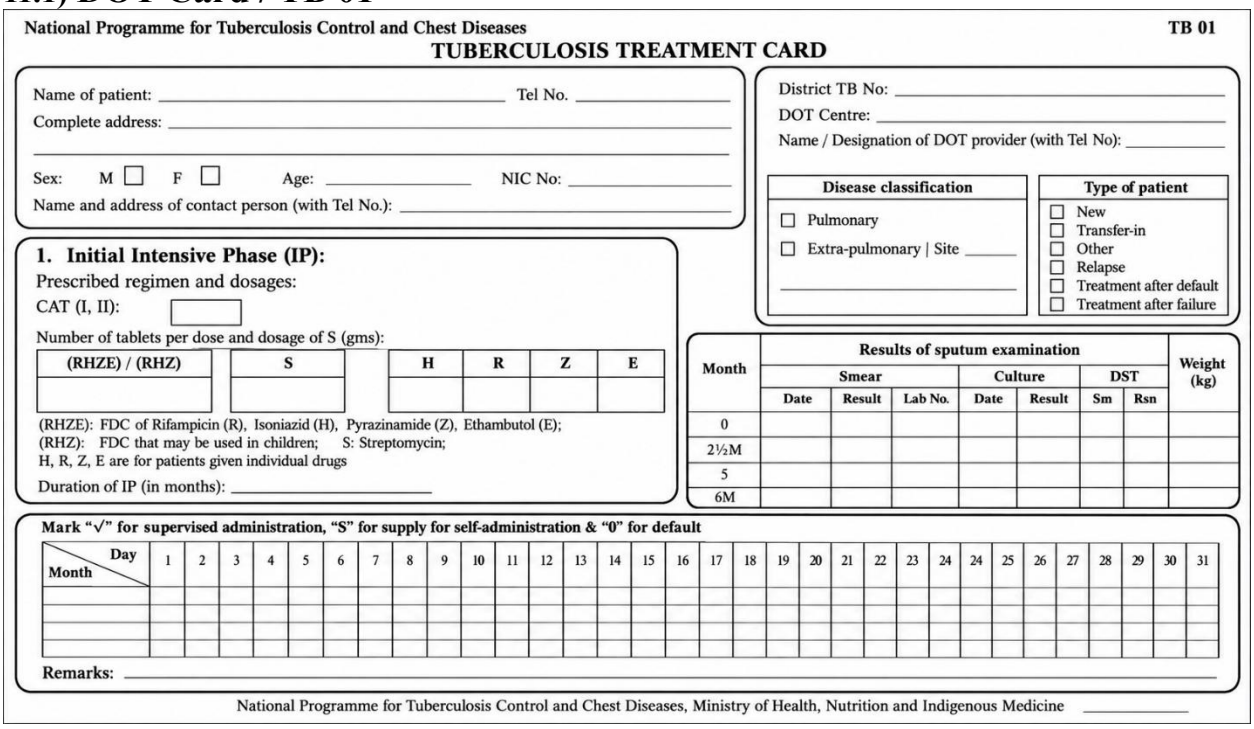
When a major adverse effect or other significant clinical problem is identified, do not simply reassure the patient. Contact/refer the patient to the relevant DCC/medical officer promptly according to local TB programme arrangements.

10) Management of a Missed Dose / Missed DOT Visit

(10.1) If the patient does not attend, contact the patient or relative and attempt to bring the patient back for treatment on the same day.
(10.2) If this is unsuccessful, advise the patient to return at the earliest opportunity, preferably the next day.
(10.3) If the patient cannot be contacted on day 1, promptly inform the DCC PHI and DTCO.
(10.4) Document the missed visit and all follow-up actions
(10.5) These actions follow the NPTCCD DOT provider training material.

11) Documentation

11.1) DOT Card / TB 01



National Programme for Tuberculosis Control and Chest Diseases — TB 01

TUBERCULOSIS TREATMENT CARD

Name of patient: _____ Tel No. _____

Complete address: _____

Sex: M ☐ F ☐ Age: _____ NIC No: _____

Name and address of contact person (with Tel No.): _____

District TB No: _____

DOT Centre: _____

Name / Designation of DOT provider (with Tel No): _____

Disease classification	Type of patient
☐ Pulmonary	☐ New
☐ Extra-pulmonary | Site _____	☐ Transfer-in
	☐ Other
	☐ Relapse
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1. Initial Intensive Phase (IP):

Prescribed regimen and dosages:

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Duration of IP (in months): _____

Month	Results of sputum examination							Weight (kg)
	Smear			Culture		DST		
	Date	Result	Lab No.	Date	Result	Sm	Rsn	
0								
2½M								
5								
6M								

Mark "√" for supervised administration, "S" for supply for self-administration & "0" for default

Month \ Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	24	25	26	27	28	29	30	31

Remarks: _____

National Programme for Tuberculosis Control and Chest Diseases, Ministry of Health, Nutrition and Indigenous Medicine _____

(11.1.1) Ensure patient name and contact details are available.
(11.1.2) Check District TB number and patient category.
(11.1.3) Confirm correct DOT provider information.
(11.1.4) Confirm sputum examination results where recorded.
(11.1.5) Confirm prescribed drugs and dosage.
(11.1.6) Record relevant remarks, including expected visit dates or other important information.
(11.1.7) Record each observed treatment dose/attendance accurately and contemporaneously.

The NPTCCD material states that two DOT cards are prepared for each patient: one for the patient file and one for the DOT provider; a third may be used by the patient in some settings.

11.2) DOT Register

National Tuberculosis Programme

TB 03

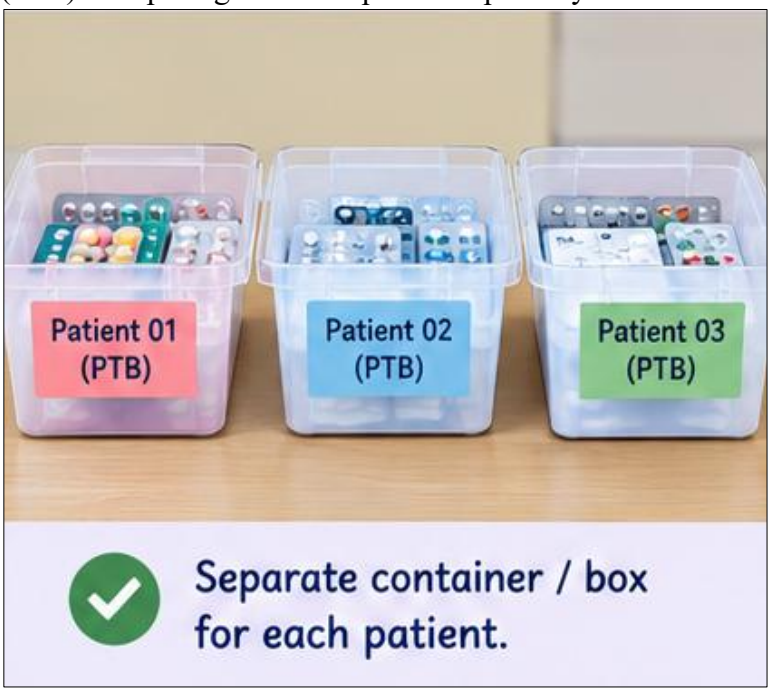
DISTRICT TUBERCULOSIS REGISTER

DATE REGISTERED	DISTRICT TB NO.	NAME IN FULL	SEX (M/F)	AGE	COMPLETE ADDRESS	LGA / M Area	DOT CENTRE / DOT PROVIDER	Referred By	DATE TREATMENT STARTED	HISTORY OF PREVIOUS TREATMENT					
										NEW	RELAPSE	TREATMENT AFTER FAILURE	TREATMENT AFTER LOST TO FOLLOW UP	OTHER PREVIOUSLY TREATED	PREVIOUS HISTORY

Maintain the DOT register according to the local programme requirements, ensuring that attendance, missed visits and relevant follow-up are traceable.

12) Drug Storage

(12.1) Keep drugs for each patient separately.



(12.2) Store medicines in a secure storeroom protected from unauthorized access.



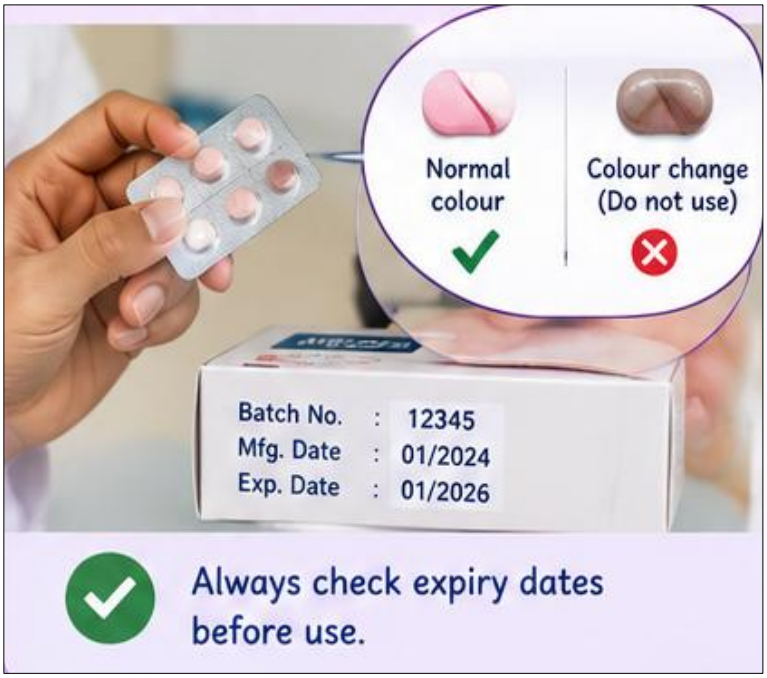
(12.3) Protect medicines from direct sunlight, heat, moisture/rain, dust, pests and fire.



(12.4) Maintain air circulation between storage boxes.



(12.5) Check medicines for colour changes and expiry dates.



(12.6) Report any abnormality or concern to the DCC.





Chest Clinic Badulla (DCC District Chest Clinic)

Drug quantities supplied by the DCC depend on the adequacy of storage conditions; the National Programme for Tuberculosis Control and Chest Diseases (NPTCCD), Sri Lanka. (4th Floor Public Health Complex, No 555/5 Elvitigala Mawatha, Narahenpita, Colombo, Sri Lanka-Near the National Blood Bank Building) material describes usual monthly supply and shorter supply when storage conditions are unsatisfactory.

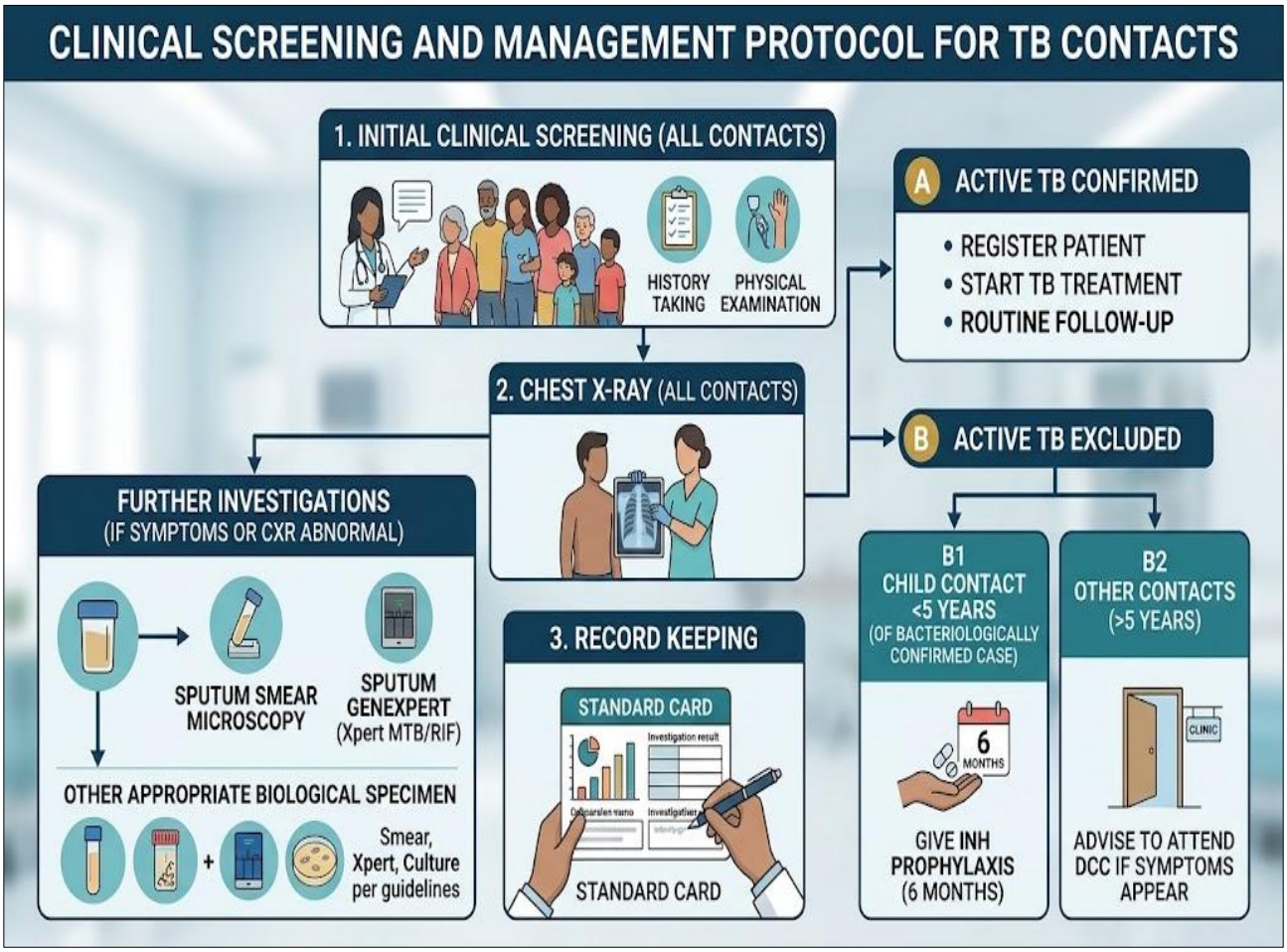
13) Contact Screening

Regularly exposed household and other close contacts should be screened through the TB programme.

The NPTCCD SL material identifies higher-risk contacts including young children, older adults, people with kidney disease or diabetes, people living with HIV, immunocompromised individuals, people receiving immunosuppressive treatment, people in congregate settings, and relevant occupational/risk groups.

Clinical screening of the contacts should be done as follows:

1. Clinical screening (history and examination/symptoms and signs) and Chest X-ray (all contacts)
2. Sputum examination (Smear/GeneXpert)
3. Appropriate biological specimen including smear, Xpert MTB/RIF (Mycobacterium TB / Rifampicin) and/or Culture as considered appropriate as per the guidelines.
4. Maintain all the records in the standard card (results of the investigations)
5. All the contacts who were diagnosed to have active TB through screening should be registered, started treatments, and routinely followed up. •

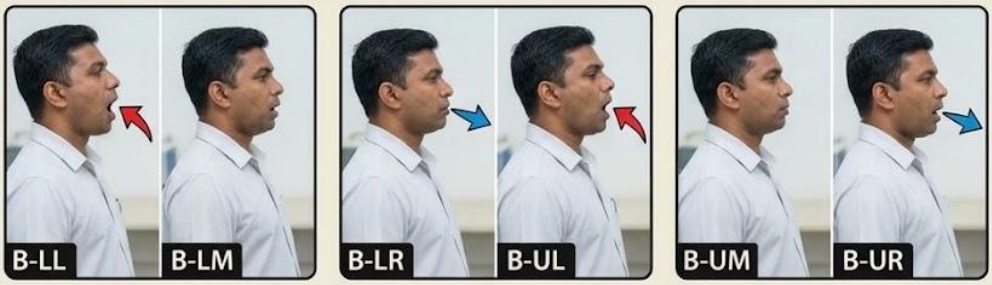


සෙම ලබා දිය යුතු පිළිවෙළ
SPUTUM COLLECTION PROCEDURE

මුඛය ජලයෙන් සෝදා පිරිසිදු කරන්න
CLEAR YOUR MOUTH



ගැඹුරින් හුස්ම තුන්වරක් ගන්න
BREATH IN AND OUT THREE TIMES



ඉදිරියට තරමක් නැමී ගැඹුරින් කහින්න
COUGH OUT DEEPLY FROM THE CHEST



මී.ලි 5 ක් පමණ සෙම ලබා දෙන්න කෙළ ලබාදීමෙන් වලකින්න
PRODUCE ABOUT 5 ml OF FLAME, NOT SALIVA

14) Patient Communication and Confidentiality

- Get to know the patient and build trust.
- Protect confidentiality.
- Use a non-discriminatory and non-judgmental approach.
- Communicate clearly.
- Avoid criticizing the patient's behavior; provide respectful suggestions for change.
- Be punctual and consistent.
- Link the patient with appropriate social support when available.

15) Completion of Treatment and Communication with DCC

- Confirm that the prescribed course has been completed according to the treatment plan.
- Complete and return the required TB treatment documentation to the DCC.
- Return any remaining drugs belonging to a patient who has interrupted treatment.
- Communicate any outstanding clinical, adherence or documentation issues to the DCC.

16) Quality and Safety Checks

- Correct patient verified before each observed dose.
- Correct prescribed medicines and dose verified.
- Swallowing observed.
- Attendance documented immediately.
- Adverse effects actively checked.
- Missed visits followed up promptly.
- Drug storage conditions checked regularly.
- Confidentiality maintained.
- Problems communicated promptly to the DCC.

17) Records to be Maintained

- Patient's DOT card/TB 01,
- DOT register entries,
- Relevant follow-up documentation
- communications/referrals as required by the local TB programme.

18) Key Reference

1) World Health Organization. WHO consolidated guidelines on tuberculosis. Module 4: treatment and care. 2nd edition.Geneva:WHO;2026. https://www.who.int/publications/i/item/9789240125124
2) National Programme for Tuberculosis Control and Chest Diseases (NPTCCD), Sri Lanka.
3) Training of Directly Observed Therapy (DOT) Providers.

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