Revised National Tuberculosis Control Programme (RNTCP)

Training Module

for

Medical Practitioners

Central TB Division
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi 110 011

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(June 2006)

About This Module

Health care services in India are provided by multiple and diverse providers in the government, private, NGO and corporate sectors. Each sector has strengths as well as weaknesses. In India, TB patients are managed by several health providing sectors and the responsibility of providing quality patient care to achieve TB control is therefore with all these sectors. Effective control of TB will be possible if all these sectors join together and work towards a common goal. The Central TB Division (CTD) at the Ministry of Health, Govt. of India has been interacting with all sectors of health care since the inception of the Revised National Tuberculosis Control Programme (RNTCP). There are commendable examples of collaboration among various health sectors, like private, non-government organisations (NGO), corporate and other government organisations such as ESI, Railways, etc. These collaborations have contributed significantly towards the implementation of the WHO recommended Directly Observed Treatment, Short-course (DOTS) strategy by these different health care sectors.

There was demand from medical practitioners outside the public health sector, and also a felt need, for a concise module on RNTCP that would facilitate their effective involvement in the programme. This module, produced by the CTD, is in response to the field realities and is the result of various interactions with, and feedback from, all concerned sectors. It tries to provide medical practitioners with updated information on RNTCP that will equip them to adopt and practise the diagnostic and treatment policies of RNTCP. It is expected to facilitate development of effective and sustainable partnerships among the public, private, NGO, and corporate sectors to ensure delivery of quality services under RNTCP.

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

- Get a glimpse of the global and Indian TB scenario
- Understand the principles of RNTCP
- Correctly identify patients suspected of having TB
- Ensure quality sputum microscopy for TB suspects
- Categorise TB patients correctly as per RNTCP policies
- Understand the rationale of treatment (regimens, doses, side effects)
- Understand the mechanism of Directly Observed Treatment (DOT)
- Understand the recording and reporting mechanisms
- Understand ‘Referral for Treatment’ and ‘Transfer of Patients’ protocols
- Provide monthly reports
- Understand the management of drugs and other supplies in RNTCP
- Understand monitoring and supervision in RNTCP

Facilitators

The training will be organised by the District TB Officer (DTO). The DTO will form a core group of competent facilitators from among the faculty of the State TB Training and Demonstration Centre (STDC), Medical Colleges, Medical Officers-TB Control (MO-TC), Private Practitioners, etc. The facilitator-trainee ratio should be around 1:10.

Training Schedule:

It is recommended that the training is covered in a total of six hours (e.g. 3 hours x 2 days/sessions) and be carried out as follows:

Day/Session 1		Day/Session 2	
Activity	**Duration**	**Activity**	**Duration**
Pre test	15 min.	Presentation	30 min.
Presentation	30 min.	Module reading	90 min.
Module reading	90 min.	Exercise	30 min.
Exercise	30 min	Discussion	15 min.
Discussion	15 min.	Post Test	15 min.

Certification

A certificate signed by the Chairman and Member Secretary of District TB Control Society (DTCS) may be given to the trainees on satisfactory completion of the course.

Contents

1. INTRODUCTION

Tuberculosis is an infectious disease caused by Mycobacterium tuberculosis. Pulmonary tuberculosis is the most common form of TB (more than 85% of all TB cases), while extra-pulmonary tuberculosis can affect almost any organ in the body. Transmission occurs by airborne spread of infectious droplets and droplet nuclei containing the tubercle bacilli. The source of infection is a person with sputum smear-positive pulmonary TB. Transmission often occurs indoors, where droplets and droplet nuclei can stay in the air for a long time.

Global and Indian Scenario

In 2002, there were globally an estimated 8.8 million new cases of TB, of which 3.9 million were sputum smear positive, and 80% were in 22 high burden countries. One fifth of the global TB incidence is in India, with 1.8 million new cases occurring every year and 0.8 million of these being infectious smear-positive cases. In India, an estimated 4 lakh deaths occur from TB every year.

Every Day, in India

- *more than 5000 develop TB disease*
- *more than 1000 people die of TB (2 deaths every 3 minutes)*

TB is a serious public health problem in India causing immense morbidity, mortality and distress to individuals, families and communities. TB kills more adults in India than any other infectious disease. The disease incidence peaks in people belonging to the most economically productive age group of 15-60 years. The link between TB and HIV is quite significant with WHO estimating that 5% of TB patients are also co-infected with HIV.

National Tuberculosis Programme (NTP)

During the 1950s and 1960s, significant research on TB was undertaken in India, and in 1962 the National TB Control Programme (NTP) was launched. Three decades later in 1992, a review of the NTP found that the desired results had not been achieved. There was overdependence on X-rays for diagnosis. Incomplete treatment was the norm rather than the exception. The 1992 review revealed that only 30% of existing TB cases were being diagnosed, and of these only 30% were completing treatment.

Revised National TB Control Programme (RNTCP)

On the recommendations of an expert committee, a revised strategy to control TB was pilot tested in 1993. The RNTCP applies the WHO recommended DOTS (Directly Observed Treatment, Short-course) strategy. The programme was expanded in a phased manner to cover the entire country in 2005. By June 2005, over 1 billion of the population was covered under RNTCP.

As mentioned earlier the majority of TB patients have pulmonary TB, with the sputum smear-positive pulmonary TB patients constituting the infectious pool in the community. Early diagnosis and cure of these patients can break the chain of transmission of TB infection in the community. However, RNTCP provides treatment services to all patients including both pulmonary and extra-pulmonary TB patients.

The objectives of the RNTCP are:

1. To achieve and maintain a cure rate of at least 85% among newly detected infectious (new sputum smear-positive) cases, and
2. To achieve and maintain detection of at least 70% of all such cases in the population.

Since the inception of RNTCP and up to June 2005, more than 4.5 million patients were initiated on treatment and about 750,000 additional lives were saved. Each month more than 100,000 patients are initiated on treatment.

Structure of the RNTCP

The RNTCP is lead by Central TB Division (CTD) in the Ministry of Health and Family Welfare, Govt. of India in Delhi. The state, district and sub-district levels and peripheral health institutions implement the programme.

Central TB Division

At the Ministry of Health and Family Welfare, the Central TB Division is responsible for TB control in the entire country. The Deputy Director General (DDG-TB) is the national programme manager. The main functions of the CTD are to formulate technical policy, plan, implement, monitor and coordinate the programme at the national level.

State level

At the state level, a State TB Officer (STO) is responsible for planning, training, implementing, monitoring and coordinating the programme. A State Tuberculosis Control Society (STCS) has been established for increased state ownership and accountability and also for the smooth transfer of funds from CTD to the state and then to districts.

District level

The District Tuberculosis Centre (DTC) is the nodal point for TB control activities in the district and also functions as a specialised referral centre. There is a District TB Control Society (DTCS) in every RNTCP district. It is responsible for budgeting and providing financial resources and also for monitoring the programme implementation. It also arranges necessary logistics such as transport, hiring of contractual staff and procurement of materials including laboratory consumables. The District Collector (or Corporation Commissioner, or District Magistrate) is the Chairman and the District Tuberculosis Officer (DTO) is the Member Secretary. The DTCS has representatives from government and non-government sectors. The DTO has the overall responsibility to implement the programme at the district level and is assisted by a Medical Officer and other technical and administrative staff.

Sub-district level

A team comprising of a designated Medical Officer-Tuberculosis Control (MO-TC), a Senior Treatment Supervisor (STS) and a Senior TB Laboratory Supervisor (STLS) is based at the Tuberculosis Unit (TU). This is the sub-district unit of TB control activities and is usually based in health institutions such as Community Health Centres (CHC), Taluk Hospitals or Block PHCs. The sub-district covers a population of approximately 5 lakh (2.5 lakh in hilly, tribal and difficult areas) and is responsible for the TB control activities at this level. The TU is also responsible for accurate maintenance of the TB register and for preparing quarterly reports.

Designated Microscopy Centre

Designated Microscopy Centres (DMC) are usually situated at tertiary and secondary level health care institutions and Block PHCs or other equivalent institutions including private and NGO facilities. Each usually caters to a population of 1 lakh (0.5 lakh in hilly, tribal and difficult areas). Designated microscopy centres will have doctors and laboratory technicians trained in RNTCP. The laboratory of the DMC will have adequate facilities including a binocular microscope for sputum microscopy. For the convenience of patients and based on local needs, the DTO may approve a DMC in health facilities such as an ESI hospital, a private nursing home, an NGO hospital, etc. However, certain criteria should be followed while designating laboratories as RNTCP DMCs. In addition, all DMCs should be included in the standard RNTCP External Quality Assessment (EQA) system.

The laboratories must have sufficient workload to justify being a DMC. The DMC either must be covering a population of 1 lakh, or having about 60 -100 new adult outpatient attendance per day. The laboratory technician must be examining an average of at least 3 – 5 smears and not more than 20 – 25 smears per day. This will ensure an optimum workload in the lab to maintain proficiency of the laboratory technicians. If the lab does not fulfill any of the above criteria, it can function as a sputum collection centre. Hence a limited number of the laboratories could be DMCs and there would be either a referral system to these laboratories by the private practitioners for sputum smear examination, and/or a referral between the labs either of TB suspects or samples.

Peripheral Health Institutions

For the purpose of RNTCP, a PHI is a health facility which is manned by atleast a medical officer (even if the post is currently vacant). At this level are the dispensaries, PHCs, CHCs, referral hospitals, major hospitals, specialty clinics / hospitals (including other health facilities) / TB hospitals / Medical colleges within the district. All health facilities in the private/NGO sector participating in RNTCP are also considered as PHIs under the programme. Some of these PHIs will also be DMCs. All PHIs with/without DMCs should submit a monthly PHI level report to the respective TUs and the district.

Public Private Mix (PPM)

India has one of the largest private health care sectors in the world. This sector is often the first point of contact for a significant number of TB suspects and patients.

Other sectors like non-governmental organisations (NGO), corporate sector, etc. also cater to a considerable percentage of TB patients. Because of their flexibility and easy accessibility, these service providers have gained credibility and are popular among patients. The strengths of these sectors can be utilised to supplement the government's efforts to control TB. Standard quality of care and free drugs can be provided through effective public-private collaboration under RNTCP.

Experiences from pilot projects in the country and elsewhere show that partnerships between government, private, corporate and NGO health care sectors can increase TB case detection rates and improve patient adherence. Such partnerships reduce diagnostic delays and cost to the patients, who get quality RNTCP services from the provider of their choice. RNTCP has made a concerted effort to develop partnerships with all health care sectors. Guidelines for collaboration with NGOs (2001) and private practitioners (2002) have been developed in consultation with experts from related sectors and are widely disseminated. There are different schemes for participation of the private practitioners (PPs) and NGOs in RNTCP. Information and documents on these schemes are available with DTOs and at the RNTCP website ***www.tbcindia.org***.

To health providers participating in the programme, the RNTCP provides:

- Technical training
- Laboratory consumables
- Registers and forms
- Health education materials, and
- Free drugs in patient-wise boxes

There are different roles which the partners of RNTCP can take up. These include:

- Referral for diagnosis
- Diagnosis
- Referral for treatment
- Treatment initiation
- Provision of Directly observed treatment (DOT)
- Health education and related activities
- Management and supervision of diagnostic and treatment activities at the sub district level

A health provider can get involved in a single activity or in multiple activities depending on the provider's capacity, interest and the requirements of the programme.

Continuous interaction and mutual trust between the public and the private sectors are essential prerequisites for the success of the collaboration. At the same time, the standard diagnostic and treatment guidelines of the programme need to be followed by all sectors to ensure the quality of RNTCP service delivery. RNTCP will provide supportive supervision. **All partners have to ensure that each patient with a history of cough for more than three weeks undergoes sputum smear**

examination for TB and patients diagnosed to have TB, receive treatment as per RNTCP guidelines. It is also essential that all patients put on DOTS, receive treatment under direct observation.

Increasing life expectancy, population growth, urban poverty, and factors like the HIV epidemic may potentially increase the incidence of TB. Unless TB control efforts are intensified on a war footing, it will continue to remain a major public health problem in the community. Recognition of the innate strengths and pooling the resources of different sectors will have a synergistic effect on the control of TB in India.

Points to Remember

- *TB continues to be the leading killer disease for Indian adults amongst all infectious diseases*
- *One fifth of the world's TB incident cases are in India*
- *More than 80% of TB patients have pulmonary TB*
- *In developing countries, more than 75% of TB patients are in the economically productive age group of 15-45 years*
- *The WHO recommended DOTS strategy is the most effective tool for TB control*
- *The DTO has the overall responsibility of implementing the programme at the district level*
- *Involvement of all sectors of health care is necessary for the control of TB in India*

2. GOAL, COMPONENTS AND SCIENTIFIC BASIS OF DOTS

Goal of RNTCP

The **goal** of RNTCP is to decrease mortality and morbidity due to TB and cut transmission of infection until TB ceases to be a major public health problem. It **aims** to control TB by detecting and curing sputum smear-positive patients thereby interrupting the chain of transmission. The **objectives** of RNTCP are to achieve and maintain a cure rate of at least 85% among new sputum smear positive cases and to achieve and maintain detection of at least 70% of such cases in the population. The only effective means to achieve the goal of RNTCP is the application of DOTS strategy.

Components of DOTS

DOTS is a systematic strategy having 5 components.

- Political and administrative commitment
- Good quality diagnosis, primarily by sputum smear microscopy
- Uninterrupted supply of good quality drugs
- Directly observed treatment (DOT)
- Systematic monitoring and accountability

Political and administrative commitment: TB is the leading infectious cause of death among adults. As TB can be cured, and the epidemic reversed, it warrants topmost priority. TB Control has been given this priority by the Government of India as well as the state, district and local governments and administration.

Good quality diagnosis: Diagnosis of TB is made primarily by sputum smear microscopy among chest symptomatic patients attending health facilities. This policy allows effective diagnosis in all settings and appropriate prioritisation of efforts. Sputum microscopy is a reliable, simple and cost effective test.

Good quality drugs: An uninterrupted supply of good quality anti-TB drugs must be available. In the RNTCP, a box of medication containing the entire course of treatment is earmarked for each patient, ensuring the availability of drugs for the full course of treatment. Hence in RNTCP, the treatment never fails on account of non-availability of medicines.

Short-course chemotherapy given in a programme of direct observation: The RNTCP uses the best anti-TB drugs available. But, unless these drugs are consumed properly by the patient, the treatment will fail. This is why the heart of the DOTS strategy is ‘Directly Observed Treatment’ (DOT) in which a health worker or a trained person watches while the patient swallows the medicines. This simple principle ensures adherence, helps prevent drug resistance to anti-TB medicines and achieves high cure rates.

Systematic monitoring and accountability: Quality of treatment is monitored by (a) follow-up sputum examinations during and at the end of the treatment, and (b) by using a robust and comprehensive recording and reporting system that evaluates and monitors the outcome of every patient on treatment. This is carried out by trained supervisory staff in the programme. Sputum smear conversion rate, cure rate and other key indicators are monitored at different levels. If a defined area is not achieving 90% sputum smear conversion rate at the end of three months and 85% cure rate, supervision is intensified.

In RNTCP, **the patient is the VIP**. RNTCP has shifted the responsibility for cure from the patient to the health system

Scientific basis of DOTS

DOTS is primarily based on sputum microscopy, domiciliary treatment, short course chemotherapy, and directly observed treatment.

Sputum smear microscopy provides definitive diagnosis. It is easy to perform, is replicable and cost effective. If good diagnostic practices are followed, it is expected that more than 50% of the new pulmonary TB patients will be smear positive. Chest **X-ray** examination, though sensitive, is not specific and has a wide inter-observer variability. The **tuberculin test** gives only evidence of infection and does not differentiate between infection and disease. **ESR** is also not specific and is unreliable as a tool for diagnosis or evaluation. **Culture of sputum** is highly sensitive and specific, but it is costly, not freely available and takes a long time in reporting.

Other new investigations are not reliable, are expensive and not useful in tackling a public health problem like TB. The high false positivity (non-TB patients getting diagnosed as TB) and low replicability (repeated tests giving different results) are the factors which make newer tests inferior to sputum smear examination. Besides, the high specificity of sputum microscopy (only actual TB cases getting diagnosed as positive) almost eliminates the chance of a non-TB patient getting treated for TB.

Domiciliary chemotherapy has been proved to be as effective as sanatoria treatment. Studies in India have shown that TB patients do not get any additional benefit by bed rest or special diet. The risk of infection among contacts of patients does not increase with domiciliary treatment and there is no need for hospitalisation for most patients. The economic burden on society is also lowered by domiciliary treatment.

Several studies in India by reputed researchers have shown that six months of chemotherapy gives favourable results when compared with longer terms of treatment for new sputum positive TB patients. It has also been proven that eight months of treatment is adequate for patients undergoing retreatment. These durations of treatment are adequate to prevent emergence of drug resistance. **Short-course chemotherapy (SCC)** is therefore more convenient and economical than conventional treatment with longer durations. In addition the shorter period of time makes direct observation more feasible and improves patient adherence to treatment.

Fully **intermittent chemotherapy** has been found to be as effective as daily chemotherapy. Studies in animal models demonstrated that for Isoniazid, Rifampicin, and Pyrazinamide, intermittent dosing actually increased the efficacy of treatment. In vitro experiments demonstrated that, after a culture of *M. tuberculosis* is exposed to certain drugs for some time, it takes several days before new growth occurs (the 'lag' phase). All the commonly used anti-TB drugs induce lag phases ranging from two days to forty days. Therefore these drugs can be given intermittently. Intermittent regimens make treatment observation more feasible and convenient for DOT providers and patients. They achieve high levels of treatment success with low relapse rates. As the quantity of drugs consumed is less, adverse reactions and costs are also lowered. In addition, intermittent dosing increases the efficacy of treatment by allowing organisms to re-enter the active metabolic phase in which the bactericidal drugs are more effective.

Direct observation of treatment (DOT) ensures the best possible results in treatment of TB. 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 **bacillary sub-population in TB** is of four kinds and different drugs act on different kind of bacteria. These are tabled below:

Type of TB Bacilli	**Effective Drugs**
Extra-cellular rapidly multiplying	Rifampicin, Isoniazid Streptomycin, Ethambutol
Extra-cellular intermittently multiplying/semi-dormant	Rifampicin
Intra- and extra-cellular acidic environments intermittently multiplying/semi-dormant	Pyrazinamide
Dormant	No drug

The phenomenon of **'persisters'** explains to some extent why all bacilli are not killed during treatment. Relapse with drug-susceptible organisms after the end of treatment or endogenous reactivation may be due to bacilli that have persisted in residual lesions for a long time in a semi-dormant / dormant state.

Currently recommended treatment regimens aim to:

- Cure the patient

- Prevent death from active disease or from its late effects
- Prevent the emergence and spread of drug-resistant organisms
- Minimise relapse
- Protect the community from continued transmission of infection

All treatment regimens consist of two phases:

Intensive Phase (IP) aims for a rapid killing of bacilli. This means a shorter duration of infectiousness (≤ 2 weeks), usually with rapid smear conversion (80% – 90%) after 2 to 3 months of treatment. Each dose in this phase should be directly observed to ensure adherence and involves 3 to 5 drugs depending on the category into which the patient has been placed.

Continuation Phase (CP) eliminates most residual bacilli and reduces failures and relapses. At the start of the CP, there are low numbers of bacilli and less chance of drug resistant mutants. Therefore fewer drugs are needed during this phase.

Numerical factor: The number of tubercle bacilli in a patient varies widely with the type of lesion the patient has. Data shows that the number of bacilli in a medium-sized cavity communicating with the bronchi is about 10^8 (one hundred million) whereas, in an encapsulated nodular lesion of the same size with no bronchial communication, it can be as low as 10^2 (one hundred). The numbers are also low in extra-pulmonary lesions of the skin, lymph glands, meninges and bones. The larger the bacterial load, the higher is the probability that resistant mutants are present even before treatment has been initiated.

Extra-pulmonary tuberculosis (EP TB): The management of extra-pulmonary TB differs from that of pulmonary TB mainly due to the difficulty in making a conclusive diagnosis. This can lead to empirical treatment and thereby to over-diagnosis and unnecessary treatment of a large number of patients.

EP TB is usually paucibacillary (with relatively less number of bacilli). Any treatment regimen effective in pulmonary TB is equally effective in EP TB as well. For the purpose of treatment, extra-pulmonary TB is classified into seriously ill and not-seriously ill forms (detailed under the section on treatment). The difficulty in establishing a clear-cut ‘end-point’ of treatment in EP TB often leads to treating these patients for longer durations than required. Studies have clearly established the efficacy of short-course chemotherapy in children and adults. Intermittent regimens in EP TB have also been proven to be as effective as daily regimens.

Points to remember

- *RNTCP has shifted the responsibility for cure from the patient to the health system*
- *Sputum microscopy is the recommended diagnostic tool for patients suspected to have pulmonary TB*
- *Directly observed treatment ensures the best possible results*
- *Intermittent regimen is as effective as daily regimen and causes lesser side effects*
- *All treatment regimens in RNTCP have two phases; an intensive phase and a continuation phase*

3. DIAGNOSIS OF TUBERCULOSIS

Identification of tuberculosis suspects

TB affects the lungs in more than eighty percent of cases. This form of disease is called pulmonary tuberculosis. As TB spreads mainly by droplet infection, close contacts of a sputum smear positive pulmonary TB patient can get infected. It is estimated that an untreated smear positive pulmonary TB patient infects 10 to 15 persons annually. It is therefore very important to suspect and identify such patients early and advise sputum examinations to arrive at a diagnosis. Prompt treatment of such patients prevents further spread of infection in the community.

Patients who have symptoms suggestive of TB usually visit those health facilities most convenient to them. These may belong to government or other sector health care providers. **The most common symptom of pulmonary TB is persistent cough, usually with expectoration.** Persistent cough may be accompanied by other symptoms such as weight loss, tiredness, fever with evening rise, night sweats, chest pain, shortness of breath, anorexia and haemoptysis.

About 2-3% of new adult outpatients in a general health facility are expected to suffer from cough for three weeks or more. The medical practitioner should identify such TB suspects and they should be investigated by sputum smear microscopy to arrive at a diagnosis. On an average, 10% of TB suspects are expected to have sputum smear positive pulmonary TB. **Sputum examination and anti-TB treatment is free of cost under RNTCP.**

A patient with extra-pulmonary TB may have general symptoms like weight loss, fever with evening rise and night sweats. Other symptoms depend on the organ affected. Examples of these symptoms are, swelling of a lymph node in TB lymphadenitis, pain and swelling of a joint in TB arthritis and neck stiffness and disorientation in a case of TB meningitis.

Patients with EP TB who also have cough of any duration, should have 3 sputum samples examined. If the smear result is positive, the patient is classified as pulmonary TB and his/her treatment regimen will be that of a case of smear positive pulmonary TB.

Three sputum specimens should be collected on two consecutive days as explained later in this chapter. If at least two sputum specimens are smear positive for AFB, the patient is classified as a smear positive TB case. They are further classified as new or retreatment cases based on the history of previous treatment for TB.

Patients with only one positive result out of three sputum smear examinations should undergo a chest X-ray examination. Patients who have one positive smear and a chest X-ray suggestive of TB (as determined by treating doctor) are also classified as smear-positive pulmonary TB patients.

If all three sputum specimens are negative, the patient should be treated for 10 to 14 days with broad spectrum antibiotics, such as Co-trimoxazole. Care must be taken to prescribe only those antibiotics which do not have anti-TB activity. Antibiotics like

Fluoroquinolones, Rifampicin or Streptomycin should never be used as they have anti-TB activity.

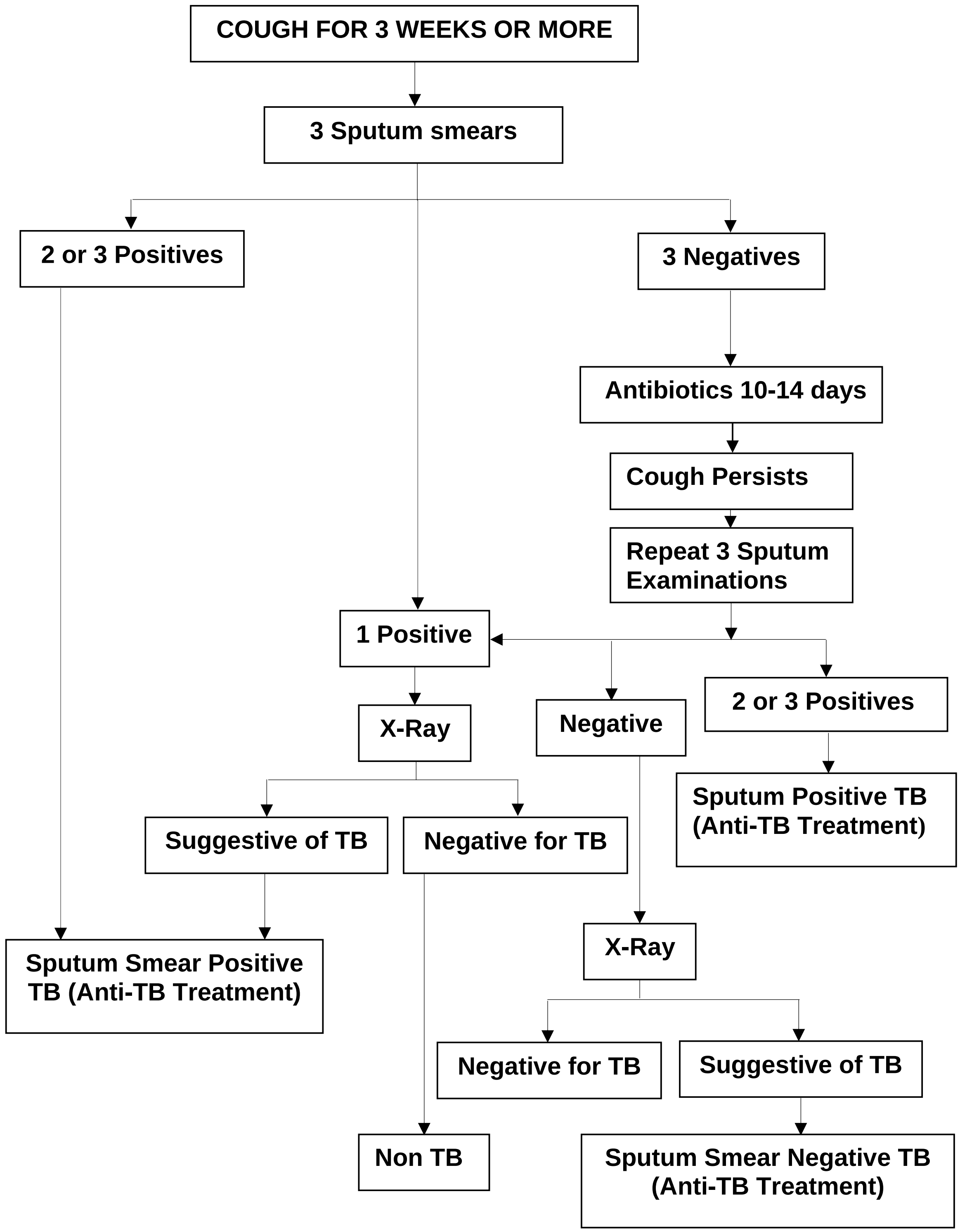
If symptoms persist even after a course of treatment with an appropriate antibiotic, a repeat sputum examination should be done. If the result of the repeat sputum examination is positive, (two or three samples out of three positive or one out of three samples positive with X-ray suggestive of pulmonary TB), then the patient is classified as smear-positive TB.

If the results for all the three sputum samples of repeat examination for diagnosis are found negative then a chest X-Ray is taken. If the findings of the X-ray are consistent with active pulmonary TB, and the medical practitioner decides to treat the patient with anti-TB drugs, the patient will be diagnosed as having pulmonary smear-negative TB. Such patients will be designated as 'seriously ill' (e.g. patients with extensive bilateral parenchymal lesion, miliary TB, Cavitatory lesions or those TB patients with voluntarily disclosed concomitant HIV infection) or 'not seriously ill' based on their clinical condition. They will then be appropriately categorised and treated.

Patients with suspected EP TB should be referred to a competent medical practitioner for expert opinion. Diagnosis of such patients may be made by using appropriate diagnostic procedures (such as **FNAC/Biopsy**) as well as clinical methods.

Diagnosis of TB by chest X-ray alone is unreliable because **no radiological pattern is pathognomic of pulmonary TB**. Unless the prescribed algorithm given below is followed a large number of patients who do not have TB will be falsely diagnosed and treated.

Diagnostic Algorithm for Pulmonary TB



Diagnosis by Sputum Microscopy

A medical practitioner at a health facility screens patients and advises those who are suspected of having TB (cough for three weeks or more) to undergo sputum smear examination. If sputum microscopy is not available at the facility, the patient is referred to the nearest RNTCP designated microscopy centre. A laboratory form (which is also used as a referral form for diagnosis) for sputum examination has to be filled and sent to the laboratory with the patient. The sputum specimen may be collected and transported to the laboratory if the patient is unable to travel to microscopy centre. Only one laboratory form needs to be filled for all the three specimens of the patient.

Guidelines for collecting sputum for smear microscopy

- When a TB suspect reports to the laboratory a specimen is collected on the spot. (S)he is given a sputum container with the lab serial number written on its side and is instructed to inhale deeply two to three times with his/her mouth open, cough out deeply from the chest, open the container, spit out the sputum into it and close the container tightly. This specimen is called a spot specimen.
- The patient is then given a similarly marked sputum container to collect an early morning specimen on the next day and bring it to the laboratory. This specimen is called an early morning specimen.
- When the patient brings the early morning specimen, a second spot specimen is collected under the supervision of a staff member.

Thus there will be three samples: **SPOT - EARLY MORNING - SPOT.**

Obtaining a good sputum specimen is crucial for good sputum microscopy. The following steps have to be observed to get good sputum specimen:

1. Tasks performed before sputum collection: The laboratory form for sputum examination should be filled up completely. This form is sent to DMC along with the sputum specimens. The form accompanies the sputum specimens when they are transported from the peripheral health facility to the DMC for examination.

2. Tasks performed during sputum collection: A specimen collected under the proper guidance of a health worker is likely to yield more conclusive results than one produced by a patient without any guidance. Sputum should preferably be collected in open air or in a vacant room with open windows. Patient should be given a sputum container with the laboratory serial number written on its side. If the sputum is being collected at a location other than the DMC, then the Specimen Identification Number (or patient's name) is written on the side of the container. The health worker or the laboratory technician should stand behind the patient. The health worker should also ensure that no-one stands in front of the patient. If a patient coughs out only saliva, (s)he should be asked to try again to bring out sputum.

3. Tasks performed after sputum collection: If a specimen cannot be sent to laboratory immediately, it should be stored in a refrigerator or in another cool place. Sputum specimens should be examined immediately whenever possible and not later than a week after collection. A smear is made, fixed and stained using the **Ziehl-Neelsen** staining technique (for staining procedure, see Appendix 6)

Sputum smears are examined and interpreted as indicated in the table below:

Examination finding	Result as recorded	Grading	No. of fields examined
> 10 AFB per oil immersion field	Positive	3+	20
1–10 AFB per oil immersion field	Positive	2+	50
10–99 AFB per 100 oil immersion fields	Positive	1+	100
1–9 AFB per 100 oil immersion fields	Positive	Scanty*	100
No AFB in 100 oil immersion fields	Negative	Negative	100

* Record exact number seen in 100 fields

When the referring Medical Practitioner receives the results of sputum examination, and it is decided to put the patient on chemotherapy, health education must be imparted to the patient. The patient is told about TB, how it spreads, precautions to be taken to prevent the spread, importance of directly observed treatment and its duration, and the need for prompt evaluation of children under six years or contacts with cough of any duration living in the household. The patient should also be informed that his address would be verified by a competent person prior to the start of treatment.

Diagnosis by other methods

For diagnosis of pulmonary TB, sputum smear microscopy is the primary tool. A chest X-ray is required only when a single sputum out of three examined is positive or when all three sputum smears are negative for AFB on two consecutive days.

Diagnosis of extra-pulmonary TB should be based on:

1. One culture positive specimen from the site of disease, or
2. Histological evidence of TB, or
3. Strong clinical evidence, consistent with active extra-pulmonary TB, followed by the diagnosing medical practitioner’s decision to treat the patient with a full course of anti-TB treatment

Depending upon the site of the infection, various diagnostic tools may be used. For example, FNAC/biopsy is used for diagnosing TB lymphadenitis which is the most common variety of EP TB.

Quality Assurance

An effective quality assurance (QA) system for sputum smear microscopy is an integral part of RNTCP. QA is a total system consisting of internal quality control (IQC), assessment of performance using external quality assessment (EQA) methods and continuous quality improvement (QI) of laboratory services.

Points to Remember

- *The most common symptom of pulmonary TB is a persistent cough for three weeks or more*
- *Sputum samples should be examined as soon as possible and not later than a week after it is collected*
- *Patients suspected to have pulmonary TB should have three sputum smears examined*
- *The role of chest X-rays in the diagnosis of pulmonary TB is only supportive*
- *2 – 3% of new adult outpatients in a general clinic will be TB suspects and should be sent for sputum examination*
- *10% of TB suspects are expected to have sputum smear-positive pulmonary TB*

Exercise 1

PART A: Write your opinion on the following case studies and complete the laboratory forms if the patient needs sputum examination:

Meena Patel, a 25 year old resident of 225, Bapu Nagar of your city complains that she feels tired for the last few days. On further questioning, she reveals that she has had a cough for 4 weeks. She does not have any other symptoms. She has never taken any anti-TB drugs.

Lakshmi Kumari, 41 years and resident of 18, M.G. Road of your city, has had a cough for two months with fever, night sweats and occasional coughing up of blood. She had taken treatment for TB two years back for about 5 months and discontinued treatment on her own.

Ashok Patel, a 30 year old man who lives with his parents, is having cough for the past 8 days. His father is under treatment for sputum smear positive pulmonary TB for the past 1 month. Ashok does not have any other complaint.

Paravathi Sinha, an 18 years old resident of 12, Bapu Nagar of your city presented with non-tender swelling of the lymph nodes in neck region which appeared 3 months ago. These nodes are slowly growing in size. She does not have cough.

Lallan Prasad, a 30 year old resident of 19, Sidharth Apartment, Main road, of your city presented with complaints of fever for 1 month. He also complained of having cough for 1 month and loss of weight.

PART B: Complete the bottom section of the laboratory form. Start with the laboratory serial number. Specimens have been examined on 10th June 2003. Sign your own name.

Patient	Number of AFB (visual appearance)
Meena Patel – A	30 AFB are seen in 100 oil immersion fields (mucopurulent) 140 AFB are seen in 50 oil immersion fields (mucopurulent) 70 AFB are seen in 100 oil immersion fields (mucopurulent)
Lakshmi Kumari -B	200 AFB are seen in 50 oil immersion fields (mucopurulent) 400 AFB are seen in 50 oil immersion fields (mucopurulent) 100 AFB are seen in 50 oil immersion fields (mucopurulent)
Ashok Patel – C	0 AFB are seen in 100 oil immersion fields (mucopurulent) 0 AFB are seen in 50 oil immersion fields (saliva) 0 AFB are seen in 100 oil immersion fields (mucopurulent)
Lallan Prasad – E	0 AFB are seen in 100 oil immersion fields (mucopurulent) 0 AFB are seen in 50 oil immersion fields (mucopurulent) 0 AFB are seen in 100 oil immersion fields (blood)

PART C: Complete the first page of the Laboratory Register using the laboratory forms you have prepared with information in Part ‘A’ and Part ‘B’.

(NB: training facilitators may distribute photocopies of laboratory register page)

4. ADMINISTERING TREATMENT

Diagnosis of TB in itself has little purpose unless it is followed by effective treatment. The goal of anti-TB treatment is to ensure cure, while preventing the emergence of drug resistance. A patient with TB should be put on treatment **within one week** of diagnosis.

The following is required before starting treatment:

- History of patient, including history of any previous treatment for TB
- Sputum smear examination results from an approved DMC
- Chest x-ray report if the case warrants radiographic examination
- Other supporting investigation reports, if any

The disease classification, type of case, sputum result, severity of illness and history of previous treatment are the factors that determine the regimen used for treating a TB patient.

Disease Classification:

TB cases are classified as pulmonary and extra-pulmonary. Pulmonary TB is further classified as smear positive and smear negative.

Pulmonary tuberculosis

a. Smear-positive patient

A patient with at least 2 initial sputum smear examinations (direct smear microscopy) positive for acid-fast bacilli (AFB);

Or: A patient with one sputum examination positive for AFB and radiographic abnormalities consistent with active pulmonary TB as determined by the treating MO;

Or: A patient with one sputum specimen positive for AFB and culture positive for M. tuberculosis.

b. Smear-negative patient

A patient having symptoms suggestive of TB with at least 3 sputum examinations negative for AFB, and radiographic abnormalities consistent with active pulmonary TB as determined by the treating MO, followed by a decision to treat the patient with a full course of anti-TB therapy;

Or: A patient whose diagnosis is based on culture positive for M. tuberculosis but sputum smear examinations negative for AFB.

The following forms of smear-negative pulmonary TB are classified as seriously ill: Miliary TB, Extensive parenchymal infiltration, Co-infection with HIV, Pulmonary disease with cavitations and All forms of pediatric sputum smear negative pulmonary TB except primary complex

Extra Pulmonary Tuberculosis

This includes TB of organs other than the lungs. Patients who have both pulmonary and extra-pulmonary TB are classified as having pulmonary tuberculosis. The site of the EPTB lesion is documented. Certain forms of EPTB are considered as seriously ill (Please see table below).

Seriously ill EPTB	Not seriously ill EPTB
• Meningitis • Pericarditis • Peritonitis • Bilateral or extensive pleural effusion • Spinal TB with neurological involvement • Intestinal • Genito-urinary • Co-infection with HIV • All forms of pediatric extra-pulmonary TB other than lymph node TB and unilateral pleural effusion are considered to be seriously ill	• Lymph node • Pleural effusion (unilateral) • Peripheral joints

Any patient, with pulmonary or extra-pulmonary TB, who is known to be HIV positive based on voluntary sharing of results and/or history of anti-retroviral therapy, is considered as seriously ill. **For the purpose of categorisation, HIV testing should not be done. In addition, HIV status should not be revealed or recorded in any of the RNTCP documents.**

Types of Tuberculosis Patients

New: A TB patient who has never had treatment for TB or one who has taken anti-TB drugs for less than one month.

Relapse: A TB patient who was declared cured or treatment completed by a physician, but who reports back to the health service and is now found to be sputum smear-positive.

Transferred in: A TB patient who has been received for treatment in one Tuberculosis Unit, after starting treatment in another unit (TU) where (s)he has been registered.

Treatment after default: A TB patient who received anti-TB treatment for one month or more from any source and returns to treatment after having defaulted, i.e., not taken anti-TB drugs consecutively for two months or more, and who is found to be sputum smear-positive.

Failure: Any TB patient who is smear-positive at 5 months or more after starting treatment. Failure also includes a patient who was treated with Category III regimen but who becomes smear-positive during treatment.

Chronic: A TB patient who remains smear-positive after completing a re-treatment regimen.

Others: TB patients who do not fit into the above mentioned types. Reasons for putting a patient in this type must be specified.

Categories of Treatment

Category of Treatment	Type of Patient	Regimen*
Category I	New sputum smear-positive Seriously ill** new sputum smear-negative Seriously ill** new extra-pulmonary	$2H_3R_3Z_3E_3$+ $4H_3R_3$
Category II	Sputum smear-positive Relapse Sputum smear-positive Failure Sputum smear-positive Treatment After Default Others***	$2H_3R_3Z_3E_3S_3$ + $1H_3R_3Z_3E_3$ + $5H_3R_3E_3$
Category III	New Sputum smear-negative, not seriously ill New Extra-pulmonary, not seriously ill	$2H_3R_3Z_3$ + $4H_3R_3$

**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: H: Isoniazid (600 mg), R: Rifampicin (450 mg), Z: Pyrazinamide (1500 mg), E: Ethambutol (1200 mg), S: Streptomycin (750 mg). Patients who weigh 60 kg or more receive additional rifampicin 150 mg. Patients who are more than 50 years old receive streptomycin 500 mg. Patients who weigh less than 30 kg, receive drugs as per body weight. Patients in Categories I and II who have a positive sputum smear at the end of the initial intensive phase receive an additional month of intensive phase treatment.*

*** Seriously ill also includes, any patient, pulmonary or extra-pulmonary who is HIV positive and declares his sero-status to the categorizing/ treating medical officer. For the purpose of categorization, HIV testing should not be done*

**** In rare and exceptional cases, patients who are sputum smear-negative or who have extra-pulmonary disease can have Relapse or Failure. This diagnosis in all such cases should always be made by an MO and should be supported by culture or histological evidence of current, active TB. In these cases, the patient should be categorized as 'Others' and given Category II treatment.*

The **codes** and **dosage** strengths

Medication	Dose (thrice a week)	Number of pills in combipack
Isoniazid	600 mg	2
Rifampicin	450 mg	1
Pyrazinamide	1500 mg	2
Ethambutol	1200 mg	2
Streptomycin	0.75 g	-

Patients who weigh 60 kg or more receive additional Rifampicin 150 mg. Patients who are more than 50 years old receive streptomycin 500 mg. Patients who weigh less than 30 kg, receive drugs as per body weight. Patients in Categories I and II who have a positive sputum smear at the end of the initial intensive phase receive an additional month of intensive phase treatment.

In rare and exceptional cases, patients who are sputum smear-negative or who have extra-pulmonary disease can have Relapse or Failure. This diagnosis in all such cases should always be made by an MO and should be supported by culture or histological evidence of current, active TB. In these cases, the patient should be categorised as ‘Others’ and given Category II treatment.

CAT I: This is used for new patients who are sputum smear-positive or seriously ill sputum smear-negative or seriously ill EP TB patients. Treatment is given in two phases - **Intensive Phase (IP) and Continuation Phase (CP)**. IP consists of Isoniazid, Rifampicin, Pyrazinamide and Ethambutol, given under direct observation three times a week, on alternate days. IP is given for two months (8 weeks; 24 doses). At the time of the 22^{nd} dose, the patient is referred for follow-up sputum examination so that the results are available by the end of IP (24^{th} dose). If follow-up sputum examination is negative, CP is started and consists of 4 months of treatment (18 weeks; 54 doses) with Isoniazid and Rifampicin, given three times a week on alternate days. During CP, at least the first dose of every week is directly observed. Follow up sputum examinations are done two months into the start of and at the end of CP.

If the sputum smear is positive after 2 months of treatment, IP drugs are extended for another one month (12 doses from a prolongation pouch) before starting CP. A follow up sputum examination is repeated at end of the extended IP (3 months). This helps in assessment of the progress of treatment and sputum conversion rate. Irrespective of the smear status, the patient is put on CP drugs and the next follow up sputum examination is done at 5 months.

If the sputum smear is positive after 5 months or more of starting treatment, the treatment outcome of the patient is declared as ‘failure’ and (s)he is started afresh on CAT II treatment. In the rare situation in which a CAT I smear-positive patient has a negative sputum smear after 2 months of treatment and a positive sputum smear after 4 months of treatment, another sputum smear should be examined at 5 months. If this is also positive, the patient is considered a treatment ‘failure’ and is started afresh on CAT II treatment.

CAT II: This is used to treat retreatment cases namely ‘Relapse’, ‘Failure’, ‘Treatment after Default’ and ‘Others’. Such patients are generally sputum smear-positive. The IP consists of two months (8 weeks; 24 doses) of Isoniazid, Rifampicin, Pyrazinamide, Ethambutol and streptomycin; all given under direct observation three times a week on alternate days. This is followed by another one month (4 weeks; 12 doses) of Isoniazid, Rifampicin, Pyrazinamide and Ethambutol, all of which are given under direct observation three times a week on alternate days. This is immediately followed by CP, which consists of 5 months (22 weeks; 66 doses) of Isoniazid, Rifampicin and Ethambutol given three times a week on alternate days, the first dose of every week being directly observed. If the sputum smear is positive after 3 months of treatment, the four oral IP drugs are continued for another one month (4 weeks; 12 doses) before starting the 5-month CP.

Patients who have been previously treated are at an increased risk of having drug resistant bacilli. For this reason, such patients are given a more intensive regimen, namely CAT II. Experience in India and elsewhere has shown that CAT II treatment, if taken regularly by the patient, is effective and results in curing most patients.

Patients who relapse generally have better outcomes than those who are Failure or Treatment after Default cases, but even these latter types of patients respond well to treatment, provided they take it regularly and are well supervised.

CAT III: This is used for patients who are smear-negative PTB or EP TB, and are not seriously ill. The IP lasts for 2 months (8 weeks; 24 doses) with Isoniazid, Rifampicin and Pyrazinamide given under direct observation three times a week on alternate days. This is followed by CP, which consists of 4 months (18 weeks; 54 doses) of Isoniazid and Rifampicin given three times a week on alternate days, with at least the first dose of every week being directly observed. If a patient receiving CAT III regimen has a positive sputum smear at any stage of the treatment, (s)he should be declared a failure, re-registered, and treated afresh with the CAT II regimen.

Referral for Treatment

Patients after diagnosis and categorisation should be put under DOTS. The DOTS treatment should be administered from a location (also called DOT centre) which is convenient to the patient.

Many patients may have to be referred after diagnosis to a DOT centre which is convenient to him/her along with a ‘Referral for Treatment’ form. The patient should be given the choice of the DOT centre from the DOT directory available. The patient will be started on treatment at the concerned DOT centre on the basis of this referral (refer annexure 2).

Treatment categories at a glance

Category	Regimen and Duration		Total Duration
	IP	CP	
CAT I (RED)	2 ($H_3R_3E_3Z_3$) 8 weeks, 24 doses	4 (H_3R_3) 18 weeks, 54 doses	6 months, 78 doses
CAT II (BLUE)	2 ($S_3H_3R_3E_3Z_3$) 1 ($H_3R_3E_3Z_3$) 12 weeks, 36 doses	5 ($H_3R_3E_3$) 22 weeks, 66 doses	8 months, 102 doses
CAT III (GREEN)	2 ($H_3R_3Z_3$) 8 weeks, 24 doses	4 (H_3R_3) 18 weeks, 54 doses	6 months, 78 doses

- *The numbers before the letters refers to the number of months of treatment. The subscript after the letters refers to the number of doses per week.*
- *Patients in categories I and II who have a positive sputum smear at the end of the initial IP receive an additional month of IP treatment.*

Patient-wise boxes

All anti-TB drugs for the entire course of treatment for an individual patient are available as blister packs in patient-wise boxes. One such box is ear-marked for a patient as soon as (s)he is put on treatment. This ensures that patients do not interrupt treatment due to drug shortages.

Regimen for non-DOTS treatment in DOTS areas

All efforts should be made to put all the patients suffering from TB under DOTS. However, RNTCP non-DOTS treatment (self administered, non-Rifampicin containing regimens) maybe needed in exceptionally few cases, example: in case of adverse reaction to drugs or for migratory populations. Such patients should not exceed 5% of the total patients in the normal course. The prescribed regimens and dosages are given below:

Treatment*	Type of patient	Regimen
Regimen – ND1	Pulmonary Smear-positive – new Pulmonary Smear-negative – seriously ill Extra-pulmonary – seriously ill	2HSE 10 HE
Regimen – ND2	Pulmonary Smear-negative – not seriously ill Extra-pulmonary – not seriously ill	12 HE

** Note that these regimens do not contain Rifampicin*

Regimen – ND1: A 12 month conventional chemotherapy regimen, with Streptomycin given during the first two months. This is given to patients who are:

- New cases of smear-positive pulmonary TB, and
- Seriously ill cases of smear-negative pulmonary and extra-pulmonary TB

The initial two months constitute the intensive phase and the continuation phase is for 10 months. Isoniazid and Ethambutol are self-administered by the patient daily for 12 months. Streptomycin is administered daily in the initial intensive phase.

Dosage for adults is one tablet of Isoniazid (300mg) and one tablet of Ethambutol (800 mg) every day. The dosage for streptomycin injection is 0.75 g per day (0.5 g for those over 50 years of age and/or those who weigh less than 30 kg).

Regimen – ND2: A 12 month conventional chemotherapy regimen without streptomycin for:

- Patients with smear-negative pulmonary TB who are not seriously ill
- Patients with extra-pulmonary TB who are not seriously ill

Dosages of Isoniazid and Ethambutol remain the same in this regimen as in the Regimen – ND1.

Side effects of Anti-TB drugs

Serious side effects of anti-TB drugs are less with intermittent chemotherapy. Drugs should **not** be administered on empty stomach. DOT providers should be aware of the common side effects so that they can identify these early and report to the medical officer. Patient should be informed that intake of Rifampicin causes reddishorange discoloration of urine and that this is not cause for alarm. Any side effects reported during treatment should be recorded in the remarks column of the treatment card.

Symptom-based approach to evaluation of possible side effects of anti-TB drugs

Symptom	Drug (abbreviation)	Action to be taken
Gastrointestinal upset	Any oral medication	Reassure patient Give drugs with less water Give drugs over a longer period of time (e.g. up to 20 minutes) Do not give drugs on empty stomach If the above fails, give antiemetic if appropriate
Itching	Isoniazid (H) (Other drugs also)	Reassure patient If severe, stop all drugs and refer patient to a medical practitioner for evaluation
Burning in the hands and feet	Isoniazid (H)	Give pyridoxine 100 mg/day until symptoms subside
Joint pains	Pyrazinamide (Z)	If severe, refer patient for Evaluation
Impaired vision	Ethambutol (E)	STOP ethambutol, refer patient for evaluation
Ringing in the ears	Streptomycin (S)	STOP streptomycin, refer patient for evaluation
Loss of hearing	Streptomycin (S)	STOP streptomycin, refer patient for evaluation
Dizziness and loss of balance	Streptomycin (S)	STOP streptomycin, refer patient for evaluation
Jaundice	Isoniazid (H) Rifampicin (R) Pyrazinamide (Z)	STOP all drugs, refer patient for evaluation

In cases of jaundice, all anti-TB drugs should be stopped immediately and the patient referred to a medical practitioner for evaluation.

Follow-up examinations

Sputum smear microscopy is much more informative than radiological examination in monitoring the progress of chemotherapy. The erythrocyte sedimentation rate (ESR) is unreliable and has no role in diagnosing and/or evaluating the progress or results of treatment. In most cases, two sputum specimens are taken for follow-up sputum smear examinations at three specified intervals: at the end of the IP, two months into the CP and at the end of treatment.

Schedule for follow-up sputum examinations during entire Course of treatment

Category	Pre-treatment sputum	Test at month	If result is	Then…
Cat I	Positive	2	Neg	Start continuation phase, test sputum again at 4 and 6 months
			Pos	Continue intensive phase for one more month, test sputum again at 3, 5 and 7 months
	Negative	2	Neg	Start continuation phase, test sputum again at 6 months
			Pos	Continue intensive phase for one more month, test sputum again at 3,5 and 7 months
Cat II	Positive	3	Neg	Start continuation phase, test sputum again at 5 and 8 months
			Pos	Continue intensive phase for one more month, test sputum again at 4,6 and 9 months
Cat III	Negative	2	Neg	Start continuation phase, test sputum again at 6 months
			Pos	Re-register the patient and begin Category II treatment

Action for patients who interrupt treatment:

One of the principles of RNTCP is that the responsibility of curing the patient lies with the programme and not with the patient. Providers may be too far from where the patients reside or may have inconvenient timings. Patients also tend to discontinue treatment when they improve symptomatically thinking that they are cured of the disease. There can also be other socio-economic causes for discontinuation of treatment. Proper counseling is essential to motivate patients to take the prescribed medications regularly and as per the treatment schedule. The treating practitioner should take the necessary steps to prevent and help retrieve patients who interrupt treatment. The concerned supervisory staff at the sub-district level (TU) should be informed immediately, if efforts by the DOT provider prove to be futile.

If a patient interrupts treatment at any stage during the course of treatment, visits to his/her home should be made to bring them back under treatment. This should be done by the concerned DOT provider, or other health staff, no later than the day after the patient was due to come for treatment in the IP and within a week of the missed dose in the CP.

Treatment of patients retrieved depends on the type of patient, duration of treatment taken, length of interruption and the patients' sputum status. Decision on further management may be taken as per the RNTCP protocol tabled in the annexure 7.

Treatment outcomes

In RNTCP, every patient registered has **one and only one** of the following six outcomes. This needs to be reported in individual treatment cards. The possible treatment outcomes are as follows:

Cured: Initially sputum smear-positive patient who has completed treatment and had negative sputum smears, on at least two occasions, one of which was at the end of treatment.

Treatment Completed: A sputum smear-positive patient who has completed treatment, with negative smears at the end of IP but none at the end of treatment, **or**

A sputum smear-negative patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment, **or**

An EP TB patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment.

Died: Patient who died during the course of treatment, regardless of the cause of death.

Failure: Any TB patient who is smear-positive at 5 months or more after starting treatment, **or**

A patient who was treated with Category III but who becomes smear-positive during treatment.

Defaulted: A patient who has not taken anti-TB drugs for 2 months or more consecutively after starting treatment.

Transferred out: A patient who has been transferred to another TB Unit or district and for whom the treatment result (outcome) is not known.

Tuberculosis treatment card

Each patient who begins treatment for TB must have a Tuberculosis Treatment Card as shown in the annexure 3. This card contains all relevant and up-to-date information about the patient and his/her disease. General information about the patient is entered in the top section on the front page. The disease classification, type of patient, sputum smear examination results, weight of patient, history of previous anti-TB treatment, category of treatment, regimens, tablets and dosages should be entered. The front page is used for the IP and back page for the CP. In the back page the X-ray reports (for smear-negative patients) and reports of investigations done to diagnose EP cases should be noted. The back page should also note information on the children in contact with the TB patient for whom the treatment card is filled and also details regarding any retrieval actions undertaken in case of treatment interruption. At the end of the treatment, the treatment cards have to be completed by giving the outcome of the patient. This card is the property of RNTCP and should be returned to the respective TU after completion of the treatment.

Supervising Drug Administration

Studies throughout the world, including India, have shown that most patients, if left unsupervised, do not take medicines as prescribed. All efforts therefore should be made to ensure that the DOT provider directly observes every dose of medicine in the IP and at least the first dose every week in the CP. The blister pack with the remaining two doses for that week should be handed over to the patient with necessary instructions. The patient is requested to return the empty pack when (s)he comes to the DOT provider the following week.

In the RNTCP, family members should not be made DOT providers. This is in the best interest of the patient as experience shows that there could be ineffective supervision of treatment when the observer is a family member.

Ensuring proper drug administration

DOT providers must give the drugs to the patient according to what is written on the patient's treatment card. They must observe the intake of drugs to ensure that the patient has swallowed them. For patients on Cat II treatment, injection Streptomycin should be given after the other drugs have been swallowed to ensure that all drugs have been taken. Ensure periodically that the patient is receiving the correct number and type of drugs.

A DOT provider can be any person who is not a family member, and who is:

- Accessible – to the patient
- Acceptable – to the patient
- Accountable – to the programme

Recording of Drug Administration

DOT providers must record correctly the drug administration during the IP. A '✓' is marked on the days the drugs are swallowed under direct observation. During the CP, a 'X' is marked on the days the drugs are swallowed under direct observation and a line is drawn through the remaining days of the week to indicate that the drugs for the remaining period of the week have been given to the patient. If the patient does not come to take the drugs as per schedule, then it should be recorded as 'O' in the card.

Illustration

If a patient who is being treated under CAT I misses the 23rd dose of the intensive phase, but is given that dose on the following day, this would be recorded as follows:

S	✓		O	✓	✓		S
	22nd dose			23rd dose	24th dose		

If on the other hand, the dose is missed and the patient does not report to the health facility the next day, then the dose is given on the next scheduled day, as follows:

S	✓		O		✓		S	✓
	22nd dose				23rd dose			24th dose

In the same manner, if the patient misses a weekly drug collection in the continuation phase, the treatment is given and recorded as follow:

S	X						~~S~~	O						S	X						~~S~~
	17th week														18th week						

Recording Remarks

Any relevant comment about the patient can be written in the 'Remarks' section of the treatment card, for example:

- Site, in case of EP TB
- X-ray reports for smear-negative patients
- Method of diagnosis, histopathological and other reports in case of EP TB
- Transfer details
- In case of Cat-II patients: whether taken treatment in the past under RNTCP or non RNTCP regimens. In case of having taken RNTCP regimens, the old TB number (i.e. TB number when patient was on Cat I or III)
- Write the new TB number in the old TB cards of patients who had earlier taken Cat-I or Cat-III regimens, when patients are retreated in case of failure or default and are now on Cat-II regimen.
- Reason for Non-DOTS treatment initiation

Points to Remember

- *The responsibility of curing the patient lies with the programme and not with the patient*
- *Effective retrieval of patients who interrupt treatment improves outcomes of treatment and improves the quality of the programme*
- *Treatment cards should have relevant and up-to-date information about the patient and should be carefully maintained*
- *The DOT provider should observe the swallowing of all oral medications during the IP and at least the 1st dose of each week during the CP*

Exercise 2

Part A: Categorise those patients in **Exercise I** who needed anti-TB treatment.

Part B: Meena Patel was started on treatment on 16th June. Her initial weight was 41 kg. She missed the scheduled 12th dose and also the 15th and 16th doses in the Intensive Phase for which a home visit was made. However, the patient was found to be out of station. The 7th dose was missed, but taken on the subsequent day. The 9th dose was taken unsupervised as she was unable to come to DOT centre for personal reasons. She did not come in the 5th week of the Continuation Phase and completely missed the doses of that week. All follow up sputum examinations were negative, i.e., at end of Intensive Phase – laboratory no. 209, dated 13/08/03 (weight 45 kg), at the end of 4th month – laboratory no 407, dated 18/10/03 (weight 47kg) and at the end of treatment – laboratory no. 630, dated 29/12/03 (weight 49kg). Complete the treatment card. There are no children below six years of age in her family.

5. SPECIAL SITUATIONS

1. Hospitalisation

Hospitalisation has little or no effect on the outcome of treatment. A patient who takes the drugs regularly will do equally well whether treated in or out of hospital. In-patient treatment is only indicated for the severely ill, or for those with complications of TB (e.g. haemoptysis, spontaneous pneumothorax), or other serious accompanying diseases. During hospitalisation, patients should be started on treatment with DOTS, taking medicines from a prolongation pouch.

2. TB Meningitis

This form of TB is highly fatal if left untreated. Patients should be referred to a hospital for in-patient care. However, treatment should be started at the earliest under CAT I for new patients and CAT II for retreatment cases. CP should be given for up to seven months. Steroids should be given initially, to reduce meningeal inflammation, and tapered off gradually over six to eight weeks.

3. TB-HIV

TB is the most common opportunistic infection in People Living with HIV/AIDS (PLWHA). Early diagnosis and effective treatment of TB among HIV infected patients are critical for curing TB, minimizing the negative effects of TB on the course of HIV, and interrupting the transmission of TB infection to other persons in the community. Management of TB under RNTCP can significantly prolong the lives of HIV positive people with TB. Refer to appendix 2 for more details on TB and HIV co-infection. DOTS is the strategy of choice to treat TB in HIV positive individuals.

4. TB during pregnancy and whilst breastfeeding

Streptomycin should not be given during pregnancy. Other drugs are safe. Breast feeding should continue regardless of the mother's TB status. All anti TB drugs are compatible with breast feeding and a woman taking them can safely continue to breast feed.

5. TB in children

DOTS is the recommended strategy for all Pediatric TB patients. All Pediatric TB cases diagnosed should be registered under the RNTCP and intermittent SCC given under direct observation as per the RNTCP policy. Refer to the appendix 1 for more details.

6. Multi-drug resistant tuberculosis (MDR-TB)

Drug resistance in TB is a man-made amplification of a natural phenomenon. Multi-drug resistant TB is caused by strains of the TB bacteria resistant to at least the two most effective anti-TB drugs available, namely Isoniazid and Rifampicin. The most common cause of MDR-TB is lack of a properly organised system to ensure effective treatment. Studies with representative sampling have shown that MDR-TB in India is less than 3% in previously untreated patients. One of the purposes of RNTCP is to prevent MDR-TB. Directly observed treatment and the DOTS strategy, if adopted properly, is an effective way to prevent MDR-TB.

If a patient is suspected to have MDR-TB (failure of CAT II), (s)he should be referred to a competent laboratory. Diagnosis of MDR-TB cannot be made on clinical grounds and is dependant on sputum culture and sensitivity testing at a specialised laboratory. Unfortunately in our country, there is a paucity of such specialised laboratories. However, RNTCP has plans for establishing one such quality assured laboratory in each major State. Further management of the patient should be based on quality assured culture and sensitivity results and using second line drug regimens. MDR-TB may require 18-24 months of treatment with medicines that are up to 100 times more expensive than first line ant-TB treatment. These drugs are highly toxic and treatment success rate is lower.

The best way to prevent MDR-TB is to ensure the provision of effective regimens of short-course treatment with first-line drugs, under observation, to all newly diagnosed TB cases. RNTCP plans to provide second line drugs under the **DOTS Plus** strategy. However, the current priority is nation-wide DOTS expansion and improvement of the quality of DOTS.

6. RECORDING AND REPORTING

The recording and reporting system is used to systematically evaluate patients' progress and treatment outcome, as well as overall programme performance. **The programme is responsible for monitoring and reporting the outcome of each and every patient started on treatment, without exceptions.**

Recording and referral tools required in the RNTCP

Tuberculosis Laboratory Register: This is kept at the RNTCP Designated Microscopy Centres. It is used by the Laboratory Technician who fills all information concerning the patient who is referred for sputum microscopy. The results of the sputum smear examinations are entered in this register.

Tuberculosis Treatment Card: Each patient under treatment has a treatment card that is kept in the peripheral health unit responsible for the treatment of the patient. Duplicate treatment cards are also maintained by the health functionaries or volunteers who administer the patient's DOT. The information in these cards should be kept updated periodically and accurately. After completion of treatment, these cards should be kept at the TU.

Tuberculosis Register: This register is kept at the TU. It is maintained by the STS and contains information regarding a patient from the beginning of his/her treatment till his/her declared outcome.

Laboratory form for sputum examination: These are kept at all referring centres and are used for referring patients for sputum smear microscopy.

Patient Identity card: This is issued to all patients. It records the patient's address, the TB number, result of diagnosis, treatment progress and drug intake.

Documentation of drugs, lab consumables and other materials received should be carefully carried out and well maintained. A monthly report is to be generated by the participating medical practitioner/hospital, (see Annexure 5). This report is called the PHI level monthly report on programme management, logistics and microscopy. All Peripheral Health Institutions (PHIs) are required to complete this report. However, the latter section of the report is meant only for the Designated Microscopy Centres. This report contains information on drug position, staff position and their training status, referral activities, microscopy activities, treatment initiation, consumables position and status of microscopes at the PHI level. This report is to be prepared after physical verification of stock on the last working day of the month by the Medical Officer of the PHI, with the assistance of her/his staff. The report has to be sent to the CDHO/CDMO, with a copy to the TB Unit, on or before the 5th of the next month.

The responsibilities for recording and reporting of the various activities in a medical practitioner's facility can be as follows:

Activity	Responsible Provider	
	PP's clinic/PHI	RNTCP Staff
• Filling referrals for diagnosis (laboratory form for sputum examination)* • Filling referral for treatment form**	✓ (medical practitioner)	
• Entries in laboratory register	✓ (Lab. Tech. if it is a DMC)	✓ (Lab. Tech. of public sector DMC)
• Categorisation of patients • Treatment card# preparation	✓ ✓	
• Maintenance of treatment cards# • Address verification • Default retrieval	✓ (DOT provider) ✓ ✓	 ✓ ✓
• Recording in TB register		✓
• Monthly reports@ Drugs Microscopy activities Patient referral & treatment	 ✓ ✓ ✓	
• Quarterly reports		✓

* Annexure 1; ** Annexure 2; # Annexure 3; @ Annexure 5

7. LOGISTICS MANAGEMENT

The effective management of TB requires an adequate supply of drugs (in patient – wise boxes), treatment related supplies such as syringes and needles, sputum containers, slides, reagents and other laboratory consumables, forms and registers. All these supplies, except forms and registers, should be indented for each month. Registers and forms should be indented annually.

The Senior Treatment Supervisor (STS) and the Senior Tuberculosis Laboratory Supervisor (STLS) of the concerned TUs should be appraised of any impending shortages of material so as to prevent any disturbance in the running of the programme. Health providers should maintain reserve stocks of drugs and materials according to their requirement, so as to prevent expiry or wastage. An effective equation to use while ordering for material is:

Stock Ordered = (Actual Requirement + Reserve Stock) – Existing Stock

The nature of supplies required depends on the level of involvement of the health facility in RNTCP, e.g. PHIs with DMCs are supplied both lab consumables and drugs, PHIs without DMCs are only supplied drugs. Health facilities functioning as DOT centres will have no stock of drugs, but PWBs or loose drugs will be supplied to them from the concerned PHI whenever a patient is initiated on treatment at that DOT Centre. The prompt supply of drugs to the DOT centre as and when required (when a patient is initiated on treatment) is very important for early start of treatment.

It is important to store the supplies appropriately. They should be accessible and kept in places with the necessary civil amenities (such as electricity, communication, water, drainage, etc.). The store should be secure and protected from direct heat, light, moisture, dust, pests and fire. The store should also be large enough to accommodate the materials that need to be stored. It should be easy to maintain and have good ventilation.

The principle of **FEFO** (First Expired, First Out) should always be observed. The drugs kept in a store may have different dates of expiry. The principle is that those drugs with less time for expiry should be used first.

Points to Remember

- *Ensure adequate stock of supplies, but avoid overstocking*
- *The RNTCP staff should be informed of impending shortages*
- *Observe FEFO*

8. SUPERVISION AND MONITORING

Formal supervision and monitoring will be carried out by RNTCP staff. As far as RNTCP is concerned, referring units, microscopy centres and DOT centres in the private, non-government or corporate sector are treated at par with the equivalent government health facilities.

Supervision: Supervisory staff such as the STS and STLS should visit all participating PHIs at least once a month. In addition, the MO-TC and the DTO would also visit all sites on a periodic basis. The purpose of these visits is to provide technical support, identify problems faced by the individual provider and to help solve them. This type of supportive supervision from the RNTCP would help to improve the quality of the programme.

It is important that the medical practitioner supervises his/her own personnel who are involved in the various aspects of the programme in order to ensure that they are carrying out their tasks correctly. Stores should be periodically supervised to ensure adequate supply, and to avoid expiry of, or damage to, drugs and other materials. Patients should also be interviewed to ascertain that they are being treated as per RNTCP guidelines and have understood the health education information given to them.

Monitoring: There are two important ways to monitor the progress of TB patients on treatment. These are:

1. To monitor the results of sputum smear examinations at regular intervals during treatment (as explained earlier in this book)
2. To monitor the consumption and collection of drugs by the patient to ensure that these are taken and collected as per protocol (also explained earlier)

The best way to monitor progress of treatment of pulmonary smear-positive patients is to check for the smear conversion of their sputum. It is expected that at least eighty percent of new smear-positive patients will convert (become sputum smear-negative) by the end of two months of treatment. At the end of three months, more than ninety percent of such patients could be expected to have converted.

Points to Remember

- *Supervision and monitoring are the responsibility of the RNTCP staff*
- *Interview your patients regularly*
- *Monitoring of treatment is best done by regular follow up sputum examination*

Appendix 1: Tuberculosis in children

TB in children represents 5-15 % of all TB cases and **DOTS is the recommended strategy** for children with TB. All children diagnosed to have TB need to be registered under the RNTCP and should be given intermittent short-course chemotherapy under direct observation as per RNTCP/IAP (Indian Academy of Paediatrics) policy. All Paediatric TB cases should be covered under the programme and the following recommendations should be implemented

Diagnosis

Younger children with pulmonary TB rarely cough out sputum as they usually swallow it. Diagnosis of pulmonary TB by sputum microscopy is therefore very unlikely among smaller children. Gastric lavage or laryngeal swabs are difficult to carry out. Bacteriological confirmation is not possible in most cases.

Children will be suspected of having pulmonary TB if they present with fever and/or cough for more than 3 weeks, with or without weight loss or no weight gain. TB should also be suspected if there is a history of contact with a suspected or diagnosed case of active TB disease in the last 2 years. Diagnosis of TB in children should be based on a combination of clinical presentation, sputum examination (wherever possible), chest X ray, Mantoux test and history of contact.

Treatment

Intermittent short-course chemotherapy given under direct observation as for adult patients should be used in children.

To assist in

calculating required dosages and administration of anti-TB drugs for children, the programme would make available drugs in the form of 'combipacks' in patient wise-boxes, based on the weight of the children.

TB of **bone and joints** and all spinal TB cases - with or without neurological complications – are classified as seriously ill EP TB. Seriously ill smear negative pulmonary TB patients will also include all forms of pulmonary TB other than primary complex.

For children with **TB Meningitis** on Cat I regimen, the 4 drugs used during intensive phase should be H, R, Z and S (instead of H, R, Z and E) as Ethambutol does not cross the blood-brain barrier easily. **Steroids** are recommended during the early part of the treatment of TB meningitis, with the doses being tapered off over 6 to 8 weeks. Steroids are also to be used initially and tapered off in a similar manner in cases of **TB pericarditis**.

If available, a Paediatrician or an expert on TB should examine all children who are started on Cat II treatment. There is growing evidence that the use of Ethambutol in young children is safe. This is also recommended by WHO**, Ethambutol is to be used as per RNTCP regimens for all age groups.**

Chemoprophylaxis

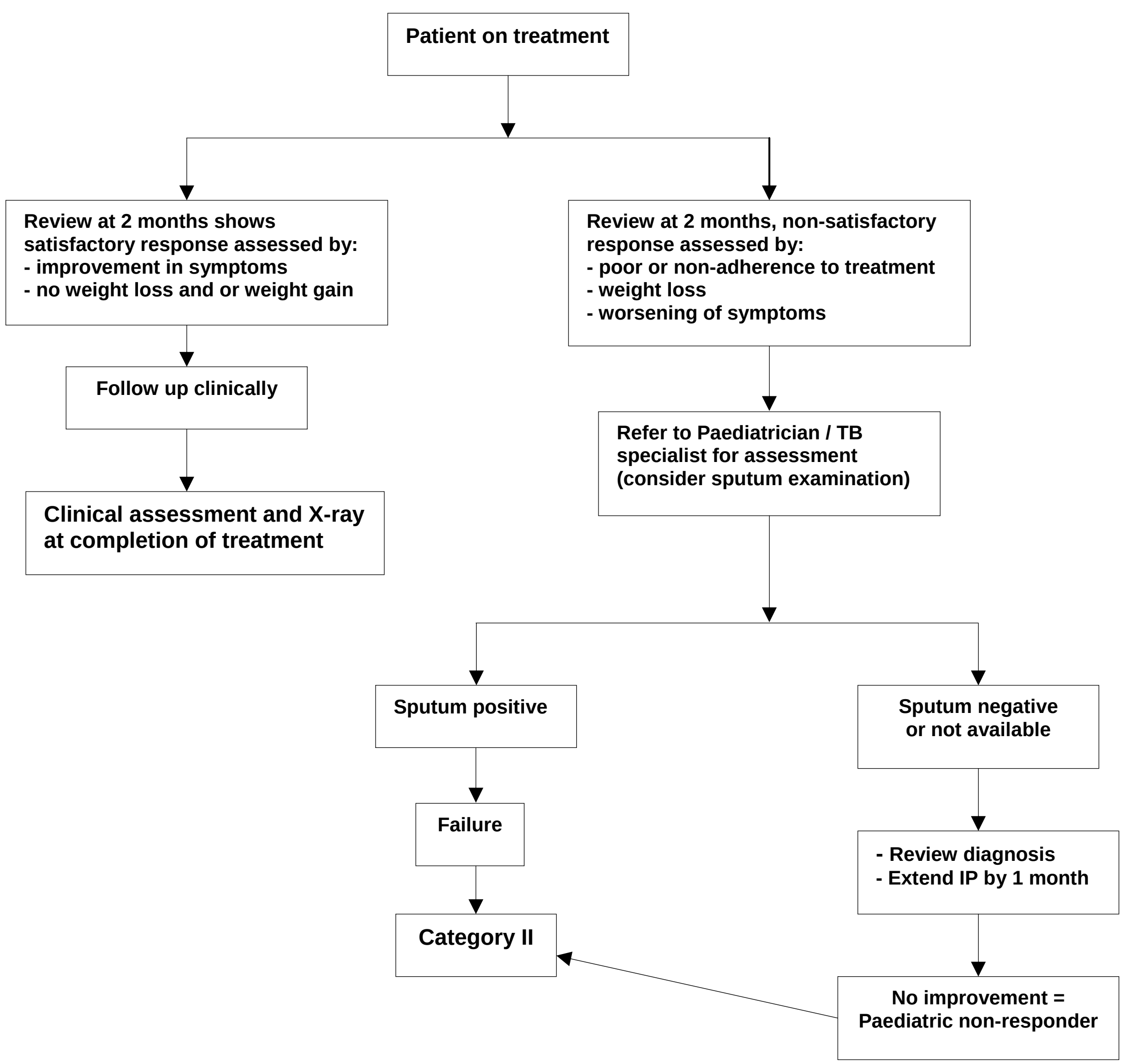
Asymptomatic children under 6 years of age, exposed to a patient with infectious (smear-positive) TB from the same household, need to be given 6 months of daily Isoniazid (5 mg per kg) as chemoprophylaxis against the disease.

.

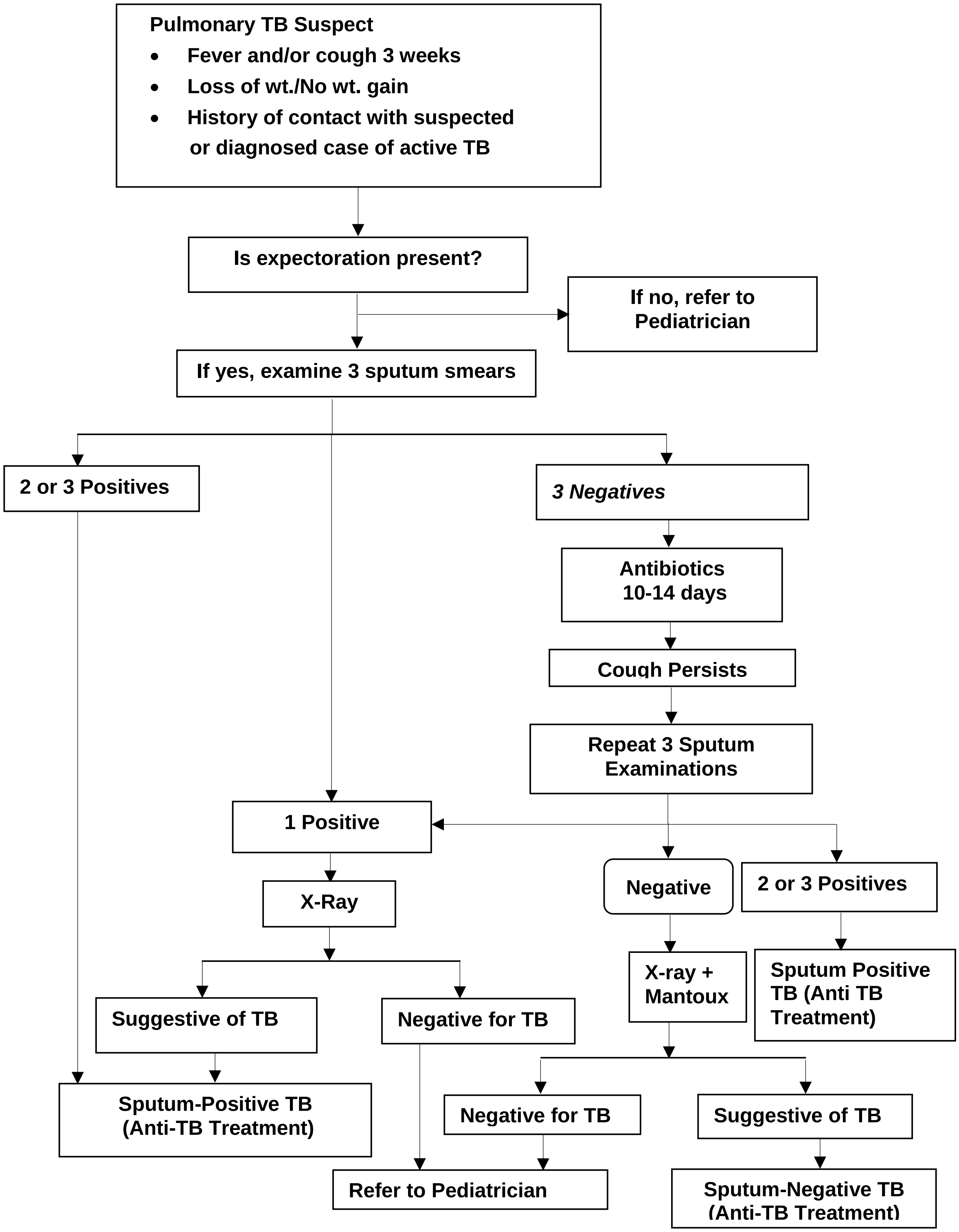
Monitoring and Evaluation

Wherever possible, follow-up sputum examination is to be performed with the same frequency as in adults. Since this may not be possible for the majority of children with pulmonary TB, clinical or symptomatic improvement is to be assessed at the end of the intensive phase of treatment and at the end of treatment. Improvement should be judged by absence of fever or cough, a decrease in the size of lymph node(s), weight gain, etc. Radiological improvement is to be assessed by a chest X-ray in all smear-negative pulmonary TB cases at the end of treatment.

Algorithm for clinical monitoring



Diagnostic Algorithm for Pediatric Tuberculosis



Recommended Paediatric Regimens and Drug Dosages

Treatment Category	Type of Patients	Treatment Regimen***	
		IP	CP
Category I	New sputum smear-positive PTB New sputum smear-negative PTB, seriously ill* New extra-PTB, seriously ill*	$2(H_3R_3Z_3E_3)$***	$4(H_3R_3)$
Category II	Sputum smear-positive relapse Sputum smear-positive treatment failure Sputum smear-positive treatment after default	$2(H_3R_3Z_3E_3S_3)$ + $1(H_3R_3Z_3E_3)$	$5(H_3R_3E_3)$
Category III	New sputum smear-negative, not seriously ill** New extra-PTB, not seriously ill**	$2(H_3R_3Z_3)$	$4(H_3R_3)$

* *In children, seriously ill sputum smear-negative pulmonary TB includes all forms of sputum smear negative pTB other than primary complex. Seriously ill EP TB includes TB meningitis (TBM), disseminated TB, TB pericarditis, TB peritonitis and intestinal TB, bilateral extensive pleurisy, spinal TB with or without neurological complications, genito-urinary TB, and bone and joint TB.*

** *Not seriously ill sputum smear negative PTB includes primary complex. Not seriously ill EP TB includes lymph node TB and unilateral pleural effusion.*

*** *Prefix indicates the number of months of that section of the treatment and the subscript after the letters indicates the number of doses each week*

Drugs	**Dosage** (three times a week)
Isoniazid	10–15 mg/kg
Rifampicin	10 mg/kg
Pyrazinamide	30-35 mg/kg
Ethambutol	30 mg/kg
Streptomycin	15 mg/kg

Appendix 2: TB Treatment in HIV infected patients

People co-infected with HIV and TB have a higher risk of developing TB disease. Irrespective of HIV status RNTCP diagnostic algorithm should be followed for all TB suspects. Anti-TB treatment is the same for HIV-infected persons as it is for HIV-negative TB patients. Hence they should be treated with RNTCP regimens. All new TB cases known to be HIV positive are classified as seriously ill and treated with Category I regimen. The re-treatment cases are to be treated with Category II regimen.

It is important to maintain confidentiality regarding HIV status of individuals including TB suspects and patients, in order to prevent stigmatization and discrimination. TB patients should be encouraged to voluntarily share their HIV status with the treating physician for the purpose of taking clinical decisions like categorization for treatment of TB, treatment of other opportunistic infections and provision of ART. The HIV-positive status should not be disclosed by the treating physician to any other staff involved in RNTCP. In addition, the HIV-positive status should not be mentioned in any RNTCP records.

TB patients who have other HIV-associated opportunistic infections, or report risk behaviour for HIV, should be offered referral to the nearest Voluntary Counseling and Testing Centre (VCTC) for voluntary counseling and HIV testing. Routine HIV testing of all TB suspects/patients is NOT the national policy.

DOTS in TB-HIV

Directly observed treatment with effective short-course treatment regimen is even more important for HIV-positive TB patients. Self-administration of treatment is associated with higher case fatality rates. Hence a DOT strategy that ensures adherence to therapy should be used for all HIV-positive TB patients.

The relapse rate of TB in HIV-positive TB patients who complete directly observed treatment with short-course regimen is low, although slightly higher than in HIV-negative TB patients. However, this increase is more likely to be due to re-infections rather than true relapse of disease. Treatment interruptions, due to higher occurrence of adverse drug reactions or inter-current opportunistic infections, could also lead to an increased risk of relapse of TB.

Anti tuberculosis therapy and antiretroviral therapy (ART)

The antiretroviral drugs, which are used in HIV-positive patients, are effective in slowing down the progress of HIV disease and prolonging life. These drugs are grouped as follows.

- Nucleoside reverse transcriptase inhibitors (NsRTI)
- Non-nucleoside reverse transcriptase inhibitors (NNRTI)
- Nucleotide reverse transcriptase inhibitors (NRTI)
- Protease inhibitors (PI) and fusion inhibitors

The current recommendations on ART are to use a triple drug combination. A combination of, Stavudine/Zidovudine plus lamivudine plus Efavirenz/Nevirapine is usually used. (For details refer to National AIDS Control Organization guidelines).

Protease inhibitors and non-nucleoside reverse transcriptase inhibitors may inhibit or induce cytochrome P-450 isoenzymes and thus alter the serum concentration of Rifamycins. Rifamycins induce cytochrome P-450 and substantially decrease blood levels of these antiretroviral drugs. Dose adjustments for Nevirapine co-administered with Rifampicin has not been established. Hence, co-administration of Rifampicin with any of the protease inhibitors (Ritonavir, Indinavir, Nelfinavir) or non-nucleoside reverse transcriptase inhibitors (Nevirapine) should be avoided.

All TB patients co-infected with HIV should be treated with a Rifampicin containing treatment regimen under DOTS. In TB patients co-infected with HIV, TB treatment should be completed prior to starting ART, unless there is a high risk of HIV disease progression and death during the period of TB treatment (i.e., a CD4 count <200/mm3 or the presence of disseminated TB). In a patient who has been on treatment with Rifampicin, at least 2 weeks should have elapsed after the last dose of Rifampicin before starting protease inhibitor or non-nucleoside reverse transcriptase inhibitors. This time gap is necessary for reduction of the enzyme inducing activity of Rifampicin prior to commencement of antiretroviral drugs.

In patients with very low CD4 counts requiring concomitant administration of ART and anti-TB treatment, the ARV regimen should be modified by replacing Nevirapine with Efavirenz. On completion of TB treatment such patients can be switched back to Nevirapine.

Failure to use DOTS in the face of HIV can lead to a rapid spread of TB.

Appendix 3: Extra Pulmonary Tuberculosis

Extra pulmonary TB comprises of about 10% to 15% of all TB cases in India. The lesions are usually paucibacillary and therefore easy to treat. They occur in all age groups and the incidence is higher in children. They can involve almost any organ and their clinical manifestations are variable. Among patients with EP TB, 75% have lymph node or pleural TB. Certain risk factors increase the chances of EP TB. These include HIV infection with a low CD4 count (< 250). Other risk factors include immuno-suppression due to other causes, chronic renal disease and bone-marrow transplantation. EP TB may mimic inflammatory and neoplastic conditions.

Diagnosis

A high degree of clinical suspicion is a pre-requisite when a patient presents with suggestive symptoms. There is no inexpensive, rapid, non-invasive screening test available for diagnosis. AFB smears and culture examination of tissues and aspirated fluid are diagnostic, if positive. So are positive histopathological examinations from fine needle aspirates or open biopsy samples.

The polymerase chain reaction (PCR) test is a newer nucleic acid amplification diagnostic method. It is highly sensitive although there is high false positivity due to contamination. It is expensive and requires a high level of technical expertise. Interpretation of PCR should be done with caution in clinical settings as it is still in the developmental stage.

Treatment

Short-course chemotherapy (6 to 9 months) has proven effective for spinal, lymph node, meningeal, pleural and abdominal forms of TB. Intermittent regimens are as effective as daily ones. Supplementation of treatment with steroids is indicated in cases of neural TB (including TB meningitis), TB pericarditis, and massive pleural effusion.

Challenges in EP tuberculosis

The clinical onset of EP TB may be acute, chronic or insidious. The resources for diagnosis are limited and expensive. Diagnosis, when based on clinical findings, could lead to over or under treatment. Delay in diagnosis could increase life-threatening complications or could even be fatal. On the other hand, empirical treatment would (if the patient is falsely diagnosed) be a waste of drugs and harmful to the patient. Cure is difficult to define as there are no criteria to go by at the end of a course of treatment.

Management of TB lymph node

This is the commonest form of EP TB. Diagnostic sensitivity of TB lymph node by aspirate and smear for AFB is 70%. Studies have shown that short course intermittent chemotherapy is effective in treating this condition. Some patients on treatment may show increase in the size of glands, appearance of fresh glands or sinus formation during the course of ATT. This does not warrant any increase in duration of treatment.

Diagnostic algorithm for TB lymphadenitis

Lymph node enlargement of > 2 cm in one or more sites, with or without periadenitis, with or without evidence of TB elsewhere; or presence of an abscess with or without a discharging sinus

↓

Prescribe a course of antibiotics for two weeks

↓

If lymph node enlargement persists, suspect TB lymphadenitis

↓

Pus from discharging sinus/aspirate from lymph node using Fine Needle Aspiration Cytology (FNAC)

Smear examination for AFB (using pus/aspirate) by Ziehl Neelsen's method

In addition, Mantoux test for children < 12 years

↓

Diagnosis confirmed if the pus/aspirate from FNAC shows:

1. ZN stain +ve for AFB, or
2. Granulomatous changes

→ Start CAT III treatment

↓

If FNAC results are inconclusive, excision biopsy is advisable for smear and histopathological examination

Management of pleural effusion

Patients presenting with chest pain with or without difficulty in breathing for more than two weeks should be referred for chest radiograph. Constitutional symptoms like fever, anorexia, loss of appetite may be present but not invariably. If the chest X-ray shows blunting of the costophrenic angle(s), a sign suggestive of pleural effusion, the patient should be started on Category III. Pleural aspiration for biochemical, cytological and smear examination by Z-N stain is an additional aid in confirming the diagnosis. Pleural fluid is generally an exudate with mainly lymphocytes and few mesothelial cells. Pleural biopsy is confirmatory in a high proportion of patients. Massive and bilateral effusions are classified as seriously ill forms of extra-pulmonary TB and treated with Category I regimen. Steroids can be used in addition to anti-TB treatment in such cases.

Management of TB spine

Ambulatory (outpatient) chemotherapy has had a 96% success rate in the treatment of TB spine. Chemotherapy alone is effective in the majority of patients and surgery is limited to patients with neurological complications or those with 3 or more vertebrae involved.

Observations on Skeletal TB

A study done at TRC on skeletal TB found that they constituted 11% of all EP TB patients and 2% of all TB patients. It is higher among children in developing countries, while it is a disease affecting the elderly in developed countries.

The commonest site for skeletal TB is the spine (40%). This is followed by TB of the hips (13%) and knees (10%). In the absence of neurological complications, skeletal TB can be effectively treated with six months of SCC. There is no role for surgery on a routine basis.

Appendix 4: Infection Control in RNTCP

There is the risk of transmission of TB infection occurring in health care facilities when patients remain undiagnosed and untreated for TB. This may be curtailed by early diagnosis and immediate initiation and adherence to RNTCP treatment regimens. This prompt and timely action will make infectious TB patients rapidly non-infectious.

It is now mandatory that any Infection Control plan of the facility should include infection control for TB and TB/ HIV. Broadly, infection control needs to be addressed at three different levels: **administrative, environmental and personal**.

Administrative control normally relies on the extent of complete implementation of RNTCP diagnostic and treatment guidelines in the health care facility. TB infection control plan includes the following:

- Giving priority to patients with cough for clinical and laboratory investigations so as to enable early detection of smear-positive pulmonary TB patients
- Reducing delay in starting appropriate RNTCP treatment once diagnosed
- Avoiding unnecessary admission for inpatient care
- Assessment of health care workers training needs and requirements under RNTCP

Sputum collection should ideally be done outside the facility and away from other people. It should not be done in closed areas such as toilets and in ill-ventilated rooms. Processing specimens for smear microscopy (after sputum collection) has not been documented to cause any increased risk to laboratory personnel. However, TB suspects amongst health care workers should be subjected to screening procedures.

Another priority is environmental control, which is used to reduce the generation and concentration of droplet nuclei in the air in high-risk areas. High-risk areas that increase transmission include relatively small, enclosed rooms in health facilities, which lack adequate cross ventilation in the form of open windows and doors to “clean” the environment through dilution or removal of infectious droplet nuclei. Hence, the TB IEC plan should also include educating the patients regarding cough, hygiene (covering the face while coughing and avoiding indiscriminate spitting), frequent identification of risk areas within the facility and providing good cross-ventilation to these areas.

Wearing of surgical or other masks for personal protection does not protect personnel from inhaling the droplet aerosols and hence is not recommended as a means to prevent hospital infection. As mentioned above, early identification and prompt initiation of RNTCP treatment under direct observation would protect all health care workers from hospital TB infection.

An Infection control plan for TB-HIV may include precautions to be observed for HIV, in addition to those observed for TB, especially when streptomycin injections are being given. The risk of acquiring HIV following percutaneous exposure (needle stick/

needle prick with inoculation) from an HIV-positive source is extremely low: 0.25-0.3%. This is because the concentration of HIV in peripheral blood is extremely low (104 infectious virions/ml). On the other hand, the risk of acquiring the hepatitis ‘B’ virus (HBV) following similar exposure ranges from 9-30% because the concentration of HBV in peripheral blood is high (>10,000,000 infectious doses /ml). The chance of acquiring Hepatitis C is approximately 3-10%. Disposable or adequately sterilised needles and syringes should be used for streptomycin injection. Following streptomycin injection needles should be destroyed using needle cutters or destroyers, wherever available. Needles and syringes should be disposed using prevailing hospital waste management system. Health care workers can effectively prevent infections acquired through contaminated blood by the adoption of “Universal Precautions” or “Bio-safety Precautions”.

The key to reducing the risk of tuberculosis transmission at health facilities is early diagnosis and prompt initiation of RNTCP treatment regimens until cure. Infectious TB patients become rapidly non-infectious once they are started on directly observed treatment under RNTCP.

Appendix 5: Solutions to Exercises

Exercise I:
PART A:

A: Meena Patel

Answer:

a. Suspect pulmonary TB
b. Refer to a designated microscopy center convenient to the patient for sputum microscopy with a properly completed laboratory form

B. Lakshmi Kumari

Answer:

a. Suspect pulmonary TB
b. Refer to a designated microscopy center convenient to the patient for sputum microscopy with a properly completed laboratory form

C. Ashok Patel

Answer:

a. Suspect pulmonary TB
b. Refer to a designated microscopy center convenient to the patient for sputum microscopy with a properly completed laboratory form (Symptomatic contacts of sputum smear-positive pulmonary TB patients should undergo sputum examination irrespective of the duration of symptoms)

D. Paravathi Sinha

Answer:

a. Suspect lymph node TB.
b. Refer the patient for lymph node biopsy/FNAC and for expert opinion

E. Lallan Prasad

Answer :

a. Suspect pulmonary TB
b. Refer to a designated microscopy center convenient to the patient for sputum microscopy with a properly completed laboratory form

PART B: (See Completed Laboratory Forms)

PART C: (See the laboratory register)

Exercise II:

Part A:

Patient A:

New sputum smear-positive pulmonary TB – CAT I

Patient B:

Retreatment – Sputum smear-positive pulmonary TB; Treatment after Default – CAT II

Patient C:

Patient treated with broad-spectrum antibiotic for 10-14 days and reassessed

Patient D:

Patient treated as EP, not seriously ill patient – CAT III

Patient E:

Patient treated as Pulmonary Sputum smear-negative – CAT III.

Part B: (See the completed treatment card)

Appendix 6: Zeihl Neelsen Staining

1. Select a new unscratched slide and label it with the laboratory serial number using a diamond marking pencil.
2. Make a smear from the yellow muco-purulent portion of the sputum sample using a broomstick. A good smear is spread evenly, is about 2 cm x 2 cm in size and is neither too thick not thin. The optimum thickness of the smear can be assessed by placing the smear on printed matter. The print should be just readable through the smear.
3. Allow the slide to dry in air for 15 to 30 minutes.
4. Fix the slide by passing it over a flame 3 to 5 times, for 3 to 4 seconds each time.
5. Pour 1% filtered carbol fuchsin to cover the entire slide.
6. Gently heat the slide with the carbol fuchsin on it, until vapours rise. Do not allow it to boil.
7. Leave carbol fuchsin on the slide for 5 minutes.
8. Gently rinse the slide with tap-water until all the free carbol fuchsin stain is washed away. At this point, the smear on the slide looks red in colour.
9. Pour 25% sulphuric acid onto the slide.
10. Let the slide stand for 2 to 4 minutes.
11. Rinse gently with tap-water, then tilt the slide to drain off the water.
12. A properly decolourised slide will appear light pink in colour. If the slide is still red, reapply sulphuric acid for 1 to 3 minutes and rinse gently with tap-water. Wipe the back of the slide clean with a swab dipped in sulphuric acid.
13. Pour 0.1% methylene blue onto the slide.
14. Leave the methylene blue on the slide for 30 seconds.
15. Rinse gently with tap-water.
16. Allow the slide to dry.
17. Examine the slide under the microscope using the x40 lens to select a suitable area and then examine this area under the x100 lens using a drop of immersion oil.
18. Record the results in the laboratory form and also in the laboratory register.
19. Store all positive and negative slides serially in the same slide-box until instructed by the supervisor.
20. Disinfect all the contaminated material before discarding.

Appendix 7: References

1. Managing the Revised National Tuberculosis Control Programme in Your Area- A Training Course, Modules (1-9), Central TB Division.
2. Technical and Operational Guidelines for tuberculosis Control, Central TB Division.
3. TB India 2005- RNTCP Status Report, Central TB Division.
4. Joint Tuberculosis Programme Review, India, September 2003, World Health Organisation.
5. Toman's Tuberculosis, Second Edition.
6. TB- A Clinical Manual for South-East Asia, World Health Organisation, 1997.
7. Key Concepts of RNTCP, Central TB Division.
8. Treatment Guidelines for TB in HIV infected, NACO and Central TB Division.
9. Global Tuberculosis Control, Surveillance, Planning, Financing, WHO Report 2005.

Annexure – 1

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Laboratory Form for Sputum Examination

Name of Referring Health Facility: ____________________ Date: ___________
Name of patient: ______________________________ Age: ____ Sex: M ❑ F ❑
Complete address: ____
____
Type of suspect / disease: ❑ Pulmonary
❑ Extra-pulmonary Site: ______________
Reason for examination:
❑ Diagnosis
❑ Repeat Examination for Diagnosis
❑ Follow-up of anti-TB treatment Patient's TB No ____________

(Name and signature of referring person/ official)

If sputum sample are being transported:
Specimen identification No.: __________ Date of sputum collection: __________
Specimen Collector's name and signature ______________________________

RESULTS (To be completed in the laboratory of DMC)
Name of DMC: ____
Lab. Serial No.: ____

Date of examination	Specimen	Visual appearance (M, B, S)*	Results (Neg or Pos)	Positive (grading)			
				3+	2+	1+	Scanty**
	a						
	b						
	c						

* M = Mucopurulent, B = Blood stained, S = Saliva
** Write actual count of AFB seen in 100 oil immersion fields
Date: ______________ Examined by (signature): _____________________

The completed form (with results) should be sent to the referring PHI within one day of the examination.

Annexure – 2

Form A **Serial Number**

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Referral for treatment form

(Fill in triplicate. send one to the respective DTO receiving the patient [Form A], send one copy to the health facility where the patient is referred to [Form B], and give one copy to the patient [Form C])

Name and address of referring health facility______________________________________

____

Name of health facility to which patient is referred__________________________________

____

Name of patient _____________________ **Age** _____________ **Sex M F**
Complete Address ____

____

Disease Classification
- ☐ Pulmonary
- ☐ Extra-Pulmonary
- ☐ Site

Category of Treatment
- ☐ Category I
- ☐ Category II
- ☐ Category III

Type of patient
- ☐ New ☐ Relapse
- ☐ Failure ☐ Treatment after default
- ☐ Other (specify)

Sputum Status

Date Month Year

Result
Laboratory number
Name of Laboratory
Relevant examination for smear negative/Extra pulmonary cases

Remarks

Signature

Date referred **Designation**

-----------------✂---✂---

Form A Serial Number_____________

For use by the health facility where the patient has been referred

Name of patient_________________________ TB no. (if available)___________
Age Sex M☐ F☐ Date of referral
Name of receiving health facility _________________ Name of TB Unit and District _________________
The above-named reported at this facility on ________ and has been put on treatment on____________
Signature _________________ Designation ________________________ Date _________________

(Send this part back to the referring unit as soon as the patient has reported has been initiated on RNTCP treatment.)

Annexure – 3

Revised National Tuberculosis Control Programme
Treatment Card

State ______________ City / District with code___________________ Name of TB Unit with Code__________________________________
Name ____________________ Patient TB No / Year:______________________________
Sex M ☐ F ☐ Age _______ Occupation ___________________ PHI: ____
Complete Address____ Name and designation of DOT provider________________
____
DOT center___________________________________
Name and Address of Contact Person ______________________________ Signature of MO with date_________________________
____

Initial home visit by ___________ Date____________

Disease Classification
☐ Pulmonary
☐ Extra Pulmonary
site________________

Type of patient
☐ New
☐ Transfer in
☐ Treatment after default
☐ Relapse
☐ Failure
☐ Other(Specify)_________

Month	Date	DMC	Lab No.	Smear Result	Weight
Pretreatment					
End IP/Extended IP					
2 Months CP					
End treatment					

H/o previous Anti-TB treatment with duration ____________________________________

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

Category ☐
New Case
(Pulmonary Smear-Positive,
Seriously ill Smear Negative, or
Seriously ill extra pulmonary)

3 times / week

H	R	Z	E

Category II ☐
Retreatment,
(relapses, failure,
treatment after
default, others)

3 times / week

H	R	Z	E	S

Category III ☐
New Case
(Pulmonary Smear 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

II Continuation Phase

Prescribed regimen and Dosages

Category I ☐ 3 times / week ☐ ☐ H R

Category II ☐ 3 times / week ☐ ☐ ☐ H R E

Category III ☐ 3 times / week ☐ ☐ H R

Enter X on date when the first dose of drugs has been swallowed under direct observation and draw a horizontal line (x_______________) to indicate the period during which medicines will be self administrated.

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

Treatment out come with date ________

Details of X ray / EP tests

Contacts (Children < 6 yrs)

No	Chemoprophylaxis

Remarks

____

____

____

____

____

____

____

____

____

Retrieval actions for missed doses

Date and time	By whom	Whom contacted	Reason for missed doses	Outcome of retrieval

Annexure – 4

Tuberculosis Identity Card

Front

Revised National
Tuberculosis Control Programme
IDENTITY CARD

Name of Patient: ________________________

Complete address:______________________

____

TU / district name ___________________

____________________________**Ph**________

Sex: M ☐ F ☐ Age:_____ **TB No.**_________

PHI:_____________

Disease Classification
☐ Pulmonary
☐ Extra-pulmonary
Site:______

Treatment Started on

Date Month Year

Type of Patient

- New
- Relapse
- Treatment after default
- Failure
- Transfer In
- Other-Specify _______ ____________________

Category of Treatment

☐ Category I
☐ Category II
☐ Category III

Back

Follow up sputum examination

Time point	Date	Lab No.	Result
Pretreatment			
End of IP/extended IP			
2 months in CP			
End of treatment			

Appointment dates

IP	CP
____________	____________
____________	____________
____________	____________
____________	____________
____________	____________
____________	____________

Treatment outcome with date:

Signature and stamp of MO with date: __________

REMEMBER

1. Keep your card safely
2. You can be cured if you take treatment as advised.
3. You may infect your near and dear if you do not take your medicines as advised

Annexure – 5

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Monthly Report on Programme Management, Logistics and Microscopy

Peripheral Health Institution Level

Note: All PHCs/ CHCs/ referral hospitals/ major hospitals/ specialty clinics/ TB hospitals/ Medical colleges to submit their monthly reports in this format.

Name of Peripheral Health Institution: ____

TU: ______________________ **District:** __________________

Month: ______________________ **Year:** __________________

Medications

Item	Unit of Measurement	Stock on first day of month (a)	Stock received during month (b)	Patients initiated on treatment (c)	Stock on last day of month (d) =a+b-c	Quantity Requested (e)= (c X 2) – d
Category I	**Boxes**					
Category II	**Boxes**					
Category III	**Boxes**					

Item	Unit of Measurement	Stock on first day of month	Stock received during month	Consumption during month	Stock on last day of month	Quantity Requested
Pouches of blister strips for prolongation of intensive phase	Pouches each with 12 blister strips					
INH 300 mg	Tablets					
INH 100 mg	Tablets					
Streptomycin 0.75 g	Vials					
Rifampicin 150 mg	Capsule					
Pyrazinamide 500	Tablets					
Ethambutol 800 mg	Tablets					

Staff Position and Training

Category of staff	Sanctioned	In place	Trained in RNTCP
Medical Officer			
Laboratory Technician			
Pharmacist			
MPH Supervisors			
Multipurpose Health			
TBHV			
STLS*			

** STLS to be reported by medical colleges only*

Referral Activities (To be filled in by all PHIs from OPD Register)

a	Number of new adult outpatient visits	
b	Out of (a), number of chest symptomatic patients referred for sputum examination	

Microscopy Activities (To be filled in by only PHIs which are a DMC from Laboratory Register)

c	Number of TB suspects whose sputum was examined for diagnosis	
d	Out of (c), number of sputum smear positive patients diagnosed	
e	Number of TB suspects subjected to repeat sputum examination for diagnosis	
f	Out of (e), number of sputum smear positive patients diagnosed	
g	Total number of sputum smear positive patients diagnosed (d + f)	

Treatment Initiation (To be filled in by only PHIs which are a DMC from Laboratory Register and Referral for Treatment Register)

h	Of the smear-positive patients diagnosed (g), number put on DOTS	
i	Of the number of smear-positive patients diagnosed (g), number put on RNTCP Non-DOTS	
J	Of the smear-positive patients diagnosed (g), the number referred for treatment to other TUs within the district	
k.	Of the smear-positive patients diagnosed (g), the number referred for treatment outside the district	

Consumables (To be filled in by only PHIs which are a DMC)

Item	Unit of Measurement	Stock on first day of Month	Stock received during Month	Consumption during Month	Stock on last day of Month	Quantity requested
Sputum	Nos.					
Slides	Nos.					
Carbon Fuchsin	Litres					
Methylene Blue	Litres					
Sulphuric Acid	Litres					
Phenol	Litres					
Immersion Oil	mL					
Methylated Spirit	Litres					

*** PHIs that are not a DMC, but have been supplied with sputum containers should complete this row.**

Equipment in place (To be filled in by only PHIs which are a DMC)

Item	Number in place	In working condition	Not in working condition
Binocular			
Monocular			

Name of officer reporting (in Capital Letters) : ______________________________ .

Signature : ____________________ .

Date : ___________________________ .

Annexure: 6

Table 1: Management of patients who were *smear-negative* at diagnosis and who interrupt treatment

Treatment received before Interruption	Length of interruption	Do a sputum Smear examination	Result of sputum Smear examination	Outcome	Re-registration	Treatment
Less than 1 month	Less than 2 months	No	—	—	—	Resume Treatment and Complete All doses
	2 months or more	Yes	Neg	—	—	Resume Treatment
			Pos	Default	New	Begin CAT I afresh
More than 1 month	Less than 2 months	No	—	—	—	Resume Treatment and Complete All doses
	More than 2 months	Yes	Neg	—	—	Resume Treatment and Complete All doses
			Pos	Default	Treatment After Default	Begin CAT II Treatment afresh

Table 2: Treatment for New smear-positive cases who interrupt treatment (Category I)

Treatment received before interruptio	Length of interruption	Do a sputum Smear examinatio	Result of sputum Smear examinatio	Outcome	Re-registration	Treatment
Less than 1 month	Less than 2 weeks	No	—	—	—	Continue CAT I*
	2-7 weeks	No	—	—	—	Start again on CAT I**
	8 weeks or more	Yes	Positive	Default	New	Start again on CAT I**
			Negative	—	—	Continue CAT I*
1-2 months	Less than 2 weeks	No	—	—	—	Continue CAT I*
	2-7 weeks	Yes	Positive	—	—	1 extra month of intensive phase of CAT I
			Negative	—	—	Continue CAT I*
	8 weeks or more	Yes	Positive	Default	Treatment After Default	Start on CAT II*
			Negative	—	—	Continue CAT I*
More than 2 months	Less than 2 weeks	No	—	—	—	Continue CAT I*
	2-7 weeks	Yes	Positive	Default***	Other	Start on CAT II**
			Negative	—	—	Continue CAT I*
	8 weeks or more	Yes	Positive	Default	Treatment After Default	Start on CAT II**
			Negative	—	—	Continue CAT I*

* A patient must complete all **24 doses** of the initial intensive phase. For example, if a patient has to continue his previous treatment and he took 1 month of treatment (12 doses) before interrupting. He will have to take 1 more month (12 doses) of the intensive phase treatment. The patient will then start the continuation phase of treatment.

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

*** Although this patient does not strictly fit the definition of default. Default most closely describes the outcome of this patient. although at re-registration the patient should be categorised as 'Other'.

Table 3: Treatment for smear-positive retreatment cases who interrupt treatment (Category II)

Treatment received before interruption	Length of interruption	Do a sputum Smear examination ?	Result of sputum Smear examination	Outcome	Re-registration	Treatment
Less than 1 month	Less than 2 weeks	No	—	—	—	Continue CAT II*
	2-7 weeks	No	—	—	—	Start again on CAT II**
	8 weeks or more	Yes	Positive	Default	Treatment After Default	Start again on CAT II**
			Negative	—	—	Continue CAT II*
1-2 months	Less than 2 weeks	No	—	—	—	Continue CAT II*
	2-7 weeks	Yes	Positive	—	—	1 extra month of intensive phase of CAT II
			Negative	—	—	Continue CAT II*
	8 weeks or more	Yes	Positive	Default	Treatment After Default	Start again on CAT II**
			Negative	—	—	Continue CAT II*
More than 2 months	Less than 2 weeks	No	—	—	—	Continue CAT II*
	2-7 weeks	Yes	Positive	Default***	Other	Start again on CAT II**
			Negative	—	—	Continue CAT II*
	8 weeks or more	Yes	Positive	Default	Treatment After Default	Start again on CAT II
			Negative	—	—	Continue CAT II*

* A patient must complete all 36 doses of the initial intensive phase.

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

*** Although this patient does not strictly fit the definition of default. Default most closely describes the outcome of this patient. although at re-registration the patient should be categorised as 'Other'.

Annexure: 7

Instructions for the trainers

Trainees should be: (Criteria for undergoing training)

- Doctors of Modern Medicine
- Willing to participate in RNTCP
- Not trained previously

A Training Package including the following may be provided to the trainees:

- Training Module
- Copies of presentations
- DOT Directory of DMCs and DOT Providers
- Schemes for involvement of NGOs and Private Practitioners
- IEC materials like poster, calendar, brochure,

Presentations:

Day I- May include: Introduction

- Scientific basis of DOTS
- Diagnosis
- Categorisation

Day II- May include: Administering Treatment

- Special Settings
- Recording and Reporting
- Logistics
- Supervision & Monitoring

Posters:

1. Definitions
2. Diagnostic algorithm
3. Regimens

DOTS Directory:

1. Names and addresses with telephone no. of DTC, TU & DMC with working timings with name of contact person
2. List of DOT Centres
3. Addresses of Referring centres
4. Area Map

Annexure: 8

INTERNATIONAL STANDARDS FOR TUBERCULOSIS CARE (ISTC)

ISTC

The international Standards for Tuberculosis Care describes a widely accepted level of care, that all practitioners, public and private, should follow in dealing with people who have, of are suspected of having, tuberculosis. The standards are intended to facilitate the effective engagement of all care providers in delivering high-quality care for patients of all ages, including those with sputum smear-positive, sputum smear-negative, and extra pulmonary tuberculosis; tuberculosis caused by drug-resistant Mycobacterium tuberculosis complex (M. tuberculosis) organisms; and tuberculosis combined with human immunodeficiency virus (HIV) infection.

The ISTC was developed by the Tuberculosis Coalition for Technical Assistance and US Agency for International Development. This document is endorsed by the World Health Organization, Stop TB Partnership, American Thoracic Society, Centres for Disease Control and Prevention (USA), International Union Against Tuberculosis and Lung Disease, and KNCV Tuberculosis Foundation.

ISTC IN THE CONTEXT OF RNTCP

India has contributed to the development of the ISTC. The Indian Medical Association (IMA) was a member in the steering committee which supervised the development of the ISTC. IMA was nominated by the Revised National Tuberculosis Control Programme (RNTCP) of India to the steering committee to represent RNTCP. The RNTCP and the IMA has jointly decided to disseminate the ISTC among all the health care providers in India.

It is expected that after undergoing the training using this module, you have gathered the basic principles of RNTCP and have understood the ways of getting involved in RNTCP. It is imperative that all health care providers in India ensure international standards in the management of TB cases. The RNTCP conforms to all the standards prescribed in the ISTC. In India, practicing RNTCP in its entirety is the only means to ensure that the international standards are observed in the management of TB cases

INTERNATIONAL STANDARDS FOR

Tuberculosis Care

DIAGNOSIS TREATMENT PUBLIC HEALTH

Summary

The purpose of the *International Standards for Tuberculosis Care (ISTC)* is to describe a widely accepted level of care that all practitioners, public and private, should seek to achieve in managing patients who have, or are suspected of having, tuberculosis. The *Standards* are intended to facilitate the effective engagement of all care providers in delivering high-quality care for patients of all ages, including those with sputum smear-positive, sputum smear-negative, and extra pulmonary tuberculosis, tuberculosis caused by drug-resistant *Mycobacterium tuberculosis* complex (*M. tuberculosis*) organisms, and tuberculosis combined with human immunodeficiency virus (HIV) infection.

The basic principles of care for persons with, or suspected of having, tuberculosis are the same worldwide: a diagnosis should be established promptly and accurately; standardized treatment regimens of proven efficacy should be used with appropriate treatment support and supervision; the response to treatment should be monitored; and the essential public health responsibilities must be carried out. Prompt, accurate diagnosis and effective treatment are not only essential for good patient care—they are the key elements in the public health response to tuberculosis and the cornerstone of tuberculosis control. Thus, all providers who undertake evaluation and treatment of patients with tuberculosis must recognize that, not only are they delivering care to an individual, they are assuming an important public health function that entails a high level of responsibility to the community, as well as to the individual patient.

The Standards are intended to facilitate the effective engagement of all care providers in delivering high-quality care for patients of all ages and all forms of TB including drug-resistant TB and TB combined with HIV infection.

Although government tuberculosis program providers are not exempt from adherence to the *Standards*, non-program providers are the main target audience. It should be emphasized, however, that national and local tuberculosis control programs may need to develop policies and procedures that enable non-program providers to adhere to the *Standards*. Such accommodations may be necessary, for example, to facilitate treatment supervision and contact investigations.

In addition to healthcare providers and government tuberculosis programs, both patients and communities are part of the intended audience. Patients are increasingly aware of and expect that their care will measure up to a high standard as described in the *Patients' Charter for Tuberculosis Care*. Having generally agreed-upon standards will empower patients to evaluate the quality of care they are being provided. Good care for individuals with tuberculosis is also in the best interest of the community.

The *Standards* are intended to be complementary to local and national tuberculosis control policies that are consistent with World Health Organization (WHO) recommendations. They are not intended to replace local guidelines and were written to accommodate local differences in practice. They focus on the contribution that good clinical care of individual patients with or suspected of having tuberculosis makes to population-based tuberculosis control. A balanced approach emphasizing both individual patient care and public health principles of disease control is essential to reduce the suffering and economic losses from tuberculosis.

The *Standards* should be viewed as a living document that will be revised as technology, resources, and circumstances change. As written, the *Standards* are presented within a context of what is generally considered to be feasible now or in the near future.

The *Standards* are also intended to serve as a companion to and support for the *Patients' Charter for Tuberculosis Care* developed in tandem with the *Standards*. The *Charter* specifies patients' rights and responsibilities and will serve as a set of standards from the point of view of the patient, defining what the patient should expect from the provider and what the provider should expect from the patient.

Standards for Diagnosis

Standard 1. All persons with otherwise unexplained productive cough lasting two–three weeks or more should be evaluated for tuberculosis.

Standard 2. All patients (adults, adolescents, and children who are capable of producing sputum) suspected of having pulmonary tuberculosis should have at least two, and preferably three, sputum specimens obtained for microscopic examination. When possible, at least one early morning specimen should be obtained.

Standard 3. For all patients (adults, adolescents, and children) suspected of having extrapulmonary tuberculosis, appropriate specimens from the suspected sites of involvement should be obtained for microscopy and, where facilities and resources are available, for culture and histopathological examination.

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

Standard 5. The diagnosis of sputum smear-negative pulmonary tuberculosis should be based on the following criteria: at least three negative sputum smears (including at least one early morning specimen); chest radiography findings consistent with tuberculosis; and lack of response to a trial of broad-spectrum antimicrobial agents. (NOTE: Because the fluoroquinolones are active against *M. tuberculosis complex* and, thus, may cause transient improvement in persons with tuberculosis, they should be avoided.) For such patients, if facilities for culture are available, sputum cultures should be obtained. In persons with known or suspected HIV infection, the diagnostic evaluation should be expedited.

Standard 6. The diagnosis of intrathoracic (i.e., pulmonary, pleural, and mediastinal or hilar lymph node) tuberculosis in symptomatic children with negative sputum smears should be based on the finding of chest radiographic abnormalities consistent with tuberculosis and either a history of exposure to an infectious case or evidence of tuberculosis infection (positive tuberculin skin test or interferon gamma release assay). For such patients, if facilities for culture are available, sputum specimens should be obtained (by expectoration, gastric washings, or induced sputum) for culture.

Standards for Treatment

Standard 7. Any practitioner treating a patient for tuberculosis is assuming an important public health responsibility. To fulfill this responsibility the practitioner must not only prescribe an appropriate regimen but, also, be capable of assessing the adherence of the patient to the regimen and addressing poor adherence when it occurs. By so doing, the provider will be able to ensure adherence to the regimen until treatment is completed.

Standard 8. All patients (including those with HIV infection) who have not been treated previously should receive an internationally accepted first-line treatment regimen using drugs of known bioavailability. The initial phase should consist of two months of isoniazid, rifampicin, pyrazinamide, and ethambutol. The preferred continuation phase consists of isoniazid and rifampicin given for four months. Isoniazid and ethambutol given for six months is an alternative continuation phase regimen that may be used when adherence cannot be assessed, but it is associated with a higher rate of failure and relapse, especially in patients with HIV infection.

The doses of antituberculosis drugs used should conform to international recommendations. Fixed-dose combinations of two (isoniazid and rifampicin, three (isoniazid, rifampicin, and pyrazinamide), and four (isoniazid, rifampicin, pyrazinamide, and ethambutol) drugs are highly recommended, especially when medication ingestion is not observed.

Standard 9. To foster and assess adherence, a patient-centered approach to administration of drug treatment, based on the patient's needs and mutual respect between the patient and the provider, should be developed for all patients. Supervision and support should be gender-sensitive and age-specific and should draw on the full range of recommended interventions and available support services, including patient counseling and education. A central element of the patient-centered strategy is the use of measures to assess and promote adherence to the treatment regimen and to address poor adherence when it occurs. These measures should be tailored to the individual patient's circumstances and be mutually acceptable to the patient and the provider. Such measures may include direct observation of medication ingestion (directly observed therapy—DOT) by a treatment supporter who is acceptable and accountable to the patient and to the health system.

Standard 10. All patients should be monitored for response to therapy, best judged in patients with pulmonary tuberculosis by follow-up sputum microscopy (two specimens) at least at the time of completion of the initial phase of treatment (two months), at five months, and at the end of treatment. Patients who have positive smears during the fifth month of treatment should be considered as treatment failures and have therapy modified appropriately. (See Standards 14 and 15.) In patients with extrapulmonary tuberculosis and in children, the response to treatment is best assessed clinically.

Follow-up radiographic examinations are usually unnecessary and may be misleading.

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

Standard 12. In areas with a high prevalence of HIV infection in the general population and where tuberculosis and HIV infection are likely to co-exist, HIV counseling and testing is indicated for all tuberculosis patients as part of their routine management. In areas with lower prevalence rates of HIV, HIV counseling and testing is indicated for tuberculosis patients with symptoms and/or signs of HIV-related conditions and in tuberculosis patients having a history suggestive of high risk of HIV exposure.

Standard 13. All patients with tuberculosis and HIV infection should be evaluated to determine if antiretroviral therapy is indicated during the course of treatment for tuberculosis. Appropriate arrangements for access to antiretroviral drugs should be made for patients who meet indications for treatment. Given the complexity of co-administration of antituberculosis treatment and antiretroviral therapy, consultation with a physician who is expert in this area is recommended before initiation of concurrent treatment for tuberculosis and HIV infection, regardless of which disease appeared first. However, initiation of treatment for tuberculosis should not be delayed. Patients with tuberculosis and HIV infection should also receive cotrimoxazole as prophylaxis for other infections.

Standard 14. An assessment of the likelihood of drug resistance, based on history of prior treatment, exposure to a possible source case having drug-resistant organisms, and the community prevalence of drug resistance, should be obtained for all patients. Patients who fail treatment and chronic cases should always be assessed for possible drug resistance. For patients in whom drug resistance is considered to be likely, culture and drug susceptibility testing for isoniazid, rifampicin, and ethambutol should be performed promptly.

Standard 15. Patients with tuberculosis caused by drug-resistant (especially multiple-drug resistant [MDR]) organisms should be treated with specialized regimens containing second-line antituberculosis drugs. At least four drugs to which the organisms are known or presumed to be susceptible should be used, and treatment should be given for at least 18 months. Patient-centered measures are required to ensure adherence. Consultation with a provider experienced in treatment of patients with MDR tuberculosis should be obtained.

Standards for Public Health Responsibilities

Standard 16. All providers of care for patients with tuberculosis should ensure that persons (especially children under 5 years of age and persons with HIV infection) who are in close contact with patients who have infectious tuberculosis are evaluated and managed in line with international recommendations. Children under 5 years of age and persons with HIV infection who have been in contact with an infectious case should be evaluated for both latent infection with *M. tuberculosis* and for active tuberculosis.

Standard 17. All providers must report both new and retreatment tuberculosis cases and their treatment outcomes to local public health authorities, in conformance with applicable legal requirements and policies.

Research Needs

As part of the process of developing the *ISTC*, several key areas that require additional research were identified. Systematic reviews and research studies (some of which are underway currently) in these areas are critical to generate evidence to support rational and evidence-based care and control of tuberculosis. Research in these operational and clinical areas serves to complement ongoing efforts focused on developing new tools for tuberculosis control.

NOTES

Training Module

for

Medical Practitioners

Central TB Division
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi 110 011