

Revised National Tuberculosis Control Programme



सत्यमेव जयते



REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

**TRAINING MODULE FOR
COMMUNITY
PHARMACISTS**

2013

Developed jointly by:

Government of India

Central TB Division, Directorate General of Health Services,
Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi
www.tbcindia.nic.in

And



Indian Pharmaceutical Association (IPA)

www.ipapharma.org

About the Training Module for Community (Retail) Pharmacists

AIM OF MODULAR TRAINING:

This module aims to train pharmacists in various aspects of tuberculosis and role of pharmacist in Tuberculosis (TB) care and control.

The content of the module is similar to RNTCP training module for Multi Purpose Workers, however modified to adapt for training of pharmacists.

At the end of this modular training, the participants will be able to:

- Get introduced to Global and Indian TB scenario
- Understand basics of Tuberculosis (TB) and Drug Resistant TB
- Understand the principles and strategy of Revised National Tuberculosis Control Program (RNTCP) and Directly Observed Treatment Short course(DOTS)
- Understand Role of pharmacist in generating community awareness on TB, identification and referral of TB suspects, DOT provision, recording and reporting and rational use of anti TB drugs.

INDEX

INDEX

	Page No.
CHAPTER 1 INTRODUCTION	4
CHAPTER 2 TUBERCULOSIS - A PUBLIC HEALTH PROBLEM	5
CHAPTER 3 CLINICAL MANIFESTATION OF TUBERCULOSIS	10
CHAPTER 4 DIAGNOSIS OF TUBERCULOSIS	12
CHAPTER 5 TREATMENT OF TUBERCULOSIS	16
CHAPTER 6 ROLE&RESPONSIBILITIES OF THE PHARMACIST	19
CHAPTER 7 ADVERSE DRUG REACTIONS TO ANTI-TB DRUGS	26
CHAPTER 8 IMPORTANT CONCERNS IN MANAGEMENT OF TB	27
CHAPTER 9 SUPERVISION And MONITORING OF PHARMACIES BY RNTCP STAFF	31
Annexure 1 Guidelines for Facilitators	32
Annexure 2 Undertaking by the pharmacist for participation in DOTS	34
Annexure 3 Format for "Authorization Letter or Certificate from RNTCP"	35
Annexure 4 Format for attendance sheet for Training Programme	36
Annexure 5 Diagnostic Algorithm and treatment regimen for Pediatric Tb	37
Annexure 6 TB Notification Format	39
Annexure 7 Pharmacists Reporting Format	40
Annexure 8 TB Notification Order	41
Annexure 9 Serology Ban Notification	42
Annexure 10 Exercise	43

ABBREVIATIONS

ABBREVIATIONS

Abbreviation	Full Form
TB	Tuberculosis
MDRTB	Multidrug - Resistant TB
XDRTB	Extensively Drug- Resistant TB
PTB	Pulmonary TB
RNTCP	Revised National Tuberculosis Control Programme
TNF	Tumor Necrosis Factor
STLS	Senior Tuberculosis Laboratory Supervisor
MO	Medical Officer
DTC	District Tuberculosis Centre
AFB	Acid-Fast Bacilli
HIV	Human Immunodeficiency Virus
FDCs	Fixed Dose Combinations
WHO	World Health Organization
DOTS	Directly Observed Treatment Short Course
I P	Intensive Phase
CP	Continuation Phase
DST	Drug Susceptibility Testing
DR-TB	Drug Resistant TB
FIP	International Pharmaceutical Federation
IPA	Indian Pharmaceutical Association
FDA	Food and Drug Administration
PHI	Peripheral Health Institution
STS	Senior Treatment Supervisor
STLS	Senior TB Lab Supervisor
IEC	Information, Education And Communication

CHAPTER 1

INTRODUCTION

1.1 What is Tuberculosis?

Tuberculosis (TB) is a highly infectious bacterial disease caused by *Mycobacterium tuberculosis*. TB can affect any part of the body. When it affects the lungs it is called pulmonary TB. The commonest form of TB is pulmonary TB. TB in any other part of the body (i.e. other than lungs) is called extra pulmonary TB.

1.2 Mode of Infection

TB germs usually spread through air. When a patient with pulmonary tuberculosis coughs or sneezes, TB germs are spread in the air in the form of tiny droplets. When these droplets are inhaled by a healthy person s/he gets infected with tuberculosis. This infected person will have a 10% lifetime risk of developing tuberculosis.

1.3 Source of infection and exposure

Patients suffering from smear positive pulmonary TB (PTB) constitutes the most important source of infection. The infection occurs most commonly through droplet nuclei generated by coughing, sneezing etc., inhaled via the respiratory route. The chances of getting infected depend upon the duration, the frequency of exposure and the immune status of an individual.

Tuberculosis is an infectious disease caused predominantly by *Mycobacterium tuberculosis*. M tuberculosis was first discovered in 1882 by Robert Koch, hence is also called as the “Koch's bacillus.” (You will also commonly hear doctors refer to pulmonary tuberculosis as “pulmonary kochs”).

1.4 Risk of infection

A smear positive pulmonary TB case in the general community may infect 10 – 15 other persons in a year, and remain infectious for 2 to 3 years if left untreated.

1.5 Risk of developing disease

All those who get infected do not necessarily develop TB disease. The life time risk of breaking down to disease among those infected with TB is 10–15%, which gets increased to 10% per year amongst those co-infected with HIV. Other determinants such as diabetes mellitus, smoking tobacco products, malnutrition and alcohol abuse also increase the risk of progression from infection to TB disease.

CHAPTER 2

TUBERCULOSIS

A PUBLIC HEALTH PROBLEM

2.1 Extent of TB problem in the world

Every year, more than 9 million new cases of tuberculosis (TB) occur and nearly 2 million people die of the disease. Nearly half a million cases have the multidrug-resistant form of the disease. While Asia bears the largest burden of the disease, sub-Saharan Africa has the highest incidence of drug-susceptible TB and Eastern Europe has the highest incidence of multidrug-resistant TB (MDR-TB).

2.2 Extent of TB problem in India

The extent of the TB problem is generally described in terms of incidence, prevalence and mortality. Incidence is the number of new events (infection or disease) that occur over a period of one year in a defined population. Prevalence is total of new and existing events (infection or disease) at a given point of time in a defined geographical population. India accounts for 26% of the total global TB burden *i.e.* 2.0-2.5million new cases annually. In Out of all TB notified cases in India, 53% are smear positive cases and 285 are smear negative cases and 19% are extra pulmonary cases. Only 2.1% of TB cases are MDR TB cases and there are only 6% of HIV positive TB patients in India. The table below shows the estimated figures for TB burden globally and for India provided by WHO for the year 2011

2.3 Magnitude of TB - Global and Indian scenario*

	Incidence of disease	Prevalence of disease	Mortality	HIV prevalence among incident cases
Global	(125/lakh/yr)	(170/lakh/yr)	(14/lakh/yr)	13%
India	(181/lakh/yr)	(249/lakh/yr)	(24/lakh/yr)	4.2%

- Source: Global TB Report 2012

The Millennium Development Goal (MDG) target to halt and reverse the TB epidemic by 2015 has already been achieved. New cases of TB have been falling for several years and fell at a rate of 2.2% between 2010 and 2011. The TB mortality rate has decreased 41% since 1990 and the world is on track to achieve the global target of a 50% reduction by 2015.

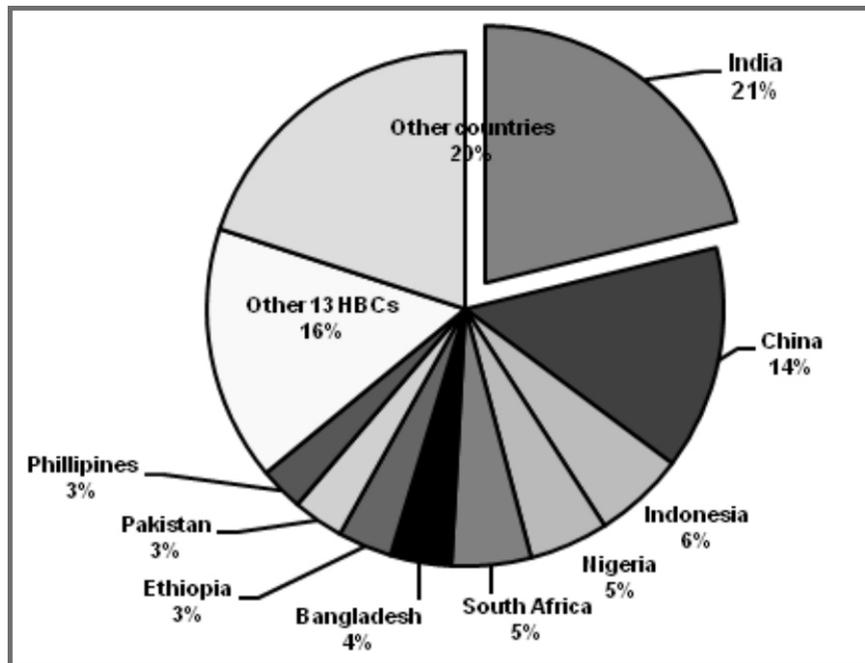


Fig. 1. India is the largest TB burden country accounting for one-fifth of the global incidence

One untreated case of pulmonary TB can infect 10 to 15 persons in one year.

2.4 HIV Co infection among TB patients

In India, it is estimated that 2.31 million individuals are living with HIV infection, which equates to approximately 0.34% of the adult population of the country. Based on available country data of 2007, it is estimated that 4.9% of new adult TB patients in India are HIV positive. Hence, the TB epidemic in India continues to be predominantly driven by the pool of HIV negative TB infected individuals.

Tuberculosis is the most common opportunistic infection amongst HIV-infected individuals. It is a major cause of mortality among patients with HIV and poses a risk throughout the course of HIV disease, even after successful initiation of antiretroviral therapy (ART). In India 55-60% of AIDS cases reported had TB, and TB is one of the leading causes of death in '*People living with HIV/AIDS*' (PLHA).

2.5 Paediatric TB

Children in the first five years of their life are likely to suffer from serious and fatal forms of TB, more so, if not vaccinated with BCG. Globally, it is estimated that about 1.1 million new cases are reported and 1,30,000 deaths occur annually due to TB among children. Reliable data on the

incidence and prevalence of the disease is not available due to the difficulties in diagnosis of paediatric TB under field conditions. However, limited data available reveals that prevalence of TB among children in the age group 0-14 years is estimated to be 0.3% of radiological cases and 0.15% of bacteriological cases.

The extent of TB in children is a reflection of the pool of infectious adult smear-positive pulmonary tuberculosis cases in the community and their ability to transmit infection.

2.6 Drug-resistant tuberculosis (DR-TB)

Multi Drug Resistant TB (MDR-TB) is defined as tuberculosis disease where the bacilli is resistant to isoniazid (H) and rifampicin (R), with or without resistance to other drugs. **Irregular consumption and frequent interruption in taking treatment, irrational treatment for TB are the most common causes of acquiring multi drug resistance.** In India, MDR-TB amongst new cases are estimated at 2-3% and amongst re-treatment cases at 14-17%. **Extensively Drug Resistant TB (XDR-TB)** is a subset of MDR-TB where the bacilli, in addition to being resistant to R and H, are also resistant to fluoroquinolones and any one of the second-line injectable drugs (namely Kanamycin, Capreomycin or Amikacin). Now, most recently, Extremely Drug Resistant (**XXDR TB**) is reported where the bacilli is resistant to all anti-TB drugs.

In India, the great concern is the potential threat of drug resistant TB (DR-TB) with the existing unregulated availability and injudicious use of first and second line anti-TB drugs in the country. The best strategy for management of drug resistant is to prevent its emergence by implementing quality DOTS services. The RNTCP rolled out services for diagnosis and management of multi-drug resistant TB (MDR-TB) in the states of Gujarat and Maharashtra in the year 2007. Complete geographical coverage is expected to be achieved across all districts in the country by March 2013.

The following interventions are being undertaken to enable system strengthening to effectively scale up treatment services of MDR TB:

- Advocate with Indian Drug Manufacturers with Global Drug Facility (GDF) support
- Adhere to WHO Prequalification and GDF Quality Assurance systems,
- Develop second-line drug production plans to meet national drug demand,
- Integrated national on-line electronic recording and reporting system,
- Advocate rational use of anti-TB drugs (Fluro Quinolones in respiratory cases) with all professional associations and practitioners.

2.7 TB Notification in India

2.7.1 Background

Tuberculosis was never a notifiable disease nationally in India. Though in some of the states it was for quite a long time, it was never properly implemented due to many reasons. India's National TB Control programme provides quality assured diagnostic and treatment services to all the TB patients including necessary supportive mechanisms for ensuring treatment adherence and completion. But these services cannot be made available to large number of patients availing services from private sector, as they are not currently reported to the programme.

A large number of patients are not benefitted with these programme services and leads to non adherence, incomplete, inadequate treatment leading to M/XDR TB, mitigating all the efforts of the programme to prevent emergence and spread of drug resistance. If the TB patients diagnosed

and treated under private sector are reported to public health authorities, the mechanisms available under the programme can be extended to these patients to ensure treatment adherence and completion. The impending epidemic of M/XDR TB can only be prevented to a large extent by this intervention.

To curb this situation, Govt of India declared Tuberculosis a notifiable disease on 7th May 2012 with the following objectives:

2.7.2 Objectives of TB Notification

- To have establish Tuberculosis surveillance system in the country
- To extend mechanisms of TB treatment adherence and contact tracing to patients treated in private sector
- To ensure proper TB diagnosis and case management and further accelerate reduction of TB transmission
- To mitigate the impending Drug resistant TB epidemic in the country

2.7.3 Implementation tools and methods

For the purpose of notification, the contact details of the nodal officer at district level and the reporting formats are available on the website www.tbcindia.nic.in. All the health establishments throughout the country in public as well as private and nongovernmental sector are expected to notify TB cases. For the purpose of notification the definition of TB cases is as below:

Microbiologically-confirmed TB case – Patient diagnosed with at least one sputum specimen positive for acid fast bacilli, or Culture-positive for Mycobacterium tuberculosis, or RNTCP-approved Rapid Diagnostic molecular test positive for tuberculosis.

OR

Clinical TB case – Patient diagnosed clinically as tuberculosis, without microbiologic confirmation and initiated on anti-TB drugs.

2.7.4 List of RNTCP endorsed TB diagnostics

Smear Microscopy (for AFB):

Sputum smear stained with Zeil-Nelson Staining or Fluorescence stains and examined under direct or indirect microscopy with or without LED.

Culture:

Solid (Lowenstein Jansen) media or Liquid media (Middle Brook) using manual, semi-automatic or automatic machines e.g. Bactec, MGIT etc.

Rapid diagnostic molecular test:

Conventional PCR based Line Probe Assay for MTB complex or Real-time PCR based Nucleic Acid Amplification Test (NAAT) for MTB complex e.g. GeneXpert

2.8 Nikshay

Improving TB surveillance by transitioning to Case Based Web Based recording and reporting (Nikshay):

RNTCP since implementation followed international guidelines for recording and reporting for Tuberculosis Control Programme with minor modifications. With the objective to improve TB surveillance in the country, programme has undertaken the initiative to develop a Case Based Web Based application named Nikshay. This ICT application (Nikshay) was launched on 15th May 2012 by NIC (HQ) and Central TB Division.

The data entry of the individual TB cases is being done at the block level DEOs (Data Entry Officers) of NRHM. Till Sept 2012, more than 2,00,000 patients are already registered under this system.

2.9 Ban on Commercial Serological Tests

In July 2011 - WHO released a policy, concluding that, since the “the harms/risks [Currently available commercial serodiagnostic tests] far outweigh any potential benefits (strong recommendation) these tests should not be used in individuals suspected of active pulmonary or extra-pulmonary TB, irrespective of their HIV status. After this WHO policy, the RNTCP published an advisory statement against the use of serological TB tests in India.

Subsequently, an expert committee convened by the Drug Controller General of India (DCGI) reviewed the evidence on 1 December 2011 and unanimously recommended a ban on sero diagnostics for TB in India as these tests provide inconsistent and imprecise results. The DCGI recommendations were formally approved and notified by the Ministry of Health and Family Welfare.

CHAPTER 3

CLINICAL MANIFESTATIONS OF TUBERCULOSIS

3.1 Symptoms of tuberculosis

3.1.1 Pulmonary tuberculosis (PTB):

The most common symptom of PTB is a **persistent cough of two weeks or more, with or without expectoration**. It may be accompanied by one or more of the following symptoms:-

Fever, night sweats, weight loss

Chest pain, haemoptysis (expectoration (coughing up) of blood or blood stained sputum), shortness of breath, tiredness and loss of appetite.

Such patients should be selected and subjected for sputum examination. This enhances the chances of detection of the bacilli in the smear microscopy.

3.1.2 Extra pulmonary tuberculosis:

A person with extra-pulmonary TB may have symptoms related to the organs affected along with constitutional symptoms stated above. For example:

- Enlarged cervical lymph nodes with or without discharging sinuses (TB Lymphadenitis)
- Chest pain with or without dyspnoea (difficulty in breathing) in pleural TB
- Pain and swelling of the joints in bone tuberculosis (fever, backache, deformity in spinal TB)
- Signs of raised intra-cranial tension like irritability, headache, vomiting, fever, stiffness of the neck and mental confusion in TB meningitis
- Painless haematuria (blood in urine) or sterile pyuria (pus in urine) in renal tuberculosis
- Infertility in genito-urinary TB.

3.2 Pulmonary TB suspects

Pulmonary smear-positive tuberculosis patients expel tubercle bacilli into the air while coughing/sneezing. Contacts of undiagnosed/untreated pulmonary smear-positive patients become infected when they inhale these tubercle bacilli.

A pulmonary TB suspect is defined as:

- An individual having cough of 2 weeks or more.
- Contacts of smear positive TB patients having cough of any duration.
- Suspected/confirmed extra-pulmonary TB having cough of any duration
- HIV positive patient having cough of any duration.

Persons having cough of 2 weeks or more, with or without other symptoms, are referred to as pulmonary TB suspect. They should have 2 sputum samples examined for Acid Fast Bacilli (AFB).

It is important to suspect tuberculosis among the chest symptomatic patients and subject them for sputum examination. If TB is not suspected, patients with smear-positive pulmonary TB will not be identified. These patients will continue to spread the infection and it is likely that more than half of them will die by three years. Hence, every pulmonary TB suspect should be referred for sputum examination in time.

Community pharmacists, all health workers and community volunteers should be encouraged to identify and refer TB suspects for early diagnosis and treatment to prevent further spread of the infection.

CHAPTER 4 DIAGNOSIS OF TUBERCULOSIS

4.1 How to diagnose Tuberculosis?

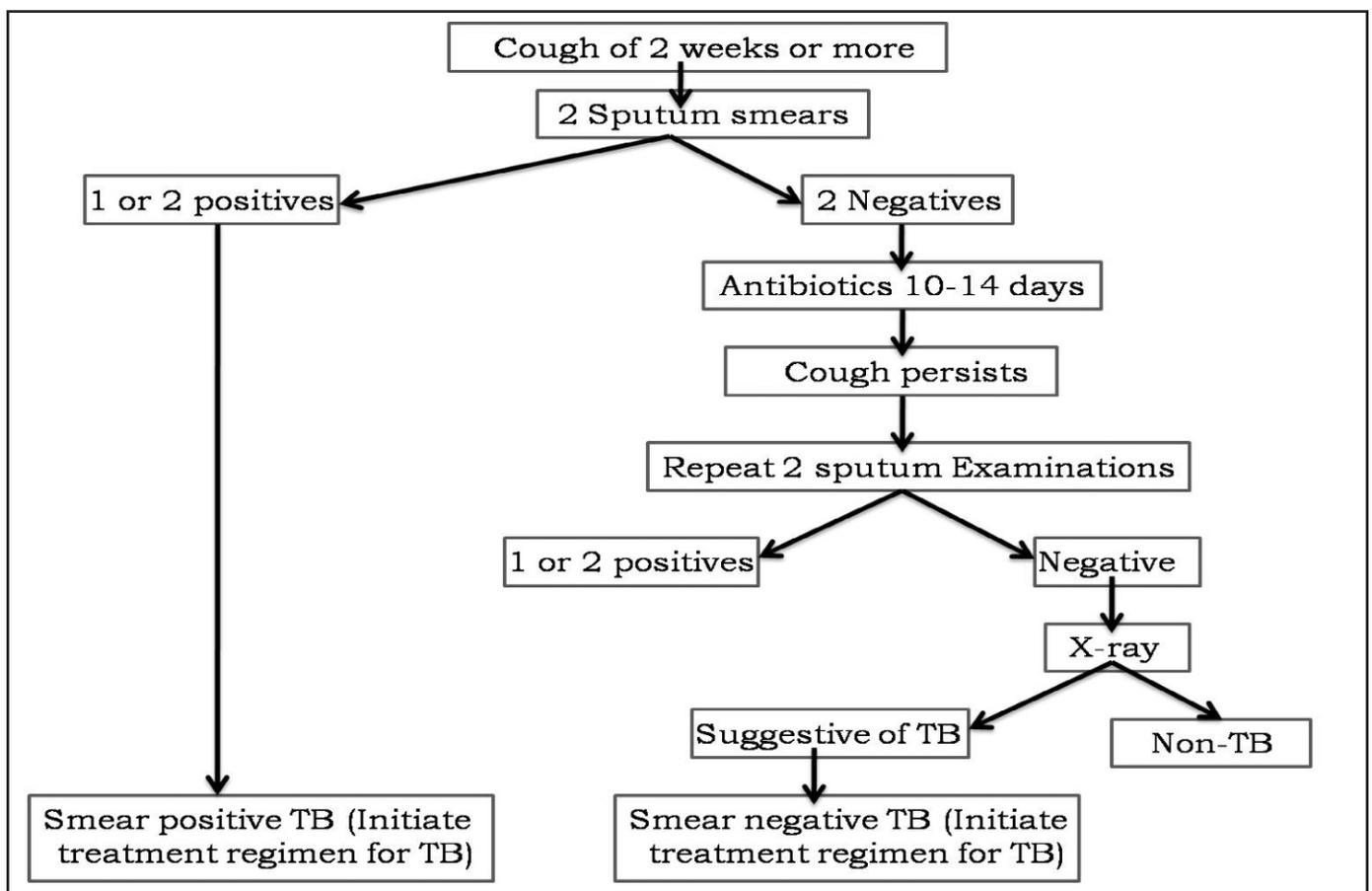
Tools for diagnosis of Pulmonary TB in adults:

- Sputum smear microscopy
- Chest X-ray
- Sputum culture
- Newer diagnosis ,including Molecular diagnosis, GeneXpert etc

Sputum examination is the main tool for diagnosing pulmonary TB.

At least 2 sputum samples (spot – morning) should be collected, preferably within two days, and examined by microscopy in the laboratory. *Diagnosis is done free of charge in the Designated Microscopy Centers (DMCs) of the Government Hospitals and selected private hospitals.*

Diagnostic Algorithm of Pulmonary TB



The diagnostic algorithm given above should be strictly followed. If not followed, patients may either be treated unnecessarily based upon X-ray results or left untreated.

On seeing the fast spread of Tuberculosis in the country and the mortality caused by it, the Government put into place a policy which would help us curb the deadly disease which, if detected in time can prevent the spread and is completely curable. The policy is described in short below. Its overview will help us understand the methods of diagnosis and treatment better.

4.2 Chest X-ray

Chest x-ray as a diagnostic tool is more sensitive but less specific with higher inter and intra reader variation. However, it should be used judiciously. It is also useful for diagnosing extra pulmonary TB, by detecting pleural effusion, pericardial effusion, mediastinal adenopathy and miliary TB. **Miliary tuberculosis**, also known as "disseminated tuberculosis", is a form of tuberculosis that is characterized by a wide dissemination into the human body and characterized by the tiny size of the lesions (1–5 mm).

RNTCP does not recommend the serological (Blood Antigen) test as confirmatory test for detection of tuberculosis.

4.3 Diagnosis of Extra Pulmonary TB

Demonstration of AFB in a smear from extra pulmonary site is often difficult because of low bacillary load. The clinical features pertaining to the system affected should be considered in the diagnosis of extra pulmonary tuberculosis. However, the following are some of the special investigations which are helpful in diagnosing extra pulmonary tuberculosis. These may be radiological, cytological / pathological, biochemical and immunological.

- (a) Fine Needle Aspiration Cytology (FNAC) and direct smear examination
- (b) Excision / Biopsy of specimen for histo-pathological examination
- (c) Fluid for cytology, biochemical analysis and smear examination
- (d) X-ray of the involved region
- (e) Ultra Sonography for Abdominal Tuberculosis
- (f) Culture for *Mycobacterium tuberculosis* (*M. Tb*)

Precise diagnosis of some forms of extra pulmonary tuberculosis is a challenge to the physicians as they present symptom complex with extraordinary diversity. Delay in the diagnosis can be fatal or result in life threatening sequelae as in the case of meningeal TB. Patients with symptoms suggestive of extra pulmonary tuberculosis should be referred to the respective speciality for further investigations.

4.4 Diagnosis of TB among HIV co-infected patients

Central TB Division (CTD) and the National AIDS Control Organization (NACO) have adopted the policy of routinely offering voluntary HIV counselling and testing to all TB patients as part of an

intensified TB/HIV package of services.

The services under the intensified TB/HIV packages are :-TB patients with unknown HIV status are to be referred to the nearest and most-convenient place where NACO HIV counselling and testing is offered. This may be an ICTC or any PHI where whole blood testing is offered for HIV screening. The referral should be made at the earliest after TB diagnosis, but may be made at any time during TB treatment if HIV status remains unknown. Treating physicians and paramedical workers should explain the need and importance for patients to be certain about their HIV status, and also that HIV testing is voluntary and not mandatory. This offer should be made at least once during the course of TB treatment. HIV-infected TB patients not already on ART should be referred as soon as possible to an ART centre for pre-ART registration and free CD4 testing, using the standard “ART Centre referral form”. Most HIV-infected TB patients will be eligible for ART. Intensified case finding activities are to be specifically monitored among HIV infected pregnant women and children living with HIV.

4.5 Diagnosis of Paediatric TB

Early and prompt diagnosis of TB in children is often difficult. A battery of tests is required to arrive at accurate diagnosis of TB in children. Generally, diagnosis should be made by a Medical Officer and the existing RNTCP case definitions are to be used for all cases diagnosed.

High index of suspicion of TB in a child is the first step in the diagnosis. Tuberculosis should be suspected among children presenting symptoms of prolonged / unexplained fever and / or cough for more than 2 weeks, with no weight gain or history of failure to thrive.

It is to be remembered that cough may not be the predominant and constant symptom unlike in an adult. Children presenting neurological symptoms like irritability, refusal of feeds/failure to thrive, headache, vomiting or altered sensorium and convulsions, may be suspected to have TB meningitis.

The National guidelines on Paediatric TB diagnosis and management were updated based on the recent evidence and advances in Paediatric TB diagnosis and treatment in consultation with Indian Academy Pediatrics during January- February 2012. A new diagnostic algorithm is developed for pulmonary TB, the commonest type of extra pulmonary TB (Lymph node TB) and for other types of extra-pulmonary TB. The diagnostic algorithms for the diagnosis of pulmonary TB and Lymph node tuberculosis are provided in Annexure.

All efforts should be made to demonstrate bacteriological evidence in the diagnosis of Paediatric TB. In cases where sputum is not available for examination or sputum microscopy fails to demonstrate AFB, alternative specimens (Gastric lavage, Induced sputum, broncho-alveolar lavage) should be collected, depending upon the feasibility, under the supervision of a pediatrician. A positive Tuberculin skin test / Mantoux positive were defined as 10 mm or more induration. The optimal strength of tuberculin 2 TU (RT 23 or equivalent) to be used for diagnosis in children.

There is no role for inaccurate/inconsistent diagnostics like serology (IgM, IgG, IgA antibodies against MTB antigens), various in-house or non- validated commercial PCR tests and BCG test. There is no role of IGRAs in clinical practice for the diagnosis of TB

4.6 Diagnosis of Drug Resistant Tuberculosis

Drug resistant TB is difficult to diagnose and requires set up of quality assured laboratories for culture and drug susceptibility testing (C/DST) which are resource intensive. RNTCP is currently in the process of setting up 43 C/DST laboratories across the country for diagnosis and follow up of patients of drug resistant TB. RNTCP is also accrediting existing laboratories in private sector, medical colleges, NGOs, ICMR to supplement the C/DST capacity.

4.6.1 MDR Suspect Criteria

Criteria A –

- All failures of new TB cases
- Smear +ve previously treated cases who remain smear +ve at 4th month onwards
- All pulmonary TB cases who are contacts of known MDR TB case

Criteria B –

in addition to Criteria A:

- All smear +ve previously treated pulmonary TB cases at diagnosis
- Any smear +ve follow up result in new or previously treated cases

Criteria C –

in addition to Criteria B

- All smear -ve previously treated pulmonary TB cases at diagnosis,
- HIV TB co-infected cases at diagnosis

In other words, for districts implementing MDR Suspect Criteria B, any smear-positive diagnostic (except in a new patient) or any smear-positive follow-up result, should prompt a referral for DST. For districts implementing MDR TB Suspect Criteria C, all patients should be referred for DST at diagnosis of TB, except new patients (smear positive and smear negative) at without HIV infection. Refer to PMDT guideline in www.tbindia.nic.in for further details

4.6.2 Diagnostic tools for MDR-TB / XDR TB

Culture and drug sensitivity

- o Solid culture
- o Liquid culture

Newer diagnostics

- o Line Probe Assay(LPA), Cartridge Based Nucleic Acid amplification Test – (CB-NAAT- Gene Xpert)

Newer tools under evaluation include, Gene Xpert – a completely closed automated system using real-time PCR which has as ensitivity of 70-90% even for smear negative cases and can also detect the presence of rifampicin resistance.

CHAPTER 5 TREATMENT OF TUBERCULOSIS

Treatment of tuberculosis under RNTCP is based on Direct observation of treatment (DOT) ensures the best possible result. Here an observer watches and assists the patient in swallowing the tablets, thereby ensuring that the patient receives the medication. Many patients who do not receive directly observed treatment stop taking drugs after two months because they feel better. Studies in India and many other countries consistently shows that at least one third of patients do not take medicines regularly.

It is neither possible to predict who these patients will be nor to reliably prevent non-adherence through health education. Studies have shown that there will be poor treatment outcome and high death rates in the absence of direct observation, even when regular supply of drugs is ensured. Hence, by observing the patients during the entire course of treatment, one ensures that they receive the right drugs, in the right doses, at the right intervals and for the right duration.

The duration of treatment is usually 6 to 9 months (Drug susceptible) . There are two phases in the treatment of tuberculosis: the intensive phase (IP) of 2-4 months and the continuation phase (CP) of 4-5 months, depending upon the category of treatment. During IP, all doses are given under direct observation, three times a week on alternate days for 2-4months. Thereafter, sputum is examined, and if found negative, the CP is started.

During CP, the first dose of every week must be administered under direct observation. The patient collects the rest of the drugs for that week from the DOT Provider and consumes them at home. The following week, the patient comes with the empty blister pack, hands it over to the DOT Provider, takes the first dose under direct observation and collects drugs for the rest of the week to be consumed at home.

Category of patients	Type of patient	Regimen ¹	
		<i>Intensive Phase(IP)</i>	<i>Continuation Phase(CP)</i>
I	Sputum smear-positive Sputum smear-negative Extra-pulmonary Others	2H ₃ R ₃ Z ₃ E ₃	4H ₃ R ₃
II	Smear-positive relapse Smear-positive failure Smear-positive treatment after default Others ²	2H ₃ R ₃ Z ₃ E ₃ S ₃ /1H ₃ R ₃ Z ₃ E ₃	5H ₃ R ₃ E ₃

The table below indicates the treatment regimen, type of patients and regimens prescribed. The number before the letters refers to the number of months of treatment. The subscript after the letters refers to the number of doses per week. The dosage strengths are as follows:

Isoniazid (H) 600mg, Rifampicin (R) 450mg, Pyrazinamide (Z) 1500mg, Ethambutol(E) 1200mg Streptomycin(S) 750mg. Patients who weigh 60kg or more receive additional rifampicin 150mg.

5.1 Management of Contacts of Sputum-Positive Cases

Any person who has a productive cough of any duration and is in contact with a smear positive case, sputum samples should be examined as soon as possible for diagnosis, and if negative, s/he should be evaluated by the Medical Officer and also followed up three months later. Children who cannot produce sputum should be examined with other recommended investigations like chest X-ray and tuberculin testing. For all such cases contact the Medical Officer.

5.2 Treatment of Paediatric TB

The intermittent therapy will remain the mainstay of treating pediatric patients. However, Among seriously ill admitted children or those with severe disseminated disease/ neuro-tuberculosis, the likelihood of vomiting or non-tolerance of oral drugs is high in the initial phase. Such, select group of **seriously ill admitted patients should be given *daily supervised therapy during their stay in the hospital*** using daily drug dosages.

The following are the daily doses (mg per kg of body weight per day) Rifampicin 10-12 mg/kg (max 600 mg/day), Isoniazid 10 mg/kg (max 300 mg/day), Ethambutol 20- 5mg/kg (max 1500 mg/day), PZA 30-35mg/kg (max 2000 mg/day) and Streptomycin 15 mg/kg (max 1gm/day). There will be six weight bands and three generic patient wise boxes will be used in combination to treat patients in the six weight bands. The dose of INH for chemoprophylaxis is 10 mg/kg (instead of currently recommended dosage of 5 mg/kg) administered daily for 6 months. The details of the new weight bands and the new generic boxes are provided in Annexure.

5.3 Chemoprophylaxis

INH TB preventive therapy should be provided at 10mg/kg to:

- a. All asymptomatic contacts (under 6 years of age) of a smear positive case, after ruling out active disease and irrespective of their BCG or nutritional status.
- b. Chemoprophylaxis is also recommended for all HIV infected children who either had a known exposure to an infectious TB case or are Tuberculin skin test (TST) positive (≥ 5 mm induration) but have no active TB disease

5.4 Treatment of TB disease in HIV-infected patients

Early diagnosis and effective treatment of TB among HIV-infected patients are critical for controlling the disease, minimizing the adverse impact of TB on the course of HIV, and interrupting the transmission of TB in the community. Treatment of TB is same as that in the HIV-negative TB patients. Patients are to be treated with the RNTCP “New” or “Previously Treated” regimen according to the patient's history of previous anti-TB treatment.

In addition to TB treatment under RNTCP, all HIV-infected TB patients must be provided access to care and support for HIV disease, including antiretroviral therapy. ART reduces TB case fatality rates (reduces deaths) and the risk of recurrent TB.

5.5 Cotrimoxazole preventative therapy (CPT)

Cotrimoxazole preventative therapy has been shown to reduce mortality among HIV-infected TB patients, and is recommended by NACP for all HIV-infected patients. All HIV-infected TB patients should therefore be provided CPT.

5.6 Treatment of MDR TB

- Treatment based on Rifampicin DST results
- Initial hospitalization followed by ambulatory care

Standardized treatment Regimen for MDR TB – daily DOT

- Intensive phase (IP) for 6-9 months Km Lfx Cs Eto Z Emb
- Continuation phase (CP) for 18 Lfx Cs Eto Emb
- Scope of strengthening the regimen in baseline Ofx / Km resistance
- PAS used as a substitute drug in case of intolerance to any drug
- Weight bands for < 16 kg, 16-25kg, 26-45kg, 46-70kg and > 70kg

Standardized treatment Regimen for XDR TB – daily DOT

- Intensive phase (IP) for 6-12 months Cm, PAS, Mfx, High dose-H, Cfz, Lzd, Amx Clv
- Continuation phase (CP) for 18 months PAS, Mfx, High dose-H, Cfz, Lzd, Amx-Clv
- Clr and Thz used as a substitute drug in case of intolerance
- States to locally procure drugs using national technical specification

CHAPTER 6

ROLE and RESPONSIBILITIES OF THE PHARMACIST

Pharmacists are on many occasions first and repeated point of contact to the community. Given the situation of TB, pharmacist could be the point of contact for a chest symptomatic, and a TB patient who is on treatment (from Public and private). The roles depicted in this chapter position pharmacist as an integral part of TB control initiatives in India. An accurate diagnosis and treatment of the tuberculosis not only cures the patients but also prevents TB in the community by preventing the transmission.

6.1 Community Awareness

- Distribution of TB information leaflets to TB patients, TB suspects as well as to any other patient who wish to know/need to know more about TB
- Creating awareness about DOTS programme by displaying posters/boards/stickers in the Pharmacy.
- Arrange and conduct group awareness activities
- TB and DOTS awareness sessions among schools, community etc

6.2 Patient Counselling

During first meeting with a patient, one has to find out whether the patient has previously been treated for tuberculosis. A patient should be made aware that tuberculosis is a life-threatening disease and tuberculosis treatment is only effective if all prescribed drugs are taken regularly for the entire prescribed duration.

Then he has to be explained about the following about tuberculosis:

- What is tuberculosis, and how it spreads.
- Symptoms of tuberculosis.
- Treatment of tuberculosis. either from private or public sector
- Information about Directly Observed Treatment (DOT).
- Importance of contact examination and chemoprophylaxis of children below 6 yrs of age.
- Taking some of the drugs or irregular taking of drugs is dangerous and makes the disease incurable.
- Motivation of the patient with respect to treatment requirements and expected duration of the treatment.

The following information should be communicated to the patients:

- Amount, frequency and duration of drugs
- Possible side-effects of drugs
- Frequency and importance of sputum examinations, ii sputum positive cases
- Inform importance of evaluation of symptomatic contacts (e.g. family member with TB symptoms) of sputum positive patients.
- Inform patient regarding the infectiousness of TB to children and hence the medical officer should be consulted about requirement of preventive treatment in children and possible infection control measures preventing the domestic transmission
- Ask patient to use handkerchief/tissue while coughing .
- Orange/ red discoloration of the body fluids especially urine which is commonly encountered due to rifampicin is not an adverse reaction and patient should be made aware of this.
- If on OCPs should be advised to use alternative methods of contraception.
- Patients who smoke should be motivated to make an informed decision to stop smoking. All cases should be informed personally about the harmful effects of smoking on health in general and the potential for poorer outcomes of anti-TB treatment with continued smoking
- Give a copy of any TB information leaflet available

6.3 Case detection and referral of TB suspects

When to refer a patient to TB Clinics (or to any Doctor for TB evaluating) and how to identify chest symptomatic cases:

- Any patients with cough more than two weeks
- Greet the patient, asking the patients who are seeking cough medication about how long the patient has the cough.
- Asking for other symptoms if the cough has persisted for a long time.
- Asking for specific TB symptoms *i.e.* persistent cough, sputum or blood in cough, chest pain, fever, night sweats, weight loss, loss of appetite, *etc.*
- Asking whether the suspect has consulted a doctor.
- Telling the patients about the importance of TB diagnosis and effective TB treatment which is free in government hospitals& also can be made available from the pharmacy.
- Counsel the suspect refer, to nearby Designated Microscopy Center (DMC) with referral form for sputum examination. Use carbon paper and keep a copy of referral form with address and phone number of the patient at the pharmacy.

Pharmacist needs to fill up at least the patient details in the referral form and keep a carbon copy at the pharmacy. Use pharmacy stamp and sign the form.

- Try to contact the DMC or STS /TB HV after sending the TB suspect for diagnosis. Try to call patient in 2 days to know if patient did go diagnosis or not. If suspect doesn't go for diagnosis, inform patient details to TB HV to follow up and convince the suspect for diagnosis
- For patient with prescription from private physician, suggest talking with the physician. Inform about DOTS.
- Provide IEC materials i.e TB leaflets, pamphlets to the suspect. Provide Sputum cup and educate about sputum expectoration.

6.4 Contact Tracing

Acquiring infection and developing TB is higher among contacts of TB patients. Therefore, pharmacists should help in tracing all child contacts and symptomatic adult contacts of smear positive cases, irrespective of the duration of symptoms should be traced, counselled and referred by pharmacists, to identify and treat TB cases and to provide preventive treatment to children.

6.5 Referral Form

Laboratory Form for Sputum Examination

Name of Referring Health Facility:

Date:

Name of patient:

Age: Sex: M/F

Complete address:.....

Contact Phone number / Mobile No.:.....

Type of suspect / disease: Pulmonary Extra-pulmonary Site:.....

Reason for examination: cough for more than 2 week, fever, loss of weight, haemoptysis

Diagnosis

Repeat Examination for Diagnosis

Follow-up examinations

For new and previously treated cases - Month of follow-up

For MDR-TB cases – Month of follow-up

Treatment Regimens (tick ✓ appropriate box):

New cases Previously treated MDR-TB

(Name and signature of referring pharmacist with Pharmacy stamp)

Flowchart: How to identify chest symptomatic cases

Identify the patients who repeatedly visit the Pharmacies for cough and fever medicines

A) Patient on Self medication (without prescription) or with Prescription



Interact with the patients, Enquire how long and what exactly the symptoms are



If symptoms are suggestive of TB, then counsel the patient ,advise for check up, direct the patient to Designated Microscopy Center by providing exact address



Use referral form, use Pharmacy stamp on referral form, keep a copy for record

6.6 DOTS provision at Pharmacy

Below is the details sequence of activities, once a TB patient is willing to take DOT from the pharmacy

- TB Health Visitor brings the DOTS box (patient wise box with 6 months medicines) with treatment record card to the pharmacy
- Keep the patient wise DOTS medicine box and the treatment record card appropriately in the Pharmacy
- Decide timing suitable to patient and to you for DOTS
- Patient starts visiting Pharmacy on alternate day in intensive phase and once in a week in continuation phase.
- Call patient inside the pharmacy and offer to sit .Give medicines from kit and let patient swallow it in front of you. Offer drinking water and use disposable cup (some patient may prefer to get the water bottle from home) Do not offer DOT in air-conditioned part of the Pharmacy. Let the administration be in the well ventilated part of Pharmacy but also care for patient's privacy and ensure patient is comfortable to take medicines.
- Enquire about how is patient feeling and record his body weight if there is Weighing Balance in the Pharmacy.
- Make appropriate entry in the treatment record card.and keep card in secure place in a file
- **If the patient doesn't visit on scheduled day, immediately make phone call to the patient or immediately informing Health Visitor about the default.**
- Ensure that all doses in the intensive phase and the first dose of each weekly blister during the continuation phase are taken under direct observation. Also ensure collection of empty blister packs which should be preserved till the end of treatment.
- Remind patient to go for follow up sputum test (if patient is sputum positive) and give a copy of

referral form

- Discuss if patient suffers from any side effects and advice patient to go to Medical Officer if needed. (Refer to table on Adverse Drug Reaction to anti-TB drugs, page)
- Ensure that partially used PWBs and treatment record cards of such cases (of patients who have died / defaulted / failed treatment / transferred out) are taken back by HWs from the pharmacy
- Allow supervision of boxes ,treatment cards anytime by RNTCP staff
- Train the assistants in the Pharmacy for DOT administration and supervise the work. This is important as to maintain continuity of medicine administration, even in absence of pharmacist.

6.7 Documentation: Making entries in the Record Card

Appropriate entries need to be made in the treatment record cards. It is easy and doesn't take much of the time.

6.8 Providing information on DOTS to all TB patients

All patients, who come with anti-TB prescription first time, can be explained following. Concentrate especially on the low economic status patients as these are patients who may not afford treatment for prescribed period and leave it half way and can become DR TB patients later.

- Explain to the patient ,the importance of direct observation of treatment
- Explain the entire DOTS treatment is free and can be made available even from the pharmacy

6.9 Rational Use of Antibiotics and anti-TB drugs

Irrational use of antibiotics by doctors, patients and pharmacists leads to drug resistance . Hence there is necessity to follow these guidelines:

- No sale of first or second line drugs (MDR-TB medicines) without prescription. Discourage self medication
- No sale of any antibiotic, especially flouroquinolones (ofloxacin, ciprofloxacin etc) without prescription. Patients need to be counseled for inappropriate self medication of these drugs and how it can lead to resistance, or can mask symptoms of active TB etc.
- Over-the-counter sale of around 92 antibiotic and anti-tuberculosis drugs in India will be restricted soon. Drug Controller General of India has written to the Union health minister to notify a new schedule, H1, in the Drugs and Cosmetics Rules. Once notified, following clearance from the law ministry, these drugs cannot be sold without prescription. The drugs will also have to carry a prominent label in red color on the left corner with the following

warning: "It is dangerous to take this prescription except in accordance with medical advice and not to be sold by retail without the prescription of the registered medical practitioner."

- The drugs to come under H1 includes Moxifloxacin, Meropenem, Imipenem, Ertapenem, Doripenem, Colistin, Linezolid, Cefpirome, Gentamicin, Amikacin, Pencillin, Oxacilin, Zolpidem, Cefalexin, Norfloxacin, Cefaclor, Cefdinir, Tigecycline, Tobramycin, Tramadol and Vancomycin

6.10 Patient awareness

Patient should be aware of:

- The number, type and the color of drugs issued.
- The duration of treatment and importance of completion of treatment.
- The location and working hours of the pharmacy
- The importance of taking all the prescribed drugs.
- Awareness of importance of direct observation of every dose in the intensive phase.
- Awareness of frequency and importance of sputum examination, and understanding of sputum results.
- Awareness of the symptoms and infectiousness of tuberculosis.
- Importance of contact examination.
- Awareness of whom to see and where to find them in case of any problems
- Regarding treatment or otherwise.
- Awareness regarding safe sputum disposal and other preventive measures.

6.11 Patient activities related to DOTS

- Swallowing of drugs during the intensive phase of treatment in the presence of DOT Provider.
- Swallowing of the first dose of the weekly course of the continuation phase under direct observation of the health functionary and bringing the empty blister-pack during the next weekly collection of drugs.
- Going for follow up sputum test
- Bringing all symptomatic contacts to the nearest health unit for a checkup.

6.12 Patient Communication

The skills involved in good interpersonal communication include:

- Listening and Understanding
- Demonstrating caring, concern and commitment
- Problem solving and Motivating

6.13 Do's and Dont's

Some key points for improving listening and understanding skills include:

6.13.1 DO:

- Greet, smile, Call person seat inside or outside Pharmacy ,as possible.
- Allow sufficient time for the interactionMaintain eye contact
- Move your head to indicate you are paying attention
- Apologize for any unforeseen interruptions
- Ask open-ended questions (questions that cannot be simply answered with a “yes”or “no”) such as questions that begin with “What”, “Why” or “How”. These questionsrequire more than just a few words in the answer
- Periodically summarize what the other person has said to ensure that you have understood; use their own words to repeat the ideas back to them.
- Convey that you understand their fears and apprehensions
- Make them comfortable
- Repeat important information in different ways each time you meet
- Emphasize that your job is to help them
- Emphasize that they will be cured
- Use examples from your own experience
- Tell them that this is what you would recommend to your family members
- Compliment the other person on what they have done well
- Recognize their progress
- Emphasize that their welfare is your concern/job

6.13.2 DON'T:

- Use technical words
- Ignore the efforts the other person has made so far
- Overlook their fear and anxiety
- Ignore or minimize practical barriers

6.14 Management of patients in special situations

Situation	Management
Treatment of TB during pregnancy and postnatal period	Streptomycin is absolutely contraindicated during entire pregnancy. Breast feeding can be continued even when mother is on treatment for TB but mother should continue to practice cough hygiene. Child should be administered preventive chemoprophylaxis as per guidelines.
Treatment in patients with renal failure	Rifampicin, isoniazid and pyrazinamide can be safely given as they are excreted in entero-hepatic circulation. Dosage of streptomycin and ethambutol, should be adjusted according to the creatinine clearance.
Women on oral contraceptive pills	Rifampicin decreases the efficiency of oral contraceptives by increasing their metabolism. Increase in dosage of the oral contraceptive or switch over to alternate methods of contraception is advisable

CHAPTER 7 ADVERSE DRUG REACTION TO ANTI TB DRUGS

No drug is free from side effects and hence, the anti-tubercular drugs are no exception. But the patient should immediately report the side effects to the concerned doctor or the pharmacist and should not stop the treatment on his own. Adverse Drug Reactions (ADR) observed during treatment for tuberculosis are comparatively less in the intermittent (alternate day) therapy than what is seen in daily regimens. Symptom-based approach to evaluation of possible side effects of anti-TB drugs

Symptom	Drug	Action to be taken by Pharmacist
Gastrointestinal (vomiting or epigastric discomfort)	Any oral medication	Reassure patient. Inform patient to take drugs with less water and over a longer period of time (e.g. 20 min). Do not give drugs on an empty stomach.
Itching/Rashes	Isoniazid (and other drugs also)	Reassure patient If severe, refer patient to MO
Tingling/burning/numbness in the hands and feet	Isoniazid	Refer to MO
Joint pains	Pyrazinamide	Reassure that it is a self limiting condition. Encourage patients to increase intake of liquids. If severe, refer patient to MO for evaluation
Ringing in the Ears. Loss of Hearing. Dizziness and loss of balance Jaundice	Streptomycin Isoniazid ,rifampicin, pyrazinamide	Immediately refer patient for evaluation Refer for evaluation

CHAPTER 8

IMPORTANT CONCERN IN MANAGEMENT OF TB

8.1 Tobacco smoking and tuberculosis

The diagnosis of TB disease is an opportune moment for imparting behaviour change in the patients' smoking habit, with patients more likely to accept the behaviour change needed for improving their health. Tobacco smoking may lead to delayed sputum conversion in sputum smear positive PTB cases, lower treatment success rates and higher rates of relapse of TB disease and death. Hence the past and present history of tobacco smoking (cigarette / beedi / pipe / cigar / hukka) should be elicited from each TB case at the time of initiating treatment. Smoking cessation advice to current smokers should become an integral part of TB case management. Such interventions may help improve outcomes of anti-TB treatment and reduce transmission of infection in the short term, and improve the quality of life of TB cases by preventing chronic respiratory and other disease associated with smoking in the long term. Tobacco cessation advice has been demonstrated to be successful in TB cases even in the absence of costly Nicotine Replacement Therapy.

Patients who smoke should be motivated to make an informed decision to stop smoking. All cases should be informed personally about the harmful effects of smoking on health in general and the potential for poorer outcomes of anti-TB treatment with continued smoking.

The potential benefits of stopping smoking to the health of the individual should be suitably communicated. The patient's past experience with cessation and relapse of smoking may be discussed in an understanding atmosphere. Patients may be told that they can be successful even if they have not been able to quit smoking at earlier attempts. During the conversation, the patients are asked to identify situations and moods that trigger smoking (working/getting out of bed/having a cup of coffee/pleasant moments/while dealing with personal or professional problems/ group smoking). They are encouraged to devise their own ways to respond to the circumstances that encourage smoking.

Patients should also be advised not to smoke in the presence of others, since increased frequency of coughing due to smoking increases the risk of TB infection among their household and other contacts. That smoking is prohibited in public places according to 'Prohibition of Smoking in Public Places Rules, 2008' may be clearly communicated to them.

8.2.5 'A's Approach to tobacco cessation

This is a form of counseling. Before saying anything to motivate the patient to quit tobacco use, the health professional needs to identify the tobacco user and find out the stage of readiness

to change that the patient is in, by asking a few questions.

1. Ask the patient if he/she is a tobacco user.
2. Briefly Advise against continuing tobacco use and link the current condition/ailment to continued tobacco use, where possible e.g. "Quitting smoking/tobacco use would improve your health and will aid in early recovery".
3. Then Assess readiness to quit by asking the patient whether he or she is ready to quit at this time. e.g. "How recently have you thought about quitting tobacco?"
If the patient appears ready to change (quit), next steps are :
4. Assist the tobacco user in making a quit plan.
5. Arrange for follow-up by setting the next contact.

8.35 'R's approach for non willing tobacco users

If the tobacco user is not yet thinking about quitting tobacco use (pre contemplation), the doctor will *promote greater awareness* of the relevance to the patient of the advice to quit, the risks of use and rewards (benefits) of quitting. Many tobacco users are largely unaware of the potential harm that tobacco use can do to them. If the patient is not ready to quit, the doctor must not push the patient. People usually need time to change (incremental nature of change).

If the patient is at least thinking about (contemplating) quitting, the doctor can find out the patients roadblocks (barriers) to quitting and help the patient see ways to overcome these. This process may be enough to help the patient get ready to quit (without pushing).

At the next visit, this process should be repeated so that the information about relevance, risks of continuing and rewards of quitting can sink in a little more and some roadblocks removed.

As you can see, the doctor must try to make the tobacco user think about quitting. This is important because there are so many other forces acting that are difficult to control, physiological compulsions to use tobacco, learned habits, social pressures, accessibility etc.,. Engaging the mind of the tobacco user, bolstering it with new knowledge and a sense of caring by the person counseling can help motivate him/her to change. Follow-up is important to help keep the tobacco user on track until he or she is confident about remaining tobacco free.

8.4 Diabetes and treatment of tuberculosis

There is conflicting evidence on the role of diabetes, it's control and response to TB treatment. Some studies suggest that there is no co-relation between the two, whereas others suggest that sputum conversion is delayed and treatment outcomes are poorer in diabetics who are poorly controlled during their treatment for TB.

However in general the treatment for TB in patients with diabetes is the same as for those patients who are non-diabetic. In a few cases, rifampicin may induce early phase hyperglycemia due to augmented intestinal absorption. Although relapse rates themselves are unchanged, in

diabetics who relapse the prognosis is poorer.

Principles of the management of co-existent TB and diabetes comprise:

1. Proper care and hospitalization in patients with poor diabetic control;
2. Ideally insulin should be used to control blood sugar during anti-TB treatment, however oral hypoglycaemics can be used if the patient is well stabilized on them;
3. Drug interactions with rifampicin need to be kept in view and recognised if they occur:
4. Glycaemic equilibrium is essential with goals of maintaining fasting blood sugar < 100mg% and glycosylated HB < 6% should be aimed towards.
5. Monitoring for adverse effects, particularly of hepatic and nervous systems should be done as Isoniazid may lead to peripheral neuropathy; and
6. Use of potentially neuropathic agents in patients with peripheral neuropathy demands special consideration and administration of pyridoxine.

8.5 Documentation: Entries in the treatment record cards

**Revised National Tuberculosis Control Programme
Treatment Card**

State Bihar City / District with code Vaishali, 1000 Name of TB Unit with Code _____
 Name Ram Prashad Singh Patient TB No / Year: 88
 Sex M F Age 34 Occupation _____ PHE: 237
 Complete Address 312 Gali Kuar Wali, Vaishali, Bihar Name and designation of DOT provider _____
 Name and Address of Contact Person 412 Gali Kuar Wali, Vaishali, Bihar DOT center _____
 Signature of MO with date _____

Initial home visit by _____ Date _____

Disease Classification	Type of patient	Month	Date	DMC	Lab No.	Smeear Result	Weight
<input checked="" type="checkbox"/> Pulmonary	<input checked="" type="checkbox"/> New	Pre-treatment	7/4		138	2+	41
<input type="checkbox"/> Extra Pulmonary site _____	<input type="checkbox"/> Relapse	End IP/Extended IP	29/5		193	Neg	43
	<input type="checkbox"/> Transfer in	2 Months CP					
	<input type="checkbox"/> Treatment after default	End treatment					
	<input type="checkbox"/> Failure						
	<input type="checkbox"/> Other (Specify) _____						

Ho previous Anti-TB treatment with duration _____

I INTENSIVE PHASE - Prescribed regimen and dosages:
 Tick (✓) the appropriate Category below

Category I New Case
(Pulmonary Smeear-Positive, Seriously ill Smeear Negative, or Seriously ill extra pulmonary)

3 times / week

3	1	3	3
H	R	Z	E

Category II Reinforcement, (relapses, failure, treatment after default, others)

3 times / week

H	R	Z	E	S

Category III New Case (Pulmonary Smeear Negative, not seriously ill; or extra pulmonary, not seriously ill)

3 times / week

H	R	Z

Tick (✓) appropriate date when the drugs have been swallowed under direct observation

Month / Year	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	28	29	30	31
April																															
May	✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓

- Date of initiation of treatment- The date of initiation of treatment regimen prescribed is ticked (✓) on the appropriate box under the date against the month. Subsequently, the dates on which the drugs were consumed under observation are also ticked. In this phase, patient comes three times a week on alternate days. Daily blisters are given either on Mondays, Wednesdays and Fridays or alternatively Tuesdays, Thursdays and Saturdays.

- The date/day (for example on 10th April) on which patient fails to attend for DOT, is denoted by a circle (0) in the appropriate box. In case the patient attends to collect the drug the next day (for example on 11th April) the drugs missed are administered on that day and continues to take the drugs as per scheduled day (for example on 12th of April).

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14
April	✓		✓		✓			✓		0				

- On the other hand, if the dose is entirely missed and the patient does not report to the health facility even on the next day then the dose is given on the next scheduled day. It should be ensured that all the doses in the intensive phase, should be administered before the continuation phase is initiated. For example, patient was scheduled to come on 17th April but does not turn up on 17th or even on 18th but reports on 19th. Hence, the dose due on 17th is given on 19th and so on and so forth.

Month	15	16	17	18	19	20	21	22	23	24	25	26	27	28
April			0											

- Only under exceptional circumstances unsupervised drug administration can be allowed for a limited number of doses. For instance, if a patient is being discharged from hospital after initiation of treatment, s/he will have to be provided with 3 doses of treatment so that her/his treatment does not get interrupted during her/his transfer to a nearby PHI. In such circumstances, the entry for unsupervised doses should be recorded by encircling the tick mark on the Tuberculosis Treatment Card and the reason for the same should be stated in the Remarks column of the treatment card.

8.6 Continuation phase

- Drug administration in the continuation phase is recorded on the reverse side of the treatment card. Treatment regimen prescribed for the patient is ticked appropriately in the box provided. Number of tablets of the drugs prescribed in the regimen is also recorded in the boxes provided above the drugs.

- During the continuation phase of treatment, patients collect the weekly blisters once a week on a designated day. First dose of the weekly blister is administered under direct observation and the remaining doses in the weekly blister are given to the patient for self-administration. The month and the year in which the patient will be collecting drugs during the continuation phase are written under the Month and year column in the table on the reverse of the Tuberculosis Treatment Card. An 'X' is recorded in the appropriate box (according to the dates of the month 1 – 31 as the case may be) to indicate the day the drugs were consumed under direct observation. A line is drawn through the remaining days.

CHAPTER 9

SUPERVISION and MONITORING OF PHARMACIST

RNTCP staff is responsible for ensuring the quality of health care provided to tuberculosis patients in their area.

9.1 Objectives of Supervision

- To have a firsthand look into the difficulties faced by pharmacists and effectively address them.
- To boost the morale and motivate the pharmacists.
- To promote team work.

9.2 Supervision of pharmacies by field staff:

- Is Pharmacy neat and clean? Potable Water facility available? Sitting arrangement made for patients
- Ensure TB IEC material is displayed in the pharmacy appropriately
- If DOT box is ongoing, supervise no. Of blisters ,treatment record card, follow up check date for patients and remind /advice pharmacist about the same.
- Enquire with pharmacist if there have been any new referrals for sputum test& check the referral book& collect patient details
- Request pharmacists to refer as many cases as possible of chest symptomatic to the DMC
- Ensure that the Lab staff enters the name of pharmacy in the lab register for referred case

Guidelines for the facilitators

Facilitators: CTO/DTO/MO TBs and WHO RNTCP Consultants
RNTCP field staff also need to be present

Training duration: 4 hours

Contents and delivery of training:

- 1) Power point Presentation/Talk on
 TB : details as a disease : 45 min
 - Simple and easy to understand PowerPoint with talk in English/Hindi/local language
 - No much technical language to be used
 - TB as a disease, global scenario, cause, risk factors ,Symptoms, types, diagnosis ,suspect detection, referrals to be discussed
 - Treatment : private/DOTS : What is DOTS and how it is different than the private sector treatment

- 2) Power point Presentation/Read from Module
 Role of Pharmacist : to be dealt in detail as given in the module 60 min

- 3) Patient Communication: From the Module 15 min

- 4) Activities: 20 min
 - Documentation practice (Practice for filling Treatment Record Cards ,Referral form for sputum test and introduction to Patient Identity Card)
 - Observation and handling of DOT kits

- 5) Interaction/linking of Pharmacists with RNTCP Field Staff 20 min
 - Introduction of RNTCP staff (STS,HVs etc) and area wise linking of staff to pharmacies, area wise .Exchange phone numbers of each other .

- 6) Pre and Post test 20 min

- 7) Question/Answers 15 min

- 8) Attendance sheet for participant pharmacists (names with contact details) to be collected by RNTCP and chemist association leader ,at the end of the training session. 10 min

- 9) Undertaking form to be signed by pharmacists (if not submitted before to Chemist Association) for participation of pharmacists in RNTCP (format enclosed at the end of Module) 5 min

- 10) Copy of MOU to each pharmacist and get it signed by pharmacist 10 min
- 11) After the training, issue an authorization letter (format enclosed at the end of Module) or certificate to participants

Training material to be given to pharmacists:

- Copy of Training Module,
- RNTCP IEC material such as Board and leaflets, posters, stickers ,calendars
- Referral forms with carbon copy
- Copy of DOTS directory or address list of RNTCP staff and Designated Microscopy Centers

Venue: TB Society Training Hall or Chemist Association Hall (if available)

Timing: Between 1.30 to 5.30 p.m. or as per mutual convenience

Who will get trained: Pharmacists from retail pharmacies

Who will do selection of pharmacists: Local Chemist association will select the willing pharmacists and will coordinate with them and RNTCP

Criteria for selection: Only those to be trained who are engaged in service delivery (actually work at the counter)

- Preferably owner pharmacists
- Willingness of pharmacists
- Location of Pharmacy in TB burden area
- Interested pharmacy owners who actually handle the counter

Format (can be modified suitably)

Undertaking by the pharmacist for participation in DOTS (to be kept by Chemist Association)

I,..... the undersigned retail pharmacist wish to participate in Revised National TB Control Programme (RNTCP). I am willing to keep the patient wise DOTS medicine boxes provided by District/City TB Society for the TB Patients in my pharmacy shop. It will be convenient for the nearby patients to visit the Shop and take the medicines under our observation.

I am aware that these medicines will ONLY BE FOR THAT PARTICULAR PATIENT SENT by TB society & i will keep the record of the medicines dispensed to these patients in a TREATMENT RECORD CARD given by the Corporation. I will never have any intention to sale these medicines. In case the patient skips the doses, I will inform the TB Health Visitors (TB HVs) and they will follow up with the patient. I will also make sincere effort to contact the patient.

I will make an effort to detect Chest Symptomatic TB suspects and refer them to the nearest Designated Microscopy Centers (DMCs). I will keep all treatment record cards and DOTS boxes available for supervision by RNTCP.

By becoming DOTS providers, I will be getting socio-professional satisfaction of utilizing our services for the SOCIETAL BENEFITS.

Thank you

Yours faithfully,

Name of pharmacist with detail address and phone number

Format for “Authorization Letter or Certificate from RNTCP” on letter head (may be modified suitably)

(Copy to be kept by each pharmacist and copy to be submitted to local FDA by Chemist Association)

Authorization letter OR CERTIFICATE

This Is to inform that City/District TB office ofhas carried out DOTS training ofnumber of pharmacists ondateat venue.

List of pharmacies with detail addresses OR Address of one pharmacy if individual letter/certificate is planned

These pharmacists are participating in DOTS and are authorized to stock patient wise DOTS boxes in their pharmacies, issued by City/District TB office .RNTCP staff will supervise the DOTS medicine boxes utilization at the pharmacies. Pharmacists will also refer the TB suspects to nearby Designated Microscopy centers.

Sign and stamp of RNTCP officer

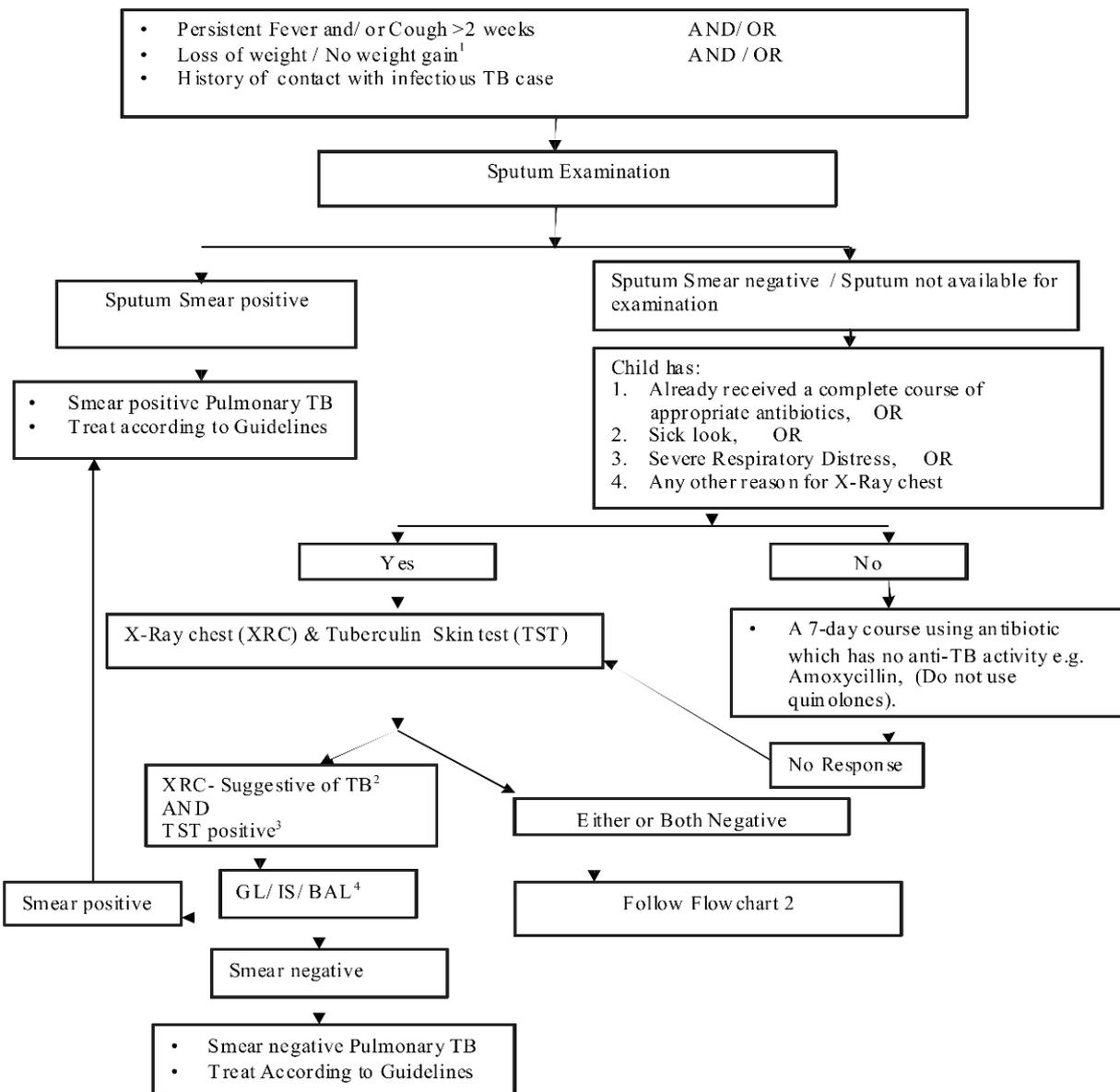
ANNEXURE 4

Format for attendance sheet for Training Programme (Copy to be kept by RNTCP and by Chemist Association for future partnership and coordination)

Name of Pharmacy	Name of Pharmacist	Address & Phone Numbers	Sign of pharmacist
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Diagnostic Algorithm for Pediatric Pulmonary Tb

Flow chart 1



¹ History of unexplained weight loss or no weight gain in past 3 months; Loss of weight defined as loss of more than 5% body weight as compared to highest weight recorded in last 3 months.

² Radiological changes highly suggestive of TB are Hilar/paratracheal lymphadenitis with or without parenchymal lesion, Miliary TB, fibrocavitary pneumonia.

³ If the radiological picture is highly suggestive of TB, then proceed to do further investigations irrespective of the TST result as the sensitivity of the test is not 100%.

⁴ All efforts including Gastric Lavage (GL) Induced sputum (IS) or Bronchoalveolar lavage (BAL) should be made to look for Acid fast bacilli (AFB) depending upon the facilities.

Treatment Categories and Regimens for Pediatric Tuberculosis

Category of treatment	Type of patients	TB treatment regimens	
		Intensive phase	Continuation phase
New cases	<ul style="list-style-type: none"> • New smear-positive pulmonary Tuberculosis (PTB) • New smear-negative PTB • New extra-pulmonary TB. 	2H ₃ R ₃ Z ₃ E ₃ *	4H ₃ R ₃
Previously treated cases	<ul style="list-style-type: none"> • Relapse, failure to respond or treatment after default • Re-treatment Others 	2S ₃ H ₃ R ₃ Z ₃ E ₃ + 1H ₃ R ₃ Z ₃ E ₃	5H ₃ R ₃ E ₃

H=Isoniazid, R= Rifampicin, Z= Pyrazinamide, E= Ethambutol, S= Streptomycin

**The number before the letters refers to the number of months of treatment. The subscript after the letters refers to the number of doses per week.*

Pulmonary TB refers to disease involving lung parenchyma. Extra Pulmonary TB refers to disease involving sites other than lung parenchyma. If both pulmonary and extra pulmonary sites are affected, it will be considered as Pulmonary for registration purposes. Extra Pulmonary TB involving several sites should be defined by most severe site.

Smear positive: Any sample (sputum, induced sputum, gastric lavage, broncho-alveolar lavage) positive for acid fast bacilli.

New Case: A patient who has had no previous ATT or for less than 4 weeks.

Relapse: Patient declared cured/completed therapy in past and has evidence of recurrence.

Treatment after Default: A patient who has taken treatment for at least 4 weeks and comes after interruption of treatment for 2 months and has active disease.

Failure to respond: A case of pediatric TB who fails to have bacteriological conversion to negative status or fails to respond clinically / or deteriorates after 12 weeks of compliant intensive phase shall be deemed to have failed response provided alternative diagnoses/ reasons for non-response have been ruled out.

Others: Cases who are smear negative or extra pulmonary but considered to have relapse, failure to respond or treatment after default or any other case which do not fit the above definitions.

Z-28015/2/2012-TB
Government of India
Ministry of Health and Family Welfare

Nirman Bhavan, New Delhi

Dated: 7th May 2012

Notification of TB cases

TB continues to be a major public health problem accounting for substantial morbidity and mortality in the country. Early diagnosis and complete treatment of TB is the corner-stone of TB prevention and control strategy. Inappropriate diagnosis and irregular/incomplete treatment with anti-TB drugs may contribute to complications, disease spread and emergence of Drug Resistant TB.

In order to ensure proper TB diagnosis and case management, reduce TB transmission and address the problems of emergence and spread of Drug Resistant-TB, it is essential to have complete information of all TB cases. Therefore, the healthcare providers shall notify every TB case to local authorities i.e. District Health Officer / Chief Medical Officer of a district and Municipal health Officer of a Municipal Corporation / Municipality every month in a given format (attached).

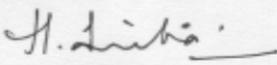
For the purpose of case notification, a TB case is defined as follows:

- A patient diagnosed with at least one sputum specimen positive for acid fast bacilli, or Culture-positive for Mycobacterium tuberculosis, or RNTCP endorsed Rapid Diagnostic molecular test positive for tuberculosis
- OR
- A patient diagnosed clinically as a case of tuberculosis, without microbiologic confirmation, and initiated on anti-TB drugs.

For the purpose of this notification, healthcare providers will include clinical establishments run or managed by the Government (including local authorities), private or NGO sectors and/or individual practitioners.

For more detailed information, the concerned State TB Officers / District TB Officers, whose details are available on www.tbcindia.nic.in, may be contacted.

Encl: As mentioned


(Manoj Sinha)

Under Secretary to the Government of India

Copy for immediate further necessary action, to:

- 1) All Principal Secretaries / Secretaries of Health of States / UTs
- 2) All Directors of Health Services of States / UTs
- 3) All State TB Officers of States / UTs

With the request to kindly immediately bring this order to the notice of all concerned for compliance, in their respective State / UT

TB Notification Order, 7th May 2012 Govt. of India, RNTCP

EXERCISE

Exercise 1

Tick the appropriate answer.

1. Tuberculosis is transmitted by

- (a) Blood transfusion _____
- (b) Faecal infection _____
- (c) Droplet infection _____
- (d) Oral infection _____

2. The most infectious form of tuberculosis is

- (a) Extra-pulmonary TB _____
- (b) Smear-positive pulmonary TB _____
- (c) Smear-negative TB _____
- (d) Miliary TB _____

3. The commonest form of tuberculosis is

- (a) Extra-pulmonary TB _____
- (b) Bone and joint TB _____
- (c) Renal TB _____
- (d) Pulmonary TB _____

4. When do you suspect pulmonary tuberculosis? Mention four common symptoms.

- (i) _____
- (ii) _____
- (iii) _____
- (iv) _____

5. How do you classify tuberculosis?

- (i) _____
- (ii) _____
- (iii) _____

6. Which is the best way to diagnose pulmonary tuberculosis?

7. When do you label a patient as smear-positive pulmonary tuberculosis?

8. Case Studies (Tick the appropriate answer).

Case Study One

(i) During your routine work, you come across Ram who complains of fever. On enquiry you find that he has been coughing for more than 3 weeks. What would you do?

- a) Give him advice and medicines for fever
- b) Advise him to go to the nearest RNTCP DMC and get his sputum test done
- c) Advise him rest and good food

(ii) Gopal has been having fever for more than a month and a cough for two weeks. Two of his sputum examinations have been reported as positive for AFB. He is suffering from

- (a) Sputum-negative tuberculosis _____
- (b) Extra-pulmonary tuberculosis _____
- © Sputum-positive tuberculosis _____

Case Study Two

Person, appears to be from lower socio-economic strata, comes to you with anti-TB prescription from private doctor. What would you do?

Case Study Three:

Person comes to you asking for some anti-biotic without prescription. Person informs he has been coughing for several days. What would you do?

