

**STANDARDS FOR TB CARE FOR
GENERAL PRACTITIONERS
&
PRIVATE HEALTH CARE INSTITUTIONS**



**NATIONAL PROGRAMME FOR TUBERCULOSIS CONTROL & CHEST DISEASES
MINISTRY OF HEALTH, NUTRITION & INDIGENOUS MEDICINE
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INTRODUCTION

Tuberculosis (TB) is still a major public health problem around the globe. An estimated 10 million people fell ill with TB in 2017. TB is the ninth leading cause of deaths worldwide and it is the leading cause of death from a single infectious disease.

Sri Lanka is a middle burden country for TB with estimated incidence of 64 per 100,000 population. In Sri Lanka, around 8000-9000 cases are detected annually and 8856 cases of all forms of TB were detected in 2018. The incidence rate for 2018 is 40.1 per 100,000 population and around 3500- 4000 cases were either not diagnosed or not treated.

Passive case detection is the main method practised for detection of TB. Once a patient with symptoms and signs suggestive of TB present to a health institution he or she should be investigated for TB. Community screening do not show much yield in a middle burden country like Sri Lanka.

Sri Lanka has a growing private health sector and shares a significant proportion of the burden of ambulatory patient care. Private health institutions and General Practitioners happened to be the first contacts of health services for most of the patients with respiratory diseases including TB.

A General Practitioner or a private health care provider can contribute in several ways to TB control by

- **Diagnosing patients**
- **Notifying patients**
- **Counselling patients and family members**
- **Providing DOT and ensuring treatment sustainability.**

In order to provide services with efficiency and with good quality at each level of provision of care, a guideline addressing key aspects of TB control is a necessity. This booklet is prepared in accordance with the International Standards of Tuberculosis Care (ISTC) published by World Health Organization in 2014.

STANDARDS FOR DIAGNOSIS (ISTC STANDARDS 1-6)

ENSURE EARLY DIAGNOSIS

All the patients presenting with signs and symptoms suggestive of TB should be subjected to prompt clinical evaluation and appropriate diagnostic testing.

In order to ensure early diagnosis a practitioner should have a clear idea about the signs & symptoms of TB. The practitioner should also be aware of the clinical manifestation of TB, available diagnostic methods and individual & population risk factors for TB.

THE SIGNS & SYMPTOMS OF TB

Cough of more than two weeks is the commonest presenting symptom of pulmonary tuberculosis. This may or may not be accompanied by fever, night sweats, loss of appetite, loss of weight, shortness of breath, chest pain, fatigue and, haemoptysis .

Symptoms of the extra pulmonary TB depend on the organ affected and also can be associated with constitutional symptoms such as fever, night sweats, loss of weight and fatigue.

INFECTIVITY

The risk of an individual developing an infection depends on the extent of exposure to an infectious agent and the susceptibility of the individual to infection. An untreated sputum positive patient has the potential to infect 10-15 persons per year. Approximately 10% of people infected with TB bacilli will develop the disease in their lifetime. The risk of transmission of infection from sputum negative patients and from patients with extra pulmonary TB is very much lower.

VULNERABILITY

TB can affect any one. However, some individuals are more vulnerable to develop TB. They are

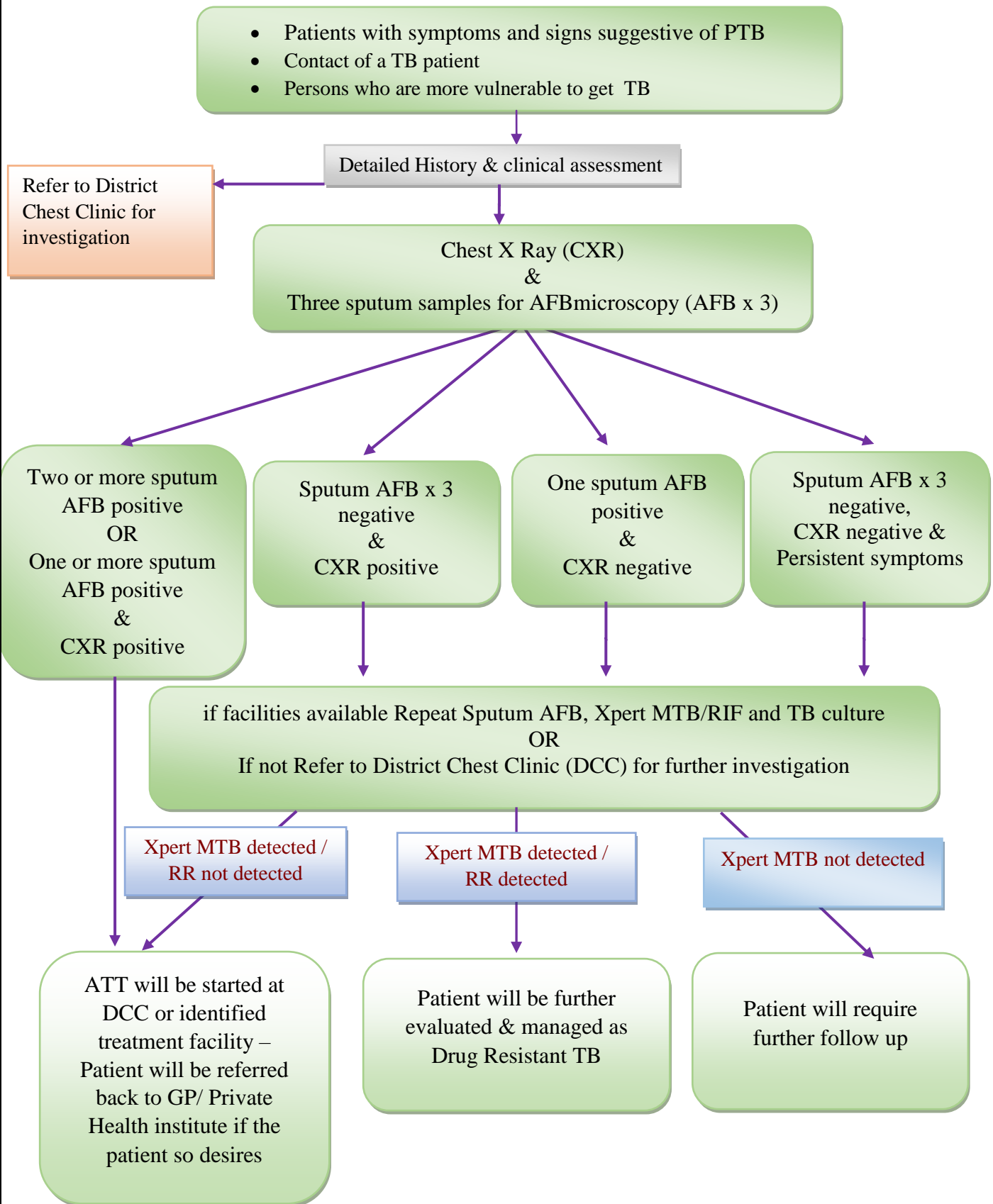
- Close contacts of infectious TB cases
- Health care workers
- Persons living with HIV
- Institutionalized persons (Prisons, Refugees, Elderly etc)
- Alcoholics, Heavy Smokers, Intravenous Drug Abusers
- Patients with poorly controlled Diabetes
- Patients on long term steroid therapy
- Patients on immunosuppressive medications
- Malnourished people
- Patients suffering from chronic lung diseases like silicosis
- People with advanced stages of renal diseases and certain cancers

THERE ARE SEVERAL INTERNATIONALLY ACCEPTED DIAGNOSTIC METHODS AVAILABLE FOR TB AT PRESENT.

- Sputum Microscopy is the most cost effective and easy to perform method of diagnosing infectious cases of pulmonary TB. In order to detect TB bacilli in a sputum sample, it should be of good quality and should contain at least 5000-10,000 bacteria per millilitre. Three sputum samples, preferably with one early morning sample should be taken from a suspected TB patient.
- Sputum culture is more sensitive and specific than direct smear microscopy and are useful in detecting cases where the number of organisms are fewer than that can be detected by direct smear microscopy. But it is more expensive and takes at least 6-8 weeks to get the results.
- Chest X-ray is a good tool for screening of TB though it has a limited value in confirming the diagnosis.
- WHO Recommended Rapid Diagnostics (WRDs) such as Xpert MTB/RIF and line probe assay for detection of TB, had been introduced to practise in recent years. Xpert MTB/RIF is an automated nucleic acid amplification test used for early detection of TB and resistance to rifampicin. The test takes around two hours, and requires minimal man power to perform and more sensitive than smear microscopy.

BLOOD-BASED SEROLOGIC TESTS AND INTERFERON-GAMMA RELEASE ASSAYS ARE NOT RECOMMENDED FOR DIAGNOSIS OF ACTIVE TUBERCULOSIS.

DIAGNOSTIC ALGORITHMS FOR PRESUMPTIVE TB CASES



- Once a patient is identified as a presumptive TB patient by a GP or a Private Health Institution, they could refer the patient to the nearest District Chest Clinic or an identified Treatment Facility.
- In the event if the initial identifier decides to investigate the patient for TB, the key initial investigations they should perform are
 1. Sputum for AFB microscopy
 2. Chest x-ray
- In doing sputum microscopy
 - They could refer the patient to the nearest public health facility (E.g. – District Chest clinic, Microscopy center ect) to do direct smears for sputum AFB. This facility will be provided to the patient free of charge.
 - If there is an already established private microscopy facility available in the district, their services could also be made use of.
- **IN SITUATIONS WHERE THE GP/ PRIVATE HEALTH INSTITUTE DECIDES TO COLLECT SPUTUM AT THEIR FACILITY, A SPUTUM COLLECTION AREA HAS TO BE ESTABLISHED.** In establishing a coughing booth/ area, the identified area should full fill the following requirements in order to provide quality services. **ENCLOSED SPACE SUCH AS TOILETS ARE NOT SUITABLE FOR COLLECTION OF SPUTUM SAMPLES**
 - **Requirements for a coughing booth/ coughing area**
 - ❖ Should be easily accessible to the patient
 - ❖ Should maintain the privacy of the patient while obtaining sample
 - ❖ Should have washing facilities and place to keep patients' belongings
 - ❖ Should have good ventilation to avoid circulation of infected air and means for infection control. (Direct sunlight will destroy the germs)



DIAGRAM OF A MODEL COUGH AREA/ BOOTH

- Should have adequate number of sputum cups. The national policy is to have 3 sputum samples (this should include at least one early morning sample). It is ideal to have a cup (size of a yogurt cup) with a transparent lid enabling microscopist to visually assess the quality of the sample. Sputum cups can be obtained free of charge from District Chest Clinics.
- Necessary arrangements have to be made by the GP or private health institution to transport the collected sputum samples to the nearest microscopy facility available & reports obtained.
- **IN SITUATIONS WHERE THE IDENTIFIED GP OR A PRIVATE HEALTH INSTITUTION IS PLANNING TO ESTABLISH THEIR OWN MICROSCOPY FACILITY OR ALREADY HAVING A MICROSCOPY FACILITIES THE FOLLOWING FACTORS NEED TO BE CONSIDERED IN ORDER TO PROVIDE QUALITY SERVICES.**
 - Microscopy facility should have a counter for receiving of sputum samples and should have a separate area for smear preparation & staining.
 - There should be a properly trained microscopist/ MLT for sputum microscopy. It is recommended to undergo training at the National Tuberculosis Reference Laboratory. **This training can be arranged on request**
 - Adequate infection control measures should be adopted during sample handling, smear preparation and staining to avoid exposure, with adequate ventilation with directional air flow.
 - A properly filled laboratory register (TB 03) should be maintained at the microscopy laboratory. It should be given for inspection by the DCC officials whenever required.
 - Sputum results need to be sent to the treating medical officer as soon as possible.
- In investigating a Presumptive TB patient further, Chest x-ray facilities in the private sector could be made use of by the GP/Private health Institution

N.B:- IN ORGANIZING THE ABOVE ARRANGEMENTS, THE ADVICE OF THE DTCCO IS VITAL. ALL GPs/ INSTITUATIONS WHO ARE INVOLVED IN TB CONTROL ACTIVITIES ARE EXPECTED TO LIASE WITH THEIR RESPECTIVE DTCCOs CLOSELY.

- If a patient has two samples of Sputum AFB positive or one sample of Sputum AFB positive with a suggestive X-ray for TB, treatment could be started by the GP/Private Health Institution. (Details of initiating treatment will be discussed below).
- If a patient's smear turns out to be negative and Chest X-ray that is suggestive or when a patient has a negative AFB smear and an equivocal Chest X-ray, it is recommended that this patient should be referred to the nearest chest clinic. At the Chest Clinics these patients will be further evaluated by a Consultant Respiratory Physician and any further investigations will be carried out if required.
- If the GP/ Private Health Institution wishes to make use of the Xpert/MTB/RIF testing available in the private sector they could make use of that facility.(At present this test is available in the private sector only in few institutions)
- The routine PCR testing available in the private sector is not recommended as a TB diagnostic by the World Health Organization.
- Any patient referred by a GP/ Private Health Institution to the District Chest Clinic or a treatment facility the outcome of that patient's evaluation will be informed to the referring GP/ Private Health Institution.

STANDARDS FOR TREATMENT (ISTC STANDARDS 7-15)

1. Any Presumptive TB patient who has two samples of sputum which are positive

Or

2. One sputum sample positive with a compatible Chest X-ray

Or

3. An EPTB patient with compatible bacteriological /histological/ radiological reports could be started on ATT.

- GP/ Private Health Institution who make the initial diagnosis of TB could refer this patient to the nearest District Chest Clinic or a treatment facility for initiation of treatment.
- If a patient is unwilling to visit the District Chest Clinic, the GP/ Private Health Institute should provide the complete details of the patient needed for registration (Annexure 2) & obtain the anti TB drugs free of charge.
- In order to ensure adherence to treatment, patient should be provided with directly observed treatment (DOTs). The management and follow up of the TB patient should be according to the standard TB guidelines.
- Presumptive TB patients who were referred by a GP/ Private Health Institution for further assessment, turn out to be a TB patient, if the patient wishes they will be handed back to the GP/ Private Health Institution for provision of DOT & further follow up.
 - A GP himself can be a DOT provider or a nurse, Pharmacist or any other person who are nominated by the GP could be a DOT provider. The Private Health institutions could also be DOT providers if they can bear the responsibility of provision of drugs in their institutions.
 - An appropriate time (convenient time for the patient) should be allocated after discussing with the patient. Importance of getting DOT should be explained to the patient.
 - During each visit, DOT provider should inquire about adverse effects/intolerance of drugs from the patient. If a major adverse reaction is identified the DOT provider should refer patient to the chest clinic or nearest treatment facility.
 - A Public Health Inspector (PHI) of the District Chest Clinic will provide you two weekly/ monthly supply of anti TB drugs required for patients under your care (on a patient basis). Stocks will be replenished on a continuous basis without interruption.
 - There should be a separate place for storing anti TB drugs and provision of DOTs

- You should have a DOT register for patients who are under your care. It should contain name and address of the patient and contact details. If a patient did not appear for treatment for two days should inform to chest clinic PHI over the phone.
- A DOT card (TB 1) for each patient should be regularly maintained.
- All Pulmonary TB patients while on treatment should be monitored by sputum smear examination as per National guidelines.
- The patients under your care should be followed up till the completion of a full course of ATT.

ENSURE TREATMENT SUSTAINABILITY

- **All the diagnosed TB patients should be treated with an appropriate treatment regimen.**
- **It is the responsibility of the treating physician to monitor adherence to the regimen and, when necessary, address factors leading to interruption or discontinuation of treatment.**

N.B: IN MANAGING A TB PATIENT, CLOSE LIASION WITH THE DTCCO IS ESSENTIAL

STANDARDS FOR PUBLIC HEALTH RESPONSIBILITIES (ISTC STANDARDS 16&17)

ENSURE CONTACT TRACING

- All care providers of TB patients should ensure that all Household & close contacts of TB patients should be evaluated and managed according to the national guidelines.

NOTIFICATION

- It is mandatory by law that all diagnosed TB patients should be notified.

CONTACT TRACING

- The national policy is to investigate all the household and close contacts of all TB patients (irrespective of bacteriological status) for TB.
- The risk of developing TB among contacts is high within the first two years of exposure.
- Contacts of a bacteriologically positive patient are a priority.
- All contacts are mandatorily examined by a Chest X-ray.
- Contacts who have a cough with a productive sputum are examined by sputum smear microscopy. If it is required they will be further investigated by Xpert/MTB/RIF
- Contacts of a bacteriologically positive patients who are less than 5 years are provided with INAH prophylaxis
- A GP/ Private Health Institution investigating a contact should follow the national guidelines of contact investigation or these contacts should be referred to the nearest District Chest Clinic or an identified health facility for contact investigation

NOTIFICATION

- TB is a notifiable disease. It is mandatory to report by law
- It is the responsibility of the diagnosing institution to notify all detected TB patients to NPTCCD by completing TB notification Form (H 816 A).
- The H 816 A form should be filled in a triplicate and one copy need to be kept at the institution and 2 copies should be sent to the NPTCCD.

REPORTING

- Sending a return on quarterly basis for patients diagnosed & continuing treatment is essential for monitoring and provision of anti TB drugs if there is a functioning DOT centre.
- A specimen reporting format is given below:

ANNEXURE 1

**QUARTERLY RETURN ON TB CONTROL ACTIVITIES IN
PRIVATE HEALTH INSTITUTIONS - TB 20**

➤ **NAME & ADDRESS OF THE INSTITUTION/DISPENSARY/GP :**

.....

➤ **QUARTER:**.....

➤ **MONTHS**

➤ **YEAR**

	TOTAL
a) Number of patients identified as presumptive TB	
b) Out of (a) number of patients referred directly to District Chest Clinic	
c) Out of (a) number of patients investigated	
d) Out of (c) No of patients diagnosed/Confirmed with TB	
e) Out of (c) number of patients referred to District Chest Clinic for further assessment	
f) Out of (c) number of patients identified as non TB and identified for further follow up	

IF MICROSCOPY LABORATORY AVAILABLE			TOTAL
	Diagnosis	Follow-up	
• Number of patients who underwent for sputum microscopy			
• Number of patients with positive smears			
• Number of patients with negative smears			
• Number of slides positive			
• Number of slides negative			

DOT PROVISION		TOTAL
• Number of patients on DOT at the beginning of the quarter		
• Number of patients recruited newly for DOT during the quarter		
• Number of patients who completed DOT during the quarter		
• Number of patients on DOT during the last day of the quarter		

CONTACT TRACING				TOTAL
	No diagnosed as TB	No started on INAH prophylaxis	No provided with health education & identified for further follow up	
Number of TB patients diagnosed during the quarter				
Number of contacts identified				
Number of contacts referred to chest clinic				
Number of contacts investigated				

ANNEXURE 2

COMPLETE DETAILS OF THE PATIENT THAT SHOULD BE PROVIDED BY THE GP/ PRIVATE HEALTH INSTITUTE TO DISTRICT CHEST CLINIC IF A PATIENT IS UNWILLING TO VISIT THE DISTRICT CHEST CLINIC

1) NAME

2) AGE

3) SEX

4) COMPLETE ADDRESS

- A. If the patient is from the same district, provide the address of permanent residence.
- B. If the patient is a resident in the district temporarily, then provide this address along with the permanent address.
- C. If the patient is a permanent resident of another district but lives in the temporary residence for a long time & plans to complete his whole ATT from the district of temporary residence, for registration purposes this address may be used & the patient may be identified with this district.

5) COMPLETE DETAILS OF HOW THE PATIENT WAS DIAGNOSED

- A. Sputum AFB direct smear reports
- B. Chest X-ray appearance
- C. Culture/Xpert-MTB/RIF if done
- D. Histology/ Radiology report if appropriate

6) PATIENT TREATMENT CATEGORY

7) TYPE OF PATIENT

8) HIV TESTING (DONE OR NOT)

NB : Refer District TB Register for the layout for a TB patient registration- (Source - National Manual For Tuberculosis Control)