

Managing the
Revised National Tuberculosis Control Programme
in Your Area

A Training Course

Modules
1-4

- 1 Course Introduction
- 2 Ensuring Identification of Tuberculosis Suspects
- 3 Supporting Laboratory Services
- 4 Administering Treatment

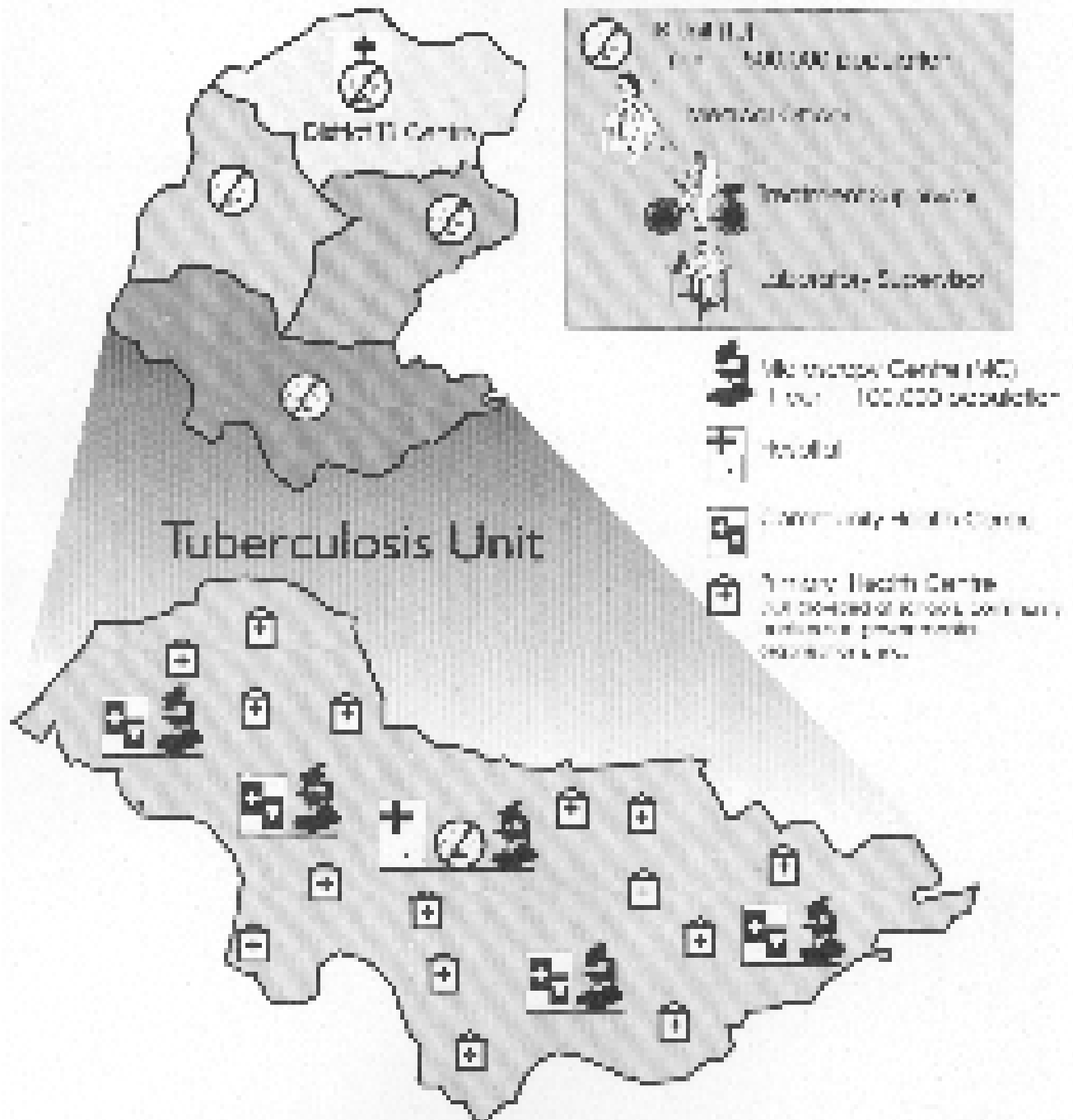


सत्यमेव जयते

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

Model District

Approximate district population
1.9 million



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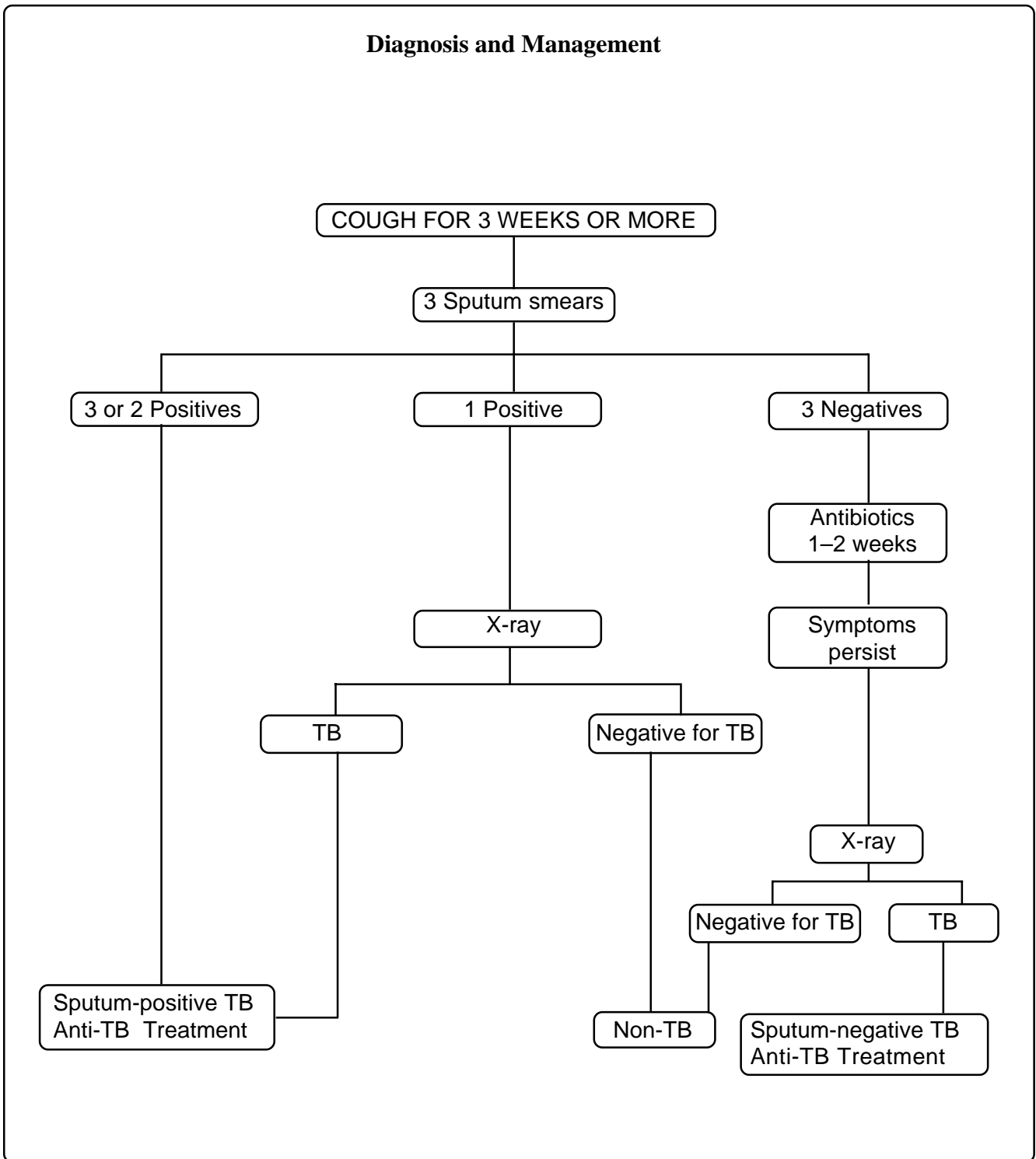
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1-4**



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Ministry of Health and Family Welfare
Nirman Bhavan, New Delhi 110 011

Diagnosis and Management



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1 COURSE INTRODUCTION

PURPOSE OF THE TRAINING COURSE

Tuberculosis (TB) kills more adults in India than any other infectious disease. More than 1000 people a day—one every minute—die of TB in our country.

India has a long history of research and demonstration projects in TB. Unfortunately, despite the existence of a National Tuberculosis Programme since 1962, the desired results have not been achieved. There is overdependence on X-rays for diagnosis. Treatment regimens used are often non-standard, and incomplete treatment is the norm rather than the exception.

On the recommendations of an expert committee, a revised strategy to control TB was pilot-tested in 1993 in a population of 2.35 million and was then extended to a population of 13.85 million in 15 states/UTs in the country. In these areas, diagnostic practices improved with effective use of quality sputum microscopy, and cure rates doubled as compared to those achieved with conventional treatment. Because of these encouraging results, the Revised National Tuberculosis Control Programme (RNTCP) is being extended, initially in a phased manner, to 102 districts covering a population of 271.2 million. By early 1999, the programme covered more than 115 million population.

The goal of the RNTCP is to cure at least 85% of New sputum smear-positive patients detected, and to detect at least 70% of all such patients after the goal for cure rate has been met. To achieve these targets, the central, state, district and sub-district levels must each do their part. A major organizational change in the RNTCP is the creation of a sub-district level. The sub-district will consist of a designated Medical Officer-Tuberculosis Control (MO-TC) who does tuberculosis work in addition to his other responsibilities, as well as two full-time supervisory staff for tuberculosis work—a Senior Treatment Supervisor (STS) and a Senior Tuberculosis Laboratory Supervisor (STLS). The state, district and sub-district staff are responsible for organizing, implementing and supervising the RNTCP, and the success of the programme depends on them.

This course draws on two sets of WHO modules: Managing Tuberculosis at District Level and Managing Tuberculosis at National Level. Because of India's size, many of the components from the 'national' modules are

directly relevant to states and districts, and many of the 'district' components are directly relevant to sub-districts. Therefore, this course provides training relevant to implementing the RNTCP at the state, district and sub-district levels. Staff who can benefit include state-level staff (State TB Officer, director and staff of State TB Demonstration and Training Centre), district-level staff (District TB Officer, Medical Officer of the DTC), and the designated Medical Officer (MO) of the sub-district. Parts of the course are also relevant for other Medical Officers and for Senior Treatment Supervisors.

At the end of this course, participants will be able to do the following tasks:

- train MOs and health workers to correctly identify patients who should be investigated for tuberculosis;
- train health workers to properly collect and transport sputum specimens and refer symptomatic patients for microscopy examination;
- monitor the maintenance of the Tuberculosis Laboratory Register;
- monitor documentation related to microscopy examinations;
- complete Tuberculosis Treatment Cards of patients;
- ensure proper administration of drugs;
- train and supervise others who give directly observed treatment (peripheral health workers and community volunteers);
- provide health education to patients and their families and train MOs and health workers to do the same;
- register patients in the Tuberculosis Register;
- verify that the correct number of sputum specimens have been examined at the stipulated intervals and record the results in the Tuberculosis Register;
- review Tuberculosis Treatment Cards to assess treatment outcomes and record treatment outcomes in the Tuberculosis Register;
- complete the quarterly reports on case-finding, sputum conversion, treatment outcomes and programme management;
- ensure maintenance of an adequate supply of drugs and other key materials;
- conduct supervisory visits; and
- evaluate the performance of the tuberculosis programme in the area.

EXTENT OF THE TUBERCULOSIS PROBLEM

Tuberculosis is an infectious disease caused by *Mycobacterium tuberculosis* and, less commonly, by other organisms of the 'tuberculosis complex'. It is estimated that 3 million people die from TB each year—the majority of them in developing countries. The annual incidence of New cases of all forms of TB (pulmonary and extra-pulmonary) worldwide is estimated to be approximately 8 million, of which about 95% occur in developing countries. Many TB cases in developing countries remain undiscovered. Of the discovered smear-positive cases, less than half complete treatment. Consequently, the estimated prevalence (the total number of tuberculosis cases at a given time) worldwide is 16 to 20 million, of whom about 8 to 10 million are sputum smear-positive and highly infectious.

The number of persons infected with the tuberculosis bacillus is estimated to be 1.7 billion, of which 1.3 billion live in developing countries. In India, more than 40% of adults are infected with TB, and approximately 1.5 million cases are put on treatment every year. An estimated 5 lakh deaths from TB occur every year.

The greatest burden of tuberculosis incidence and mortality in developing countries is in adults aged 15 to 60 years. These include the most productive members of society such as parents, workers and community leaders.

While there has been a tremendous *decrease* in tuberculosis cases in *developed* countries in the last forty years, there has been an *increase* in the number of tuberculosis cases in *developing* countries. This is due to failure to cure a high proportion of sputum smear-positive cases.

Every year, each smear-positive patient can infect approximately 10 to 15 persons, thereby increasing the pool of infected persons. Many patients who do not complete treatment have isolates which are resistant to the drugs they have taken. These patients infect other people, with drug-resistant bacilli.

Many patients who do not receive directly observed treatment stop taking drugs. Studies in India and many other countries consistently show that at least one-third of the patients do not take medicines regularly, and it is

neither possible to predict who these patients will be, nor to reliably prevent non-compliance by improving patient education.

Globally, the HIV epidemic is increasing the number of tuberculosis cases and accelerating the spread of the disease.

During this course, you will learn how to prevent the spread of tuberculosis and the development of drug resistance by improving diagnosis and treatment of patients and enhancing supervision of programme management.

AIM OF THE REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

In developing countries such as India, the fight against tuberculosis can be successfully carried out only within the setting of a National Tuberculosis Programme. This programme is part of the country's general health services.

The primary aim of the RNTCP is to **achieve a high cure rate of New sputum smear-positive patients** thereby interrupting the chain of transmission. The target cure rate is **at least 85%**.

Target: Cure at least 85% of New sputum smear-positive patients.

The only effective means by which 85% cure rate has been shown to be achievable on a programme basis is by application of the so-called DOTS (Directly Observed Treatment, Short-course chemotherapy) strategy. DOTS is a systematic strategy which has five components:

- **Political and administrative commitment:** TB is the leading infectious cause of death among adults. It kills more women than all causes associated with childbirth combined and leaves more orphans than any other infectious disease. And, since tuberculosis can be cured and the epidemic reversed, it warrants the topmost priority which it has been accorded by the Government of India. This priority must be continued and expanded at state, district, and local levels.
- **Good quality diagnosis:** Case detection is done primarily by sputum microscopy among symptomatic patients attending health facilities. This policy allows effective diagnosis in the periphery and appropriate prioritization of efforts.
- **Good quality drugs:** An uninterrupted supply of good quality anti-TB drugs must be available. In the RNTCP, a box of medications for the entire treatment is earmarked for every patient registered, ensuring the availability of the full course of treatment to the patient the moment he is registered for treatment. Hence in DOTS the treatment never fails on account of non-availability of medicines.
- **Short-course chemotherapy given in a programme of direct observation:** RNTCP uses the best anti-TB medications available. But unless treatment is taken by patients, it will fail. This is why the heart of the DOTS

programme is “directly observed treatment” in which a health worker or other trained person who is not a family member watches as the patient swallows the anti-TB medicines in their presence. With short-course chemotherapy it is easier to prevent drug resistance by using directly observed treatment, and achieve high cure rates. In addition, because short-course treatment lasts half as long as conventional treatment, at any one point in time only half the number of patients are on treatment, reducing the quantity of work and allowing increased emphasis on quality of services.

- **Systematic monitoring and accountability:** There are two means of monitoring the success of treatment. First, sputum is examined during the course of treatment to monitor the progress and cure of patients. Second, a revised recording and reporting system rigorously monitors and evaluates the outcome of every patient treated. The cure rate and other key indicators are monitored at every level of the health system, and if any area is not achieving 90% sputum conversion rate at the end of 3 months and 85% cure rate, supervision is intensified. For effective programme implementation, having well-trained and motivated staff is essential.

The RNTCP shifts the responsibility for cure from the patient to the health system.

It should be noted that the principles of diagnosis of TB by microscopy, ambulatory treatment, and direct observation of treatment were first established in India at NTI, Bangalore and TRC, Chennai.

Another objective of the RNTCP is 70% detection of New sputum smear-positive cases. **However, the target for case detection should only be attempted if the cure rate of already-detected patients is more than 85%.** When cure rates are high, health facilities will attract more patients due to the good results obtained in the cases already treated. As one Programme Manager of a successful RNTCP site in India said, ‘Every cured patient is a pamphlet’.

Remember: Increase the cure rate before attempting to achieve case detection targets.

STRUCTURE OF THE REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

The RNTCP has a central division, state, district and sub-district levels and health units. As noted above, a major organizational change is the creation of a sub-district level. Creation of a sub-district level allows for the systematic monitoring of the outcome of every patient.

An additional structure of the RNTCP is the District Tuberculosis Control Society. This society functions with the District Collector as the Chairman, the District Tuberculosis Officer (DTO) as Member Secretary, and has governmental and non-governmental representatives. It is responsible for monitoring the programme implementation, arranging necessary logistics such as transport and procuring materials such as laboratory consumables.

Central TB Division

At this level is the **Ministry of Health**, where the Central TB Division is responsible for tuberculosis control in the whole country. A National Programme Director (Deputy Director General [TB]) is in charge of the tuberculosis programme in the entire country.

Main technical responsibilities of the Central TB Division are to:

- plan, supervise, monitor and evaluate anti-tuberculosis activities throughout the country;
- coordinate with other sections of the Ministry of Health and other central government agencies;
- provide drugs, laboratory equipment and documents (e.g. manuals and modules) needed in the country; and
- train or coordinate the training of the nodal personnel involved in the RNTCP.

State level

At this level, a **State Tuberculosis Officer (STO)** is responsible for planning, training, supervising and monitoring the programme in the state. He is responsible administratively to the State Director of Health Services

and technically follows instructions of the Central TB Division. There should be a full-time STO trained in the RNTCP for each state.

Main responsibilities at the state level are to:

- work closely with the Central TB Division for performing the duties mentioned above;
- plan, supervise, monitor and evaluate anti-tuberculosis activities throughout the state;
- ensure adequate supply of drugs, laboratory equipment and documents needed in the state;
- organize training programmes in the state in collaboration with the Central TB Division, the State TB Training and Demonstration Centre (STDC) and the District Chief Medical Officers, and to give on-the-job training to the district and peripheral workers;
- ensure that the required reports on case-finding, results of treatment and programme management are completed in each district and sent to the Central TB Division in time;
- review the reports on case-finding, results of treatment and programme management from the districts and take necessary action for their improvement; and
- ensure close cooperation between the staff in case-finding and treatment of tuberculosis and the microscopy services.

District level

The district is the key level for the management of primary health care. The district level (or municipal corporation level in large metropolitan areas) performs functions similar to those of the state level in its area. The Chief District Health Officer or his equivalent is the principal health functionary in the district and is responsible for all medical and public health activities including control of TB. The District Tuberculosis Centre (DTC) is the nodal point for TB control activities in the district and also functions as a specialized referral centre. The DTO at the DTC has the overall responsibility of the Programme at the district level and is assisted by an MO, Statistical Assistant and other paramedical staff. For each district, there should be a full-time DTO who is trained in the RNTCP.

In some large metropolitan cities diagnosis is made at specialized TB Dispensaries/Chest Clinics, and microscopy and treatment administration are done by special staff based in a general health facility.

Main responsibilities at the district level are to:

- implement the RNTCP through the district health staff;
- maintain a map of the area detailing all health facilities, government organizations and NGOs which specifically carry out TB activities, including the staff responsible for these activities (name, position and location);
- train and re-train the medical and paramedical staff;
- maintain a regular supply of drugs, treatment-related materials, sputum containers and slides, laboratory-related materials, forms and registers for the district;
- supervise and ensure proper treatment of tuberculosis throughout the district, and particularly ensure that:
 - the correct treatment is prescribed in all health facilities
 - patients are receiving the appropriate drugs under direct observation of health workers during the intensive phase of treatment and at least one dose per week in the continuation phase is directly observed
 - regimens are given for the required period, and cured patients are discharged from treatment
 - sputum is examined for acid-fast bacilli (AFB) at the stipulated time intervals
 - patients are individually advised about their disease
 - patients are referred or transferred as appropriate
 - treatment outcomes of patients are determined and recorded in the Tuberculosis Register;
- organize health education and establish liaison with private practitioners and NGOs who provide TB services to promote compliance with national norms and facilitate referral;
- assist staff in the diagnosis of TB in all health facilities in the district;
- ensure that the sub-district staff visit all microscopy centres for supervision at least once a month;

- make sure, by reviewing quarterly reports and randomly spot-checking, that MOs and health workers properly identify symptomatic patients, collect and transport sputum specimens and refer patients for diagnosis;
- visit all sub-district Tuberculosis Units, hospitals, Community Health Centres (CHCs) and Block Primary Health Centres (Block PHCs) at least once a quarter; and
- complete quarterly reports on notified New and retreatment cases of tuberculosis, sputum conversion and on the results of treatment.

Sub-district level

A team comprising a specifically designated MO-TC, STLS and STS is based in a CHC or Taluk Hospital (TH) or Block PHC. The team constitutes the TU, and the STS and STLS are under the administrative supervision of the DTO. The staff from the DTC (laboratory technician and treatment organizer) will carry out the functions of the sub-district supervisory team in its respective sub-district in addition to their functions as a microscopy and treatment centre. The sub-district covers a population of approximately 5,00,000. The sub-district is responsible for accurate maintenance of the Tuberculosis Register and timely submission of quarterly reports.

Functions of the TU are to:

- maintain a map of the area detailing all health facilities, and government organizations and NGOs which specifically carry out TB activities, including the staff responsible for these activities (name, position and location);
- maintain a regular supply of drugs and other logistics and ensure their uninterrupted availability in all designated centres in the sub-district. Retrieve unfinished medicine boxes of patients who have defaulted (i.e. stopped treatment for two months or more continuously);
- establish liaison with private practitioners and NGOs providing TB services to promote compliance with national norms, facilitate referral and ensure registration and notification;
- organize sputum smear examination at the microscopy centres of the sub-district;
- carry out categorization of treatment services and DOT;
- organize regular training and continuing education;

- supervise the microscopy centres and PHCs at least once a month, and perform quality control of slides as per the Laboratory Manual;
- prepare and distribute reagents, and ensure regular and sufficient supply of reagents and sputum containers in each health facility;
- keep the Tuberculosis Register up-to-date and accurate;
- prepare quarterly reports on case detection, sputum conversion, treatment outcome and programme management;
- make sure MOs and health workers correctly identify symptomatic patients and refer patients for diagnosis;
- diagnose smear-negative patients who require X-ray examination (if facilities exist);
- act as a referral point, for example, for patients who:
 - present diagnostic problems
 - have drug reactions
 - refuse to take drugs
 - are failure cases requiring further investigation
 - do not convert to smear-negative status at the end of the intensive phase and identify the reasons for the same
 - require evaluation of treatment outcome, i.e. cured, treatment completed, defaulted, died, transferred out, failure; and
- monitor the maintenance of the Laboratory Register and the documentation related to microscopy examinations.

Health units

At this level are the rural and other hospitals, health centres, dispensaries and health facilities within a district.

Main responsibilities at the health units are to:

- send tuberculosis suspects or their sputum specimens to designated microscopy centres for examination;
- carry out categorization of treatment services and DOT;
- trace patients who do not collect their drugs and bring them back under treatment;

- keep Tuberculosis Treatment Cards and records and make them available for the STLS, STS, MO-TC, DTO and other supervisory staff when they visit the health unit;
- facilitate follow-up sputum smear examinations;
- trace and investigate contacts; and
- discharge patients who have come to the end of their treatment regimen in coordination with the designated MO-TC of the sub-district or the DTO.

STRUCTURE OF EXERCISES OF THE TRAINING MODULES

All modules have **individual** and/or **group exercises** that are designed to check if you have learned the skills that were taught. After you complete an exercise, a facilitator will assess and comment on your work.

Before each **individual exercise**, you will see a picture like this:



For the **group exercises**, you will be asked to work with other participants to discuss answers to a given situation or to participate in a role play. A facilitator will lead the small group discussions and observe and comment on each role play. Before each **group exercise**, you will see a picture like this:



For the **exercise workbooks**, you will see a picture like this:



DEFINITIONS: THE REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

CASE DEFINITIONS	TYPES OF CASES	TREATMENT OUTCOMES
<p>Pulmonary tuberculosis, Smear-positive TB in a patient with at least 2 initial sputum smear examinations (direct smear microscopy) positive for AFB.</p> <p>Or: TB in a patient with one sputum examination positive for AFB and radiographic abnormalities consistent with active pulmonary TB as determined by the treating MO.</p> <p>Or: TB in a patient with one sputum specimen positive for AFB and culture positive for <i>M. tb</i>.</p>	<p>New A patient who has never had treatment for tuberculosis or has taken anti-tuberculosis drugs for less than one month.</p> <p>Relapse A patient declared cured of TB by a physician, but who reports back to the health service and is found to be bacteriologically positive.</p> <p>Transformed In A patient who has been received into a Tuberculosis Unit/District, after starting treatment in another unit where he has been recorded.</p> <p>Treatment After Default A patient who received anti-tuberculosis treatment for one month or more from any source and who returns to treatment after having defaulted, i.e. not taken anti-TB drugs consecutively for two months or more.</p> <p>Failure A smear-positive patient who is smear-positive at 5 months or more after starting treatment. Failure also includes a patient who was initially smear-negative but who becomes smear-positive during treatment.</p> <p>Chronic A patient who remains smear-positive after completing a retreatment regimen.</p> <p>"Other" Patients who do not fit into the above-mentioned categories. Reasons for putting a patient in this category must be specified.</p>	<p>Cured Initially smear-positive patient who has completed treatment and had negative sputum smears, on at least two occasions, one of which was at completion of treatment.</p> <p>Treatment completed Sputum smear-positive case who has completed treatment, with negative smears at the end of the initial phase but none at the end of treatment. Or: Sputum smear-negative TB patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment. Or: Extra-pulmonary TB patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment.</p> <p>Died Patient who died during treatment, regardless of cause.</p> <p>Failure Smear-positive case who is smear-positive at 5 months or more after starting treatment. Also, a patient who was initially smear-negative but who became smear-positive during treatment.</p> <p>Defaulted A patient who, at any time after registration, has not taken anti-TB drugs for 2 months or more consecutively.</p> <p>Transferred out A patient who has been transferred to another Tuberculosis Unit/District and his/her treatment results are not known.</p>
<p>Pulmonary tuberculosis, Smear-negative TB in a patient with symptoms suggestive of TB with at least 3 sputum examinations negative for AFB, and radiographic abnormalities consistent with active pulmonary TB as determined by a MO, followed by a decision to treat the patient with a full course of anti-tuberculosis therapy.</p> <p>Or: Diagnosis based on positive culture but negative AFB sputum examinations.</p> <p>Extra-pulmonary tuberculosis TB of organs other than the lungs, such as the pleura (TB pleurisy), lymph nodes, abdomen, genito-urinary tract, skin, joints and bones, tubercular meningitis, tuberculoma of the brain, etc.</p> <p>Diagnosis should be based on one culture-positive specimen from the extra-pulmonary site, or histological evidence, or strong clinical evidence consistent with active extra-pulmonary TB followed by a MO's decision to treat with a full course of anti-TB therapy.</p> <p>Pleurisy is classified as extra-pulmonary TB. A patient diagnosed with both pulmonary and extra-pulmonary TB should be classified as pulmonary TB.</p>		

2 ENSURING IDENTIFICATION OF TUBERCULOSIS SUSPECTS

INTRODUCTION

Tuberculosis (TB) affects the *lungs* in more than 80% of cases. This form of the disease is called *pulmonary tuberculosis*.

Pulmonary tuberculosis is an infectious disease. This means that people living with or coming in close contact with a patient who has infectious tuberculosis (in particular, smear-positive) can catch the infection. Therefore, it is very important to identify suspects who have symptoms of tuberculosis early in the course of the disease and ensure their examination.

People with chest symptoms and other symptoms suggestive of TB consult medical staff at general health facilities which may be governmental, non-governmental or private. The physician should suspect TB in these individuals, and advise sputum smear examinations to arrive at a diagnosis. Adult outpatients should be asked if they have cough for three weeks or more. All persons with cough of 3 weeks duration or longer should have 3 sputum examinations for acid-fast bacilli (AFB). Sputum examination and anti-TB treatment are free of charge at government facilities.

Patients suspected of having extra-pulmonary TB, and patients who are contacts of sputum smear-positive patients, should have their sputum examined for AFB if they have any chest symptoms, regardless of the duration of these symptoms.

The Medical Officer (MO) at the health facility screens the patients and sends those who are suspected of having TB for sputum smear examination. The patient receives sputum containers and instructions and provides sputum samples, which are examined in the laboratory. If sputum microscopy is not available at the health facility, the patient's sputum or smears are sent to the nearest microscopy centre, or the patient himself may be referred to these centres if they are close by. Three sputum samples are collected on two days—spot on the first day, and one early morning and one spot on the second day.

Patients with **two positive smear results** are smear-positive cases and are diagnosed by the physician as having TB. They are further classified as new or old cases based on their treatment history, and appropriate therapy is prescribed.

Patients with **only one positive result** of smear examination will be referred to the nearest X-ray facility. Patients who have one smear positive and a chest X-ray compatible with TB as diagnosed by an MO are considered to be suffering from TB and are registered as smear-positive cases. This is because if a patient has only one positive result out of three sputum samples, this may be a laboratory error or may be due to another patient's sputum result. In a well functioning laboratory, patients with only one out of three sputum samples positive are exceptionally rare.

Patients in whom all 3 samples are smear-negative are prescribed symptomatic treatment or broad spectrum antibiotics for 1–2 weeks. Care must be taken to prescribe only general antibiotics (such as co-trimoxazole) which do not have anti-tuberculosis activity for such patients. It must be ensured that antibiotics such as the fluoroquinolones (ciprofloxacin, ofloxacin, etc.), rifampicin or streptomycin, which are active against tuberculosis, are never used in such cases. Most patients are likely to improve with antibiotics if they are not suffering from TB. If the symptoms persist, the patient is re-evaluated on the basis of X-ray and clinical examination. Those patients who in the opinion of the physician have active TB, based on the X-ray findings and persistence of symptoms, will be diagnosed as having smear-negative TB. They will be designated as 'seriously ill' and 'non seriously ill' and appropriately categorized and treated. If the patient is put into the seriously ill category, reasons for the same should be mentioned in the **Remarks** column of the Treatment Card and Tuberculosis Register.

Cases who are smear-negative require an X-ray for diagnosis. Diagnosis should be made at the District Tuberculosis Centre (DTC) or by the Medical Officer-Tuberculosis Control (MO-TC) who if he considers it essential may consult the District Tuberculosis Officer (DTO). If good diagnostic practices are followed as indicated above it is expected that at least 50% of the new pulmonary TB patients diagnosed will be smear-positive.

Patients suspected of having pulmonary TB may be referred by private practitioners to the government services for diagnosis and treatment. In such cases, the MO at the government health facility will have 3 sputum smears examined to arrive at a diagnosis, or will refer the patient to the DTC/Chest Clinic for this purpose. Feedback on the patient's diagnosis and treatment should generally be provided to the referring physician.

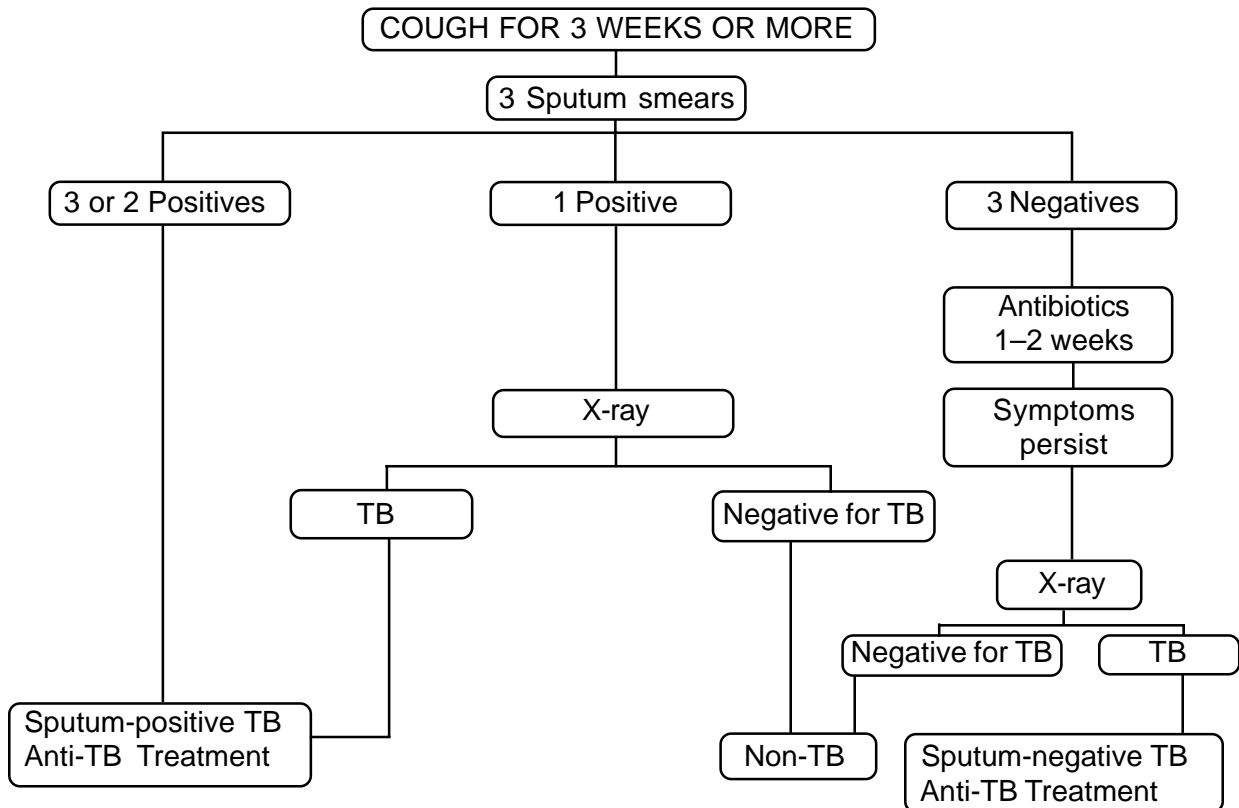
Extra-pulmonary TB cases will be diagnosed by the physicians and referred to a DTC/Chest Clinic or MO-TC. Procedures undertaken to arrive at the diagnosis must be mentioned in the Treatment Card.

Sputum should be collected properly. If sputum is not collected in the correct way and the patient has smear-positive tuberculosis, the diagnosis may be missed and the patient may continue to spread the infection and may die from tuberculosis.

The laboratory technician should properly label the sputum container, which holds the patient's sputum specimen, by writing the patient's Laboratory Serial Number on the side of the sputum container (not on the lid).

The diagnosis of tuberculosis by X-ray is unreliable. Unless the diagnostic algorithm (see below) is followed, a large proportion of patients not actually having tuberculosis may be treated for tuberculosis on the basis of abnormal X-rays alone.

Diagnosis and management



IMPORTANCE OF PROPERLY IDENTIFYING TB SUSPECTS

During supervisory visits to health units and hospitals (particularly outpatient clinics), explain the importance of correctly identifying suspects of pulmonary and extra-pulmonary tuberculosis.

Encourage health workers and MOs to identify pulmonary tuberculosis suspects as early as possible to prevent further spread of the infection. Explain that patients with smear-positive tuberculosis discharge tubercle bacilli into the air while sneezing or coughing. Contacts of smear-positive patients can become infected when they breathe in tubercle bacilli. Infection may also occur by drinking unpasteurized or unboiled milk from infected cattle.

Most patients with TB visit health facilities fairly promptly after symptoms occur. It is important that the diagnosis of tuberculosis be considered and sputum is examined. If TB is not suspected, patients with smear-positive pulmonary TB will *not* be identified. These people will continue to spread the infection to others and if not diagnosed and treated, more than half of them will die.

The **most common symptom of pulmonary TB is persistent cough for 3 weeks or more**, usually with expectoration. All persons who have this symptom should have their sputum examined as soon as possible.

Persistent cough for 3 weeks or more and may be accompanied by one or more of the following symptoms:

- weight loss
- tiredness
- fever, particularly with rise of temperature in the evening
- night sweats
- chest pain
- shortness of breath
- loss of appetite
- coughing up blood

A person with extra-pulmonary TB may have the following *general* symptoms:

- weight loss
- fever, particularly with rise of temperature in the evening
- night sweats.

Other symptoms depend on the organs affected, for example:

- swelling, occasionally with pus discharge when lymph nodes are affected
- pain and swelling of the joints if these are involved
- headache, fever, stiffness of the neck and mental confusion when the brain or meninges are involved.

Patients with extra-pulmonary TB who have pulmonary symptoms of any duration should have 3 sputum samples examined. If extra-pulmonary tuberculosis is suspected but not confirmed, examination of sputum, if positive, can help to confirm the diagnosis of tuberculosis.

Once a patient is diagnosed as having smear-positive TB, he should be told to take his contacts with him to the nearest health unit for examination, if they have any of the above-mentioned symptoms.

During visits to the health units, teach health workers and MOs to properly identify TB suspects. When you visit the health units again, try to observe health staff while they talk to patients who have symptoms of TB. If you find that the staff are not properly identifying patients suspected of having TB, demonstrate how to perform this task correctly.

Usually, at least 2% of adult outpatients in general OPD have cough for 3 weeks or more. If a health facility is obtaining sputum examinations on less than 2% of their adult outpatients, this should be discussed with the MOs and laboratory technicians and means to correct the situation should be implemented.

Every patient who has cough for 3 weeks or more, with or without other symptoms, should have 3 sputum samples examined for AFB.



EXERCISE 1

1. What is the most common symptom of pulmonary tuberculosis?

2. List the other symptoms a tuberculosis suspect may have.



EXERCISE 2

Case 1: Meena Patel

Meena Patel is 25 years old. She has come to the health care centre today because she does not feel well. By asking her questions, the health worker finds out that Meena has had cough with expectoration for 4 weeks and has felt very tired. Meena also tells the health worker that she has been coughing up blood-stained sputum.

What should the health worker suspect Meena to be suffering from?
Explain your answer.

Case 2: Shyam Patel

A patient has pulmonary tuberculosis and was initially smear-positive. Shyam Patel is the patient's brother and is 29 years old. He has come to the health care centre today with his brother.

When the health worker gives the patient his drugs, he notices that Shyam is coughing. The health worker asks Shyam how long he has been coughing. Shyam says he has been coughing for one week. After further questioning, the health worker determines that Shyam does not seem to have any other symptoms of tuberculosis.

Should the health worker suspect Shyam of having pulmonary tuberculosis? Explain your answer.

2

COLLECTING SPUTUM FROM TUBERCULOSIS SUSPECTS

When pulmonary TB is suspected, at least 3 sputum specimens (SPOT—EARLY MORNING—SPOT) should be collected and examined by microscopy. Ideally, all the three specimens should be collected within 2 days, and specimens should be sent to the microscopy laboratory as soon as possible and definitely within 1 week.

If the patient is attending a Peripheral Health Institution (PHI) which is also a designated microscopy centre, sputum will be examined at the same facility. If the patient is attending a PHI which is not a designated microscopy centre, there are two options:

- (i) either the sputum container can be transported to the microscopy centre, or
- (ii) the patient himself can be referred to the microscopy centre.

Whatever arrangement is most convenient to the patient and ensures prompt diagnosis should be used.

If sputum is collected and transported to the microscopy centre, the list of patients whose sputum is being sent should accompany the samples. An example of such a list is given below.

Health Unit: <i>PHI 101</i> Sent on: <i>4/9/96</i> Laboratory: <i>PHI 237</i> Received on: <i>4/9/96</i> Examined on: _____ Result sent back on: _____						
Health worker who collected specimens: <i>Balaraman</i>						
Specimen Identification No.	Name	Age	Sex	Address	Date of collection	AFB results
1	Lakshmi Kumari	46	F	223 Gandhi Dham	4/9/96	
2	Lakshmi Pati Rao	50	M	223 Gandhi Dham	4/9/96	
3	Girija Devi	32	F	225 Gandhi Dham	4/9/96	
4	Kailash Nath	35	M	225 Gandhi Dham	4/9/96	

Guidelines for collecting sputum

1. A specimen is collected on the spot when a patient is suspected of having TB. The patient is given the sputum container with his Laboratory Serial Number written on it. The person collecting the sputum demonstrates how to open and close the container, takes the patient to an open space far away from other people, and demonstrates with actual actions how to bring out sputum. The patient is instructed to inhale deeply 2–3 times with his mouth open, cough out deeply from the chest, open the container and spit out the sputum into it, and close the container. This is called a **spot specimen**.
2. The patient is then given a sputum container with his Laboratory Serial Number written on the external surface of the sputum container (not on the lid) to collect an early morning specimen before his second meeting with the laboratory technician. This is called an **early morning specimen**. The patient should be told to cough out sputum into the container as soon as he coughs in the morning. He should then close the container.
3. When the patient returns with the **early morning specimen**, a second **spot specimen** is collected in another container under the supervision of a staff member.

To obtain good sputum specimens and to prevent contamination, the staff must perform certain tasks:

- *before* sputum collection,
- *during* sputum collection, and
- *after* sputum collection.

The following pages describe these tasks in detail.

Tasks performed *before* sputum collection

Before a health worker collects a sputum specimen, he should briefly explain to the patient the reasons for sputum collection. The Laboratory Form for Sputum Examination should be filled up completely, generally by the MO (see page 30). This form is sent to the microscopy laboratory with *all three* sputum specimens of the patient. (Only one form needs to be filled out for all 3 sputum specimens collected from a patient.) The form is packed along with a patient's sputum specimens when they are transported to the microscopy laboratory for examination.

The **Results** section, located on the bottom half of this form is completed by the microscopy laboratory after the sputum examinations. Up to 3 sputum examination results for a patient can be recorded on this form. (The *Supporting Laboratory Services* module will describe how a laboratory technician completes this section of the form.) The top half of this form is generally completed by the MO who requests a sputum examination. The following pages describe what is to be written on each line of the Laboratory Form for Sputum Examination.

Name of Health Centre

The name of the treatment unit where the patient's sputum was collected is written in the space provided.

Date

The date (day/month/year) the patient is examined and the form is filled up is written in the space provided.

Name of patient

The patient's full name is written in the space provided.

Age

The age of the patient is written in the space provided.

Sex

The letter **M** is ticked if the patient is a male. The letter **F** is ticked if the patient is a female.

Complete address

The patient's full address is written in the space provided. It is very important to write a patient's **complete** address so that the patient can be easily traced when he does not return to the laboratory or the outpatient department of the hospital for his results.

Patient's TB No.

The Tuberculosis Number of a patient who is having his sputum examined during his prescribed treatment regimen is recorded in the space provided. However, the Tuberculosis Number is **not** written for a patient with symptoms of tuberculosis, since this patient has not been diagnosed with tuberculosis and has not been registered.

Disease classification

Pulmonary is ticked (✓) if the specimen is sputum. **Extra-pulmonary** is ticked (✓) if the source of material is extra-pulmonary, and the source of material is written down (for example, pus from the lymph nodes).

Reason for examination

The **diagnosis** box is ticked if the sputum specimen was collected from a tuberculosis suspect. The **follow-up of chemotherapy** box is ticked when a patient's sputum is collected as part of follow-up during his prescribed treatment regimen.

Specimen Identification No.

If specimens are being transported to a microscopy centre from another unit, a Specimen Identification No. is given at the referring unit, because the Laboratory Serial Number can only be assigned at the microscopy centre. Sputum specimens are assigned specific numbers to keep track of each patient's sputum results. After the Laboratory Form for Sputum Examination is filled up, this number is written on the side of the patient's sputum container. (If a sputum specimen is separated from its Laboratory Form for Sputum Examination, a laboratory technician can find out whose specimen it is by using the Specimen Identification No. on the sputum container. He can then locate the form by using the date and the identification number.) Each separate specimen will generally have its own unique Specimen Identification No. For example, 3 specimens from a single patient might have Specimen Identification Nos. A1, A2 and A3.

Date of sputum collection

The date (day/month/year) the last sputum specimen was collected is written in the space provided.

Specimen collector's name and signature

The name and signature of the health worker who collected the sputum from the suspect patient or follow-up patient is written in the space provided.

Tasks performed *during* sputum collection

Health workers should follow the guidelines specified below which explain **how** to collect a sputum specimen:

- A specimen collected in the presence of a health worker is likely to be better than a specimen produced by a patient without any guidance from a health

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME
Laboratory Form for Sputum Examination

Name of Health Centre: _____ Date: _____

Name of patient: _____ Age: _____ Sex: M F

Complete address: _____

Patient's TB No. #: _____

Source of specimen: Pulmonary
 Extra-pulmonary Site: _____

Reason for examination: Diagnosis
 Follow-up of chemotherapy*

Specimen Identification No.: _____ Date of sputum collection: _____

Specimen collector's name and signature _____

*Be sure to enter the TB No. for follow-up of patients on chemotherapy.

RESULTS (To be completed in the laboratory)

Lab Serial No: _____

Microscopy

Date	Specimen	Visual appearance (M, B, S)*	Results**	Positive (grading)			
				3+	2+	1+	Scanty
	1						
	2						
	3						

* M=Mucopurulent, B=Blood-stained, S=Saliva

** Write negative or positive

Date: _____ Examined by (signature): _____

The completed form (with results) should be sent to the Health Centre to record the results on the Treatment Card.

worker. The health worker should stand **behind** the patient and encourage good sputum collection.

- Whenever possible, sputum should be collected in open air. If this cannot be done, it should be collected in a vacant room with open windows which is used only for this purpose.
- The patient is usually more comfortable if he is separated from other patients at the time of sputum collection.
- The patient should be given a sputum container with the Laboratory Serial Number written on the side. If the sputum is being collected at a location other than the microscopy centre, then the Specimen Identification Number (or patient's name) is written on the side of the container.
- The health worker demonstrates how to open and close the container and shows with actual actions how to bring out sputum. The patient is instructed to inhale deeply 2–3 times, cough out deeply from the chest, open the container and spit out sputum into it, and close the container.
- The health worker should make sure that no one stands in front of the patient who is trying to cough up sputum.
- When a patient has only coughed up saliva or has not coughed up at least 2 ml of sputum, the health worker should ask the patient to take deep breaths with his mouth open and repeat coughing until he produces enough sputum.
- When the outside of a container is contaminated with sputum, the health worker should wipe the container clean and destroy whatever is used to clean the container.

Tasks performed *after* sputum collection

The health worker should follow the guidelines specified below which explain what tasks should be performed **after** the sputum is collected:

- The health worker should place the lid on the container and close it firmly.
- If the sputum container is to be sent immediately to the laboratory, the health worker should put the container into a special box for transport.
- If the sputum container will not be sent immediately to the laboratory, the health worker should store the specimens in a refrigerator, if possible. If a refrigerator is not available, the specimens should be stored in as cool a place as possible.

- The health worker should wash his hands thoroughly with soap and water every time he handles contaminated material.
- The health worker should give the patient a new sputum container with the Laboratory Serial Number (if microscopy centre, otherwise Specimen Identification Number) written on its side and make sure that the patient understands that as soon as he clears his mouth of food particles and coughs up sputum in the morning, he must cough out into this container, close it and then return it to the health centre. The health worker should demonstrate how to close the container securely.

TRANSPORT OF SPUTUM SPECIMENS

The health worker is responsible for making sure that after the sputum is collected it is taken to the laboratory as soon as possible. Arrangements should be made locally for transport of specimens to the microscopy centre, and for transport of results from the microscopy centre to the referring peripheral health institution. Patients should be told to come back to receive the results of sputum examination.

Sputum specimens should be examined by microscopy no later than 1 week after they are collected. However, sputum which is received in the laboratory after 1 week should also be examined because dead bacilli may be visible on a slide. Results of the examination should be reported within one day.

The specimens should be packed carefully for transport in a transport box. One Laboratory Form for Sputum Examination should accompany a patient's sputum specimens. With each transport box, an accompanying dispatch list should be prepared. This list should identify the sputum specimens it contains and the data of the patients from whom the specimens were collected.

Before sending the sputum specimens to the microscopy laboratory, the health worker should verify that in each transport box:

- (i) the total number of sputum containers corresponds to the total number on the accompanying dispatch list;

- (ii) the Specimen Identification Number on the sputum containers corresponds to the identification number on the accompanying dispatch list;
- (iii) the accompanying dispatch list contains the necessary data for each patient and clearly identifies the unit where the sputum was collected;
- (iv) one Laboratory Form for Sputum Examination is enclosed for each patient's specimens.

The health worker should then mark the date of dispatch on the dispatch list, put the list in an envelope and attach it to the outside of the transport box, and close the transport box carefully.

After sputum specimens are taken out from the sputum containers for examination, the containers MUST be destroyed as per guidelines mentioned in the Laboratory Manual.

REFER PATIENTS FOR DIAGNOSIS OR FURTHER EXAMINATION

When the treatment unit receives the **Results** section of the Laboratory Form for Sputum Examination, an MO should review the form.

If at least **2 sputum specimens** are **smear-positive** for AFB, the patient is classified as smear-positive and will be prescribed the appropriate treatment regimen. Complete a Tuberculosis Treatment Card and a Tuberculosis Identification Card and explain what tuberculosis is, that directly observed treatment is essential, what the duration of treatment is, how tuberculosis is spread, and the importance of prompt evaluation of all contacts and of any persons with symptoms of tuberculosis. If the patient is missing, you are responsible for ensuring that he is traced.

If only **2 sputum specimens** were examined and **1 specimen is smear-positive** for AFB, another sputum specimen must be collected from the patient and examined. If the third sputum is smear-positive, he will be classified as smear-positive and placed on the appropriate treatment regimen. Start the patient on appropriate treatment, make sure his name is entered in the Tuberculosis Register, and explain what tuberculosis is, that directly observed treatment is essential, what the duration of treatment is, how tuberculosis is spread, and the importance of prompt evaluation of all contacts and of any persons with symptoms of tuberculosis. If the third sputum is negative, follow the instructions below.

If **3 sputum specimens** were examined and **1 specimen is smear-positive** for AFB, the patient is referred to an MO for an X-ray examination. If the radiographic abnormalities determined by the MO are consistent with **active** pulmonary tuberculosis, the patient will be diagnosed as having pulmonary smear-positive tuberculosis. The patient should be started on appropriate treatment, entered in the Tuberculosis Register, and the physician should explain what tuberculosis is, that directly observed treatment is essential, what the duration of treatment is, how tuberculosis is spread, and the importance of prompt evaluation of all

contacts and of any persons with symptoms of tuberculosis. If the patient is missing, you are responsible for ensuring that he is traced.

If all **3 sputum specimens are negative**, the patient should be examined by an MO. If symptoms persist despite treatment for 1–2 weeks with an antibiotic such as co-trimoxazole, X-ray examination will be carried out. If the radiographic abnormalities are consistent with active pulmonary tuberculosis, **and** the MO decides to treat the patient with anti-tuberculosis chemotherapy, the patient will be diagnosed as having pulmonary smear-negative tuberculosis. The patient should be started on appropriate treatment, entered in the Tuberculosis Register, and informed about tuberculosis.



EXERCISE 3

In this exercise you will read about a health worker collecting sputum from a tuberculosis suspect. Assume you are observing this health worker. When you finish reading, answer the exercise questions in the space provided.

Nana is a health worker at a District Hospital. It is now Monday morning. She suspects her patient Meena of having pulmonary tuberculosis. Nana tells Meena about sputum examinations. She then fills out a Laboratory Form for Sputum Examination. Next, Nana writes down the Specimen Identification No. on the side of the sputum container.

Nana demonstrates to Meena how to cough up sputum. Nana stands to the side of Meena and tells her to try to cough up sputum.

Meena is embarrassed to make so much noise with other patients around. Nana takes her into a private room without any windows and successfully collects a spot sputum specimen.

Meena returns on Tuesday for a second interview. Nana prepares to collect a second sputum specimen. She then writes the Specimen Identification No. from the sputum examination form on the side of the second sputum container. Next, Nana reminds Meena how to cough up sputum. While Meena tries to cough up sputum, Nana stands at the side of Meena.

After she collects each sputum specimen, Nana places the lid on the container and closes it firmly. She washes her hands carefully with soap.

On Wednesday, she carefully packs these sputum containers for transport. The containers are received by the microscopy laboratory on Friday.

On the basis of the information provided answer the questions on the following page.

1. Did Nana collect the correct number of sputum specimens from Meena?
Explain your answer.

2. Did Nana collect sputum from Meena in a good area? Explain your
answer.

3. Did Nana stand in the correct place when she collected the sputum?
Explain your answer.



EXERCISE WORKBOOK E1: LABORATORY FORM FOR SPUTUM EXAMINATION

Top Section

Please open Exercise Workbook E1 at this time.

The upper portion of the form is to be completed by the Medical Officer.

For this exercise, assume that all patients are attending the same facility as the microscopy centre, called PHI 237, except where noted otherwise. Complete only those Laboratory Forms for patients in whom sputum examination is indicated. The date is 3 September 1996. Sputum examination is not indicated for all patients. For patients in whom sputum examination is necessary, sputum will be collected on 3 September and 4 September. For ease of reference, each patient is given a letter as well as a name. This letter should be used as the Specimen Identification No. **More blank Laboratory Forms are provided than are necessary to complete this exercise.**

1. Raman Lamba of 7 Institutional Area, Lodhi Road (Patient A) is a 24-year-old male labourer with pain in the chest for two weeks. No cough. Pain is worse with movement.
2. Parvathi Sinha of 1964 Gali Paranthe Wali, Chandni Chowk (Patient B) is a 16-year-old female student with non-tender swelling of the lymph nodes in the anterior and posterior areas of the left side of the neck. She reports that she coughs sometimes.
3. Lakshmi Kumari of 223 Gandhi Dham, Bapu Nagar (Patient C) is a 46-year-old woman who has had cough for two months with fever, sweats at night, and occasional coughing up of blood. The patient is being attended to at a remote health unit (PHI 101); sputum will be transported to the microscopy centre.
4. Lakshmi Pati Rao of 223 Gandhi Dham, Bapu Nagar (Patient D) is the 50-year-old husband of C. He has had cough for years. When asked, he reports that he has received treatment for “pneumonia” several times in the past. He remembers receiving shots for a few months once, and at another time taking a medicine which made his urine turn orange. He recalls that these medicines helped him feel much better. He is seen at the same unit as C (PHI 101).

5. Girija Devi of 225 Gandhi Dham, Babu Nagar (Patient E) is the 32-year-old neighbour of C and D. She encouraged both to come to health unit PHI 101 because of their symptoms. She reports a rash on her arm and says she sneezes often. She requests sputum examination. She has no other symptoms and no cough.
6. Kailash Nath of 225 Gandhi Dham, Babu Nagar (Patient F) is the 35-year-old husband of E. He came to health unit PHI 101 only to meet C, D and his wife E. He wants to go back home before it gets late. He is coughing and spitting blood. When asked, he reports that he has been coughing for several years.
7. Sita Devi of 2586 Gali No. 3, Gobind Puri, Near Gurudwara (Patient G) is an 80-year-old woman who complains that she feels tired. She does not have cough or fever. She has heard that people who are weak and receive treatment at this centre, get better.
8. Ashok Kumar of No. 55 Raja Garden, Near Post Office (Patient H) is a 31-year-old vendor who complains of cough and high fever for the past 10 days. He has otherwise been healthy, but now feels very ill, and is short of breath when he walks. He remembers that the fever came on suddenly.
9. Ghanshyam Singh of 124 JJ Colony, Rajiv Puram (Patient I) is a 16-year-old boy who has slight difficulty in walking over the last two years. His right knee is swollen. He saw a physician in town who took a biopsy which showed caseating granuloma. He could not afford treatment from the physician, and was referred to the centre for care. He has no cough.
10. Bhola Ram of Gali Gobi Wali No. 1704, Near Mandir (Patient J) is a 32-year-old farmer who has had cough for the past 4 months. He has lost weight.
11. Man Bahadur Lal of Tilonia, No. 25A (Patient K) is a 52-year-old man being treated for pulmonary tuberculosis at this centre (TB No. 96). Today is his last day of medication—he has completed the full six months of treatment. His sputum was positive when he began treatment and became negative after two months of treatment and after two months of the continuation phase. He brings in a sputum sample collected early in the morning.
12. Lallan Prasad Parmar of Gali Akara, Near Rivoli, No. 217 (Patient L) is a 51-year-old man who was treated at this centre one year ago and was

declared cured prior to the implementation of the RNTCP. He now has cough and fever for the past month.

13. Visweswara Reddy of A 28 Kingsway Camp (Patient M) is a 16-year-old male who reports feeling feverish and tired for the past month. He also has a running nose and sneezing. Temperature is normal.
14. Ravindra Mehrotra of No. 70 Masjid Ke Pas, Sultan Bazar (Patient N) is a 40-year-old woman who complains of rash on her scalp and trouble sleeping at night.
15. Kiran Kumar of No.15 Gulmohar Park (Patient O) is the 37-year-old nephew of the resident of 223 Gandhi Dham, Bapu Nagar (Patient K). He has had cough for one month. Though he is able to carry on work, occasionally he feels feverish and has lost weight. Since his uncle's tuberculosis is getting better, he felt it might be a good idea to be evaluated.
16. Gopalakrishnan of No.13, Street No. 22, Near Bata Shoe (Patient P) is a 27-year-old man who complains of headache for the past one year. Presently he is taking painkillers. His neighbour recently died of TB meningitis.
17. Ramakrishna of Lucknow Road B 77 Ram Nagar (Patient Q) is a 64-year-old man who complains of pain in the chest, worse with work and when walking uphill. Also, a feeling of breathlessness when walking uphill and upstairs.
18. Rakesh Roshan, No. 252 B, East of Kailash, (Patient R) is a 24-year-old man who complains of cough and fever which began acutely one week ago. Sputum is rusty in colour.
19. Rama Sharma of B 27/31 Shalimar Bagh, Gopal Mandir (Patient S) is a 6-year-old boy who has running nose and cough for 2 weeks, no other symptoms. Growing well.
20. Srinivasa Rao of Gali Pathan Wali, WB 2451 Loni village (Patient T) is a very thin, 36-year-old man who reports no prior illness, and now has had cough with yellow sputum for 1–2 months and occasional fever and coughing up of blood. He requests cough syrup.
21. Kamla Devi residing near Baji Wali Gali, Chandni Chowk (Patient U) is a four-year-old girl with diarrhoea and fever.
22. Brahma Prakash of No. 742, Police Chowki, Yamuna Pushta (Patient V) is

an 82-year-old man who is increasingly forgetful. His family reports that he has been wandering around the house aimlessly.

23. Nanda Kumar, of 54 Khan Market (Patient W) is a 24-year-old man who has been feeling increasingly weak and having fever for the past six months. He sought care from a local practitioner of indigenous medicine but is increasingly short of breath. His sputum is blood-streaked.
24. Niranjan Kumar, B1/221 Nehru Place (Patient X), is an 18-year-old male with cough for 1–2 months. He started smoking one week ago.
25. Meena Kumari of 52 Street No. 24 Rajpur Road (Patient Y) is a 36-year-old woman who complains of pain in her chest. She has been coughing occasionally for the past 6 months.
26. Ammani Amma of Palkaika, No. 24 Kishen Ganj (Patient Z) is a 40-year-old woman with fever for the past 2 months. She reports that she has cough in the morning on most days for about 2 months.

3 SUPPORTING LABORATORY SERVICES

INTRODUCTION

The Senior Tuberculosis Laboratory Supervisor (STLS) is responsible for monitoring activities of all the microscopy centres in his area/sub-district. The District Tuberculosis Officer (DTO) and the Medical Officer-Tuberculosis Control (MO-TC) are responsible for *supporting* laboratory services by visiting the laboratories and performing identified activities.

Each laboratory must have a Tuberculosis Laboratory Register which is filled up completely and accurately. The Tuberculosis Laboratory Register indicates that tuberculosis suspects have had their sputum examined the correct number of times for tubercle bacilli. The DTO and STLS are responsible for verifying that the results of sputum examinations are accurate.

You should monitor the maintenance of documentation related to microscopy examinations. This includes explaining to the laboratory technicians the importance of limiting administrative errors (for example, keeping the sputum specimens with the proper Laboratory Form for Sputum Examination and slides) and accurately recording results of sputum examinations. Ensure that the laboratory technicians keep the examined slides for review by the STLS and have an adequate supply of reagents and other materials (including boxes for storing slides) to conduct sputum examinations. You should work with the STLS to make sure the laboratory has an adequate supply.

Ensure that the microscopy centres are visited by the STLS for supervision at least once every 4 weeks.

MONITOR DOCUMENTATION RELATED TO MICROSCOPY EXAMINATIONS

Patients are placed on treatment regimens based on the results of their sputum smear examinations. If the results of sputum specimen examinations are recorded on the Laboratory Form for Sputum Examination of some other person, the patient may be prescribed the wrong treatment regimen, treated unnecessarily, or not treated despite having TB. To limit these errors it is of paramount importance to monitor how the laboratory technicians examine and record results of sputum smear examinations, i.e. to make sure they keep the sputum specimens with the correct Laboratory Form for Sputum Examination and slides, and accurately record the results of sputum examinations on the form. Also make sure that laboratory technicians keep all the slides until the STLS reviews them for accuracy.

Explain the importance of limiting administrative errors

If the patient's sputum specimens are not labelled properly at the health unit or if the Laboratory Form for Sputum Examination gets separated from the specimens, the laboratory technician may not know whose sputum specimens are in the containers when they reach the laboratory.

When you visit the microscopy centre, discuss with the laboratory technicians the process they use to be sure that the Laboratory Serial Number on the Laboratory Form for Sputum Examination matches the Laboratory Serial Number on the sputum container. Also make sure that the Laboratory Serial Number is written on the side of the sputum container and that it matches the number on the slide which is prepared. The same number should be recorded on the Laboratory Form for Sputum Examination.

Other centres which collect specimens and transport them to the microscopy centre should assign Specimen Identification Numbers and write it on the side of the container.

Make sure laboratory technicians keep slides for review

Explain to the laboratory technicians that they should keep all the examined slides so that they can be checked by the STLS. The slides should be filed according to the Laboratory Serial Numbers and smear-positive and

smear-negative slides kept in separate boxes until the next supervisory visit by the STLS. During the visit, the STLS should locate and review all smear-positive slides and 10%–20% of smear-negative slides. During your visit to the microscopy centre, check the slide boxes and ensure that all smear-positive and smear-negative slides are being preserved.

Explain the importance of accurate recording of results of sputum smear examinations

The laboratory technicians should understand the importance of accurate recording of results of sputum smear examinations on the Laboratory Form for Sputum Examination. Explain to them that patients are diagnosed and placed on the appropriate treatment regimen based on the results of their sputum smear examinations. For example, if a laboratory technician records the results of 3 sputum examinations as negative, the patient may be considered a smear-negative case and placed under Category III (CAT III) treatment regimen. If one of the results was actually **positive** and the X-ray was consistent with active tuberculosis, the patient may have been diagnosed as a smear-positive case and placed on Category I (CAT) treatment regimen. Also, at the end of the initial intensive phase, patients have their sputum examined to determine whether they have converted to (or remained) smear-negative. During the continuation phase also, smear-positive patients are monitored by microscopy examination. If sputum examination results are incorrectly recorded, it will affect the treatment given.

When you visit the microscopy centre, speak with the laboratory technicians and make sure they know how to complete the Laboratory Form for Sputum Examination. All smear-positive (including scanty) results should be recorded in red in the Tuberculosis Laboratory Register. The following table describes what should be written in the **Results** and **Positive (grading)** columns of the form according to the number of acid-fast bacilli (AFB) seen while examining the slide:

If the slide has:	Results	Positive (grading)	No. of fields to be examined
More than 10 AFB per oil immersion field	Pos	3+	20
1–10 AFB per oil immersion field	Pos	2+	50
10–99 AFB per 100 oil immersion fields	Pos	1+	100
1–9 AFB per 100 oil immersion fields	Scanty	Record exact figure	200
No AFB in 100 oil immersion fields	Neg	—	100

Grading improves the laboratory technician's attention and facilitates supervision. It also helps assess the load of disease and provides epidemiologic information. Patients who have 3+ or 2+ sputum smear examination results are less likely to convert to smear-negative by the end of the initial intensive phase, although these patients have equally high cure rates.

The laboratory technician should have little or no difficulty in reading slides that contain many AFB. However, when there are less than 10 AFB per 100 oil immersion fields, the laboratory technician may have difficulty in reading the slide and determining whether the results are scanty or negative. Therefore, if 1–9 AFB are seen in the first 100 oil immersion fields, another 100 oil immersion fields should be examined. If the result is 'Scanty' then the exact number of bacilli seen should be recorded (e.g. "6 bacilli seen in 200 fields").

Results should be reported to the treating physician within one day.

Ziehl–Neelsen staining

1. Select a new unscratched slide and label the slide with the Laboratory Serial Number.
2. Spread sputum on the slide using a broomstick.
3. Allow the slide to air dry for 15–30 minutes.
4. Fix the slide by passing it over a flame 3–5 times for 3–4 seconds each time.
5. Pour filtered carbol fuchsin to cover the entire slide.
6. Gently heat the slide with carbol fuchsin on it until vapours rise. Do not boil.
7. Leave carbol fuchsin on the slide for 5 minutes.
8. Gently rinse the slide with tap water until all free carbol fuchsin stain is washed away.
9. Pour 25% sulphuric acid onto the slide.
10. Let the slide stand for 2–4 minutes.
11. Rinse gently with tap water. Tilt the slide to drain off the water.
12. If the slide is still red, reapply sulphuric acid for 1–3 minutes and rinse gently with tap water.
13. Pour 0.1% methylene blue onto the slide.
14. Leave 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 x40 lens to select the suitable area and then examine under x100 lens using a drop of immersion oil.
18. Record the results in the Laboratory Form and the Laboratory Register appropriately as per the table given below:

Examination	Result	Grading	No. of fields to be examined
More than 10 AFB per oil immersion field	Pos	3 +	20
1–10 AFB per oil immersion field	Pos	2 +	50
10–99 AFB per 100 oil immersion fields	Pos	1 +	100
1–9 AFB per 100 oil immersion fields	Scanty	Record exact number seen	200
No AFB in 100 oil immersion fields	Neg	0	100

19. Store all positive and negative slides until instructed by the supervisor.
20. Disinfect all contaminated material before discarding.



EXERCISE WORKBOOK E1: LABORATORY FORM FOR SPUTUM EXAMINATION

Complete the Laboratory Form: Bottom Section

Start with Laboratory Serial Number 101. The appearance of the specimen is given in brackets. Specimens are examined on 4 September. Sign your own name.

Patient	Number of AFB seen (visual appearance)
B Parvathi Sinha	30 AFB are seen in 100 oil immersion fields (mucopurulent) 6 AFB are seen in 200 oil immersion fields (mucopurulent) 70 AFB are seen in 100 oil immersion fields (mucopurulent)
C Lakshmi Kumari	150 AFB are seen in 50 oil immersion fields (bloody) 80 AFB are seen in 50 oil immersion fields (mucopurulent) 25 AFB are seen in 100 oil immersion fields (mucopurulent)
D Lakshmi Pati Rao	240 AFB are seen in 20 oil immersion fields (mucopurulent) 50 AFB are seen in 100 oil immersion fields (mucopurulent) 100 AFB are seen in 50 oil immersion fields (mucopurulent)
F Kailash Nath	300 AFB are seen in 20 oil immersion fields (bloody) 200 AFB are seen in 50 oil immersion fields (bloody) 10 AFB are seen in 100 oil immersion fields (bloody)
J Bhola Ram	400 AFB are seen in 50 oil immersion fields (bloody) 60 AFB are seen in 100 oil immersion fields (mucopurulent) 0 AFB are seen in 100 oil immersion fields (mucopurulent)
K Man Bahadur Lal	0 per 100 oil immersion fields X 2, both saliva
L Lallan Prasad Parmar	80 AFB are seen in 100 oil immersion fields (mucopurulent) 0 AFB are seen in 100 oil immersion fields (mucopurulent) 0 AFB are seen in 100 oil immersion fields (mucopurulent)
O Kiran Kumar	0 per 100 oil immersion fields X 3 (saliva, mucopurulent, saliva)

Patient	Number of AFB seen (visual appearance)
T Srinivasa Rao	0 per 100 oil immersion fields X 3 (all mucopurulent)
W Nanda Kumar	0 per 100 oil immersion fields X 3 (all bloody)
X Niranjan Kumar	0 per 100 oil immersion fields X 3 (saliva, mucopurulent, saliva)
Y Meena Kumari	0 per 100 oil immersion fields X 3 (mucopurulent twice then saliva)
Z Ammani Amma	0 per 100 oil immersion fields X 3 (all mucopurulent)

TUBERCULOSIS LABORATORY REGISTER

The Tuberculosis Laboratory Register (see page 60) is used to record the results of sputum smear examinations. The laboratory technician assigns a Laboratory Serial Number (see **Lab Serial No.**) for each patient whose sputum smear was examined. The following information about the patient is then recorded:

- date of sputum smear examination
- full name
- sex
- age
- name of the treatment unit that requested the examination
- complete address (for New patients only)
- reason for examination (diagnosis or follow-up of chemotherapy)
- results of sputum smear examinations (results of specimens 1, 2 and 3 can be recorded).

If the patient is a chest symptomatic being evaluated, the technician ticks the *Diagnosis* column under *Reason for Examination*. If the patient is already on chemotherapy, the laboratory technician writes the patient's Tuberculosis Number (from the Laboratory Form for Sputum Examination) in the *Follow-up* column under *Reason for Examination*.

The last two columns of the Tuberculosis Laboratory Register are for the technician's signature and any remarks he or his supervisor want to make.

Using the Tuberculosis Laboratory Register

When you visit the microscopy centres in the district, make sure that all smear-positive patients are started on treatment. If any smear-positive patients have *not* been entered in the Tuberculosis Register, make sure they are found, placed on treatment immediately and registered in the Tuberculosis Register. If the patient lives outside the district, a copy of the Laboratory Form for Sputum Examination with the result written on it must be sent to the district where the patient will begin treatment. The Laboratory Form for Sputum Examination should indicate 'Patient not

registered. Please register patient'. A copy of the Laboratory Form for Sputum Examination should be maintained on file until receipt of intimation from the district to which the patient was referred. Information regarding transfer of a patient should be noted in the **Remarks** column of Tuberculosis Laboratory Register.

Also, during visits to the microscopy centre, make sure there is a Tuberculosis Laboratory Register that is completely and correctly filled. Since you need the results of sputum smear examinations and the laboratory serial numbers from the Tuberculosis Laboratory Register, make sure the laboratory technicians know how to complete it. You should also review the Tuberculosis Laboratory Register to ensure that correct number of sputum smear examinations were performed for 'New' patients.

You will usually get the results of follow-up sputum smear examinations when you visit the health units and review the Tuberculosis Treatment Cards. Monitoring the results of a patient's sputum smear examination is necessary to evaluate sputum conversion from positive to negative and to determine the outcome of treatment. One way to make sure that results were initially recorded correctly on the Tuberculosis Treatment Cards is to compare the results recorded in the Tuberculosis Register with those recorded in the Tuberculosis Laboratory Register.

Check the accuracy of the Tuberculosis Laboratory Register

Laboratory staff should not use the Tuberculosis Laboratory Register to record the results of any other laboratory examinations. All results of sputum smear examinations should be written in the Tuberculosis Laboratory Register, and these need not be written in any other register.

Make sure that laboratory technicians are using the correct Laboratory Serial Number. A new number should be assigned to a TB suspect whose sputum is to be examined. The Laboratory Serial Number should begin with 1 each year. When a patient is entered in the Tuberculosis Laboratory Register, '1' should be added to the last Laboratory Serial Number recorded. For example, on 2 January 1992, a laboratory technician records the results of sputum smear examinations of 3 patients. The Laboratory Serial Numbers assigned to those patients are 1, 2 and 3. On 3 January, a laboratory technician records the results of sputum smear examinations of 5

patients. The Laboratory Serial Numbers assigned to those patients are 4, 5, 6, 7 and 8.

The Laboratory Serial Number is written in the Tuberculosis Register. It is used as a cross-reference when you verify that the results of the sputum examination in the Tuberculosis Register match those in the Tuberculosis Laboratory Register. By using the name of the patient and his Laboratory Serial Number from the Tuberculosis Register, you should easily find the results of sputum smear examinations in the Tuberculosis Laboratory Register. Without this Laboratory Serial Number, you would have to look through many pages of the Tuberculosis Laboratory Register for a patient's sputum smear examination results.

A Laboratory Serial Number is assigned to a *patient*, not to a sputum specimen. Up to *three* sputum specimen examination results can be recorded for each patient on *one* line of the Tuberculosis Laboratory Register.

During visits to the microscopy centre, look through the Tuberculosis Laboratory Register and make sure all the columns have been completed. For example, you may find that a patient's address or treatment unit is missing in the Tuberculosis Laboratory Register. The laboratory technicians must understand the importance of writing the address of patients examined for diagnosis so that they can be found and placed under treatment. If the sputum smear examination was intended for diagnosis of a patient with suspected tuberculosis, the name of the treatment unit that *referred* him should be written in the **Name of Referring Health Centre** column. If the sputum smear examination was for follow-up of chemotherapy, the name of the treatment unit where the patient is *undergoing* the treatment should be written in the **Name of Referring Health Centre** column. The Tuberculosis Number of at least all smear-positive patients started on treatment should be recorded in the **Remarks** column, and the Tuberculosis Number of all patients whose sputum is examined for follow-up must be written in the space provided.

At the end of each month, the laboratory technician should summarize the information on sputum smear examinations done that month. This information should be summarized in the following format, using a blank line in the Laboratory Register itself. The number of **patients** examined and diagnosed (not the number of slides) should be given.

Number of patients whose sputum was examined for diagnosis	
Number of smear-positive patients diagnosed	
Number of patients on treatment whose sputum was examined for follow-up	
Number of patients whose follow-up sputum examination was found to be smear-positive	

Ensure that the New patients had three sputum samples examined and that follow-up cases had two sputum samples examined

When you review the Tuberculosis Laboratory Register, verify that all patients had their sputum specimens examined the correct number of times.

To define a patient as smear-negative, **3** different sputum specimens must be examined. The result of each sputum smear examination must be negative. If you review the Tuberculosis Laboratory Register and notice that only 2 sputum specimens were examined, ask why another sputum smear examination was not done. A smear-positive patient may be missed if the third sputum is not collected and examined. ***To minimize the proportion of 'false' smear-negative patients, at least 3 smear-negative sputum specimens should be available.***

To define a patient as smear-positive, there must be **at least 2 positive sputum specimens**. If 2 sputum specimens were examined and only 1 was smear-positive, you are responsible for ensuring that the patient is traced (if the patient has not returned to the laboratory). When the patient returns another sputum specimen should be collected and examined.

If 3 sputum specimens were examined and 1 was smear-positive, the patient must be found and referred to a Medical Officer (MO) for an X-ray examination.

3

Spot-check results of sputum smear examinations for follow-up

Another important task during your visits to the microscopy centre is to make sure the results of follow-up sputum smear examinations for patients who were smear-positive on entry into treatment have been accurately recorded in the Tuberculosis Register.

The schedule of follow-up sputum smear examinations is given in the table below:

Schedule of follow-up sputum smear examinations

Category of treatment	Pre-treatment sputum	Test at month	IF: result is	THEN:
Category I	+	2	-	Start continuation phase, test sputum again at 4 and 6 months [‡]
			+	Continue intensive phase for one more month, test sputum again at 3, 5 and 7 months [‡]
	-	2	-	Start continuation phase, test sputum again at 6 months [‡]
			+	Continue intensive phase for one more month, test sputum again at 3, 5 and 7 months [‡]
Category II	+	3	-	Start continuation phase, test sputum again at 5 and 8 months
			+	Continue intensive phase for one more month, test sputum again at 4, 6 and 9 months
Category III	-	2	-	Start continuation phase, test sputum again at 6 months [‡]
			+	Re-register the patient and begin Category II treatment [‡]

[‡] Any patient treated with Category I or Category III, who has a positive smear at 5, 6 or 7 months of treatment should be considered a Failure and started on Category II treatment afresh.

Patients who were initially diagnosed as smear-negative but who have a positive sputum smear after two months continue on Category I treatment. Although theoretically speaking these patients might be considered to have failed treatment, but practically it is more likely that they were initially sputum positive, but because of poor quality sputum samples or errors in microscopy, were diagnosed as being smear-negative. Therefore, extension of the intensive phase of Category I and ensuring that treatment is directly observed as per policy is the most appropriate management for such patients unless there is marked clinical worsening (i.e. documented increasing fever or significant weight loss between the time of initiation of treatment and the 2-month follow-up examination).

The follow-up sputum smear examination at the end of treatment is essential for evaluation of the outcome of treatment (to determine the cure rate). Sputum should generally be collected at the last but one week of treatment so that the result is available at the time the last week's blister pack is supplied.

Follow up of sputum smear examinations of patients put on non-DOTS regimens should be done at 2, 6 and 12 months.

Regimen	Sputum examinations for pulmonary TB			
	Pre-treatment sputum	Test at 2 months	Test at 6 months—IF: → THEN:	
R ₁ (2SHE/10HE)	+	+	+	Failure
			-	Continue treatment
		-	-	Continue treatment
			+	Failure
	-	-	-	Continue treatment
			+	Failure
		+	+	Failure
			-	Continue treatment
R ₂ (12HE)	+	+	Failure	
		-	Continue treatment	
	-	-	Continue treatment	
		+	Failure	

In the case of patients receiving R₁ or R₂, patients who are smear-positive at 6 months or more after starting treatment are classified as failure. In patients treated with R₁ and R₂, failure also includes a patient who was initially smear-negative but who is smear-positive after 6 months or more of treatment.

The most important method of follow-up for smear-positive cases are sputum smear examinations which are carried out at the end of 2 months (New smear-positive cases), at the end of 3 months (retreatment cases and New smear-positive cases who were smear-positive at the end of 2 months) and at the end of treatment. These results determine the conversion rate from smear-positive to smear-negative at the end of the intensive phase of treatment, and hence, the cure rate.

To ensure that sputum smear examinations are actually carried out in accordance with the policy, during visits to the microscopy centre spot-check the results of sputum smear examinations of approximately 15 patients in the Tuberculosis Laboratory Register who should have had their sputum examined for follow-up of chemotherapy.



EXERCISE 1

Case 1

During your visit to a microscopy centre in your district you review the Tuberculosis Laboratory Register. You notice that the laboratory technicians are beginning with a new Laboratory Serial Number every month. You also notice that the **Address** column for New patients is never completed.

1. Describe what the technicians in the microscopy centre are doing incorrectly. Also include what you should tell the technicians about the importance of maintaining an accurate Tuberculosis Laboratory Register.

Case 2

Review the sample page of the Tuberculosis Laboratory Register on the next page.

1. List the names of New patients whose sputum was examined three times and who **can** be defined as **smear-negative** pulmonary TB case provided that a Medical Officer makes the diagnosis of smear-negative tuberculosis based on clinical and X-ray examination and decides on treatment.
2. List the names of New patients who only had 2 sputum specimens examined and **cannot** be defined as **smear-negative**.
3. List the names of New patients who **can** be defined as **smear-positive**.
4. List the names of New patients who **only had 1 positive sputum specimen**. Describe what action you should take.
5. List the patients examined for follow-up whose sputum smear examination or recording was incorrect and explain why.

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Laboratory Register

Year 1997

Lab Serial No.	Date	Name (in full)	Sex M/F	Age	Complete address (for new patients)	Name of Referring Health Centre	Reason for Examination*		Results			Signature	Remarks
							Diagnosis	Follow-up	1	2	3		
499	90/3	Sita Prati	F		M. No. 211, Pocket III, Mayur Vihar	Modern TB Clinic	✓		Neg	Neg	Neg	Joshi	No. 526
500	90/3	Krishna Kaith	F	54	M. No. 60, Sector II, Jangpurgar	Jangpurgar Health Centre	✓		Neg	Neg		Joshi	
501	90/3	Aswani Lal	F	39	225, Block 4, Pappu Nagar	Chest Disease Health Centre	✓		3+			Joshi	No. 541
502	90/3	Abdel Mazan	M	44	Full No. 7, J.J. Ram Kaul Colony	Aligarh Dispensary		20	Neg			Joshi	
503	1/4	Rhim Singh		38	M. No. 422, Sector-III, Kahlua	Modern TB Clinic		102	Neg	Neg		Joshi	
504	1/4	Alex Chopra	M	45		Good Health Centre	✓		1+	1+	2+	Joshi	
505	1/4	Rama Sharma	F	37		Jangpurgar Health Centre		✓	1+	2+		Joshi	
506	2/4	Kumar Biswas	M	58	8522/Block 4, Mahra Plaza	Chest Disease Health Centre	✓		Neg	Neg	Neg		
507	2/4	Poojak Phawar	M	23		Modern TB Clinic	✓		1+	2+		Joshi	No. 448
508	3/4	Pratibha Chandra	F	28	M. No. 62, Lane No. 120, Kailash Colony		✓		Neg	Neg	Neg	Joshi	

* If sputum is for diagnosis, put a tick (✓) mark in the space under "Diagnosis".
 If sputum is for follow-up of patients on treatment, write the patient's TB No. in the space under "Follow-up".



EXERCISE 2

Complete two pages of the Laboratory Register using the Laboratory Forms you have just completed.

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME Laboratory Register

Lab Serial No.	Date	Name (in full)	Sex M / F	Age	Complete address (for new patients)	Name of Referring Health Centre	Reason for Examination*		Signature	Remarks	Year
							Diagnosis	Follow-up			

* If sputum is for diagnosis, put a tick (✓) mark in the space under "Diagnosis".
 † Sputum is for follow-up of patients on treatment, write the patient's TB No. in the space under "Follow-up".

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Laboratory Register

Lab Serial No.	Date	Name (in full)	Sex M/F	Age	Complete address (for new patients)	Name of Referring Health Centre	Reason for Examination*		Results			Signature	Remarks
							Diagnosis	Follow-up	1	2	3		

* If sputum is for diagnosis, put a tick (✓) mark in the space under "Diagnosis".
sputum is for follow-up of patients on treatment, write the patient's TB No. in the space under "Follow-up".

ENSURE THAT THE LABORATORY QUALITY CONTROL NETWORK IS FUNCTIONING

Quality control of the tuberculosis laboratory is an essential part of the strategy of the Revised National Tuberculosis Control Programme (RNTCP). Physicians and patients must have confidence in the quality of microscopy services. For this reason, every positive smear, and 10%–20% of negative smears, must be cross-checked by the STLS.

These results should be tabulated as follows:

1. Number of smears read as positive in the local microscopy centre: _____
2. Of these, number confirmed as positive by supervisor: _____
3. Number of negative smears read in the local microscopy centre: _____
4. Of these, number reviewed by supervisor: _____
5. Of the smears reviewed, number confirmed to be negative: _____

Example:

A microscopy centre reads 438 smears in April, of which 40 were positive. The supervisor reviews all 40 positive smears, and confirms that 39 were positive. One smear which was read as positive by the microscopy centre is not confirmed to be positive, and the patient's management is adjusted accordingly. Of the 398 (438 total – 40 positive = 398 negative) smears read as negative, the supervisor reviews 10% (or 40). On review, two of these 40 are found to be positive, and the remaining negative. Therefore:

1. Number of smears read as positive in the local microscopy centre: 40
2. Of these, number confirmed as positive by supervisor: 39
3. Number of negative smears read in the local microscopy centre: 398
4. Of these, number reviewed by supervisor: 40
5. Of the smears reviewed, number confirmed to be negative: 38

These figures are included in the Quarterly Report on Programme Management and Logistics, as follows:

Laboratory Quality Control Network

Initial reading	Number of slides checked	Supervisor reading		Percentage of Discordance
		Number of positives	Number of negatives	
Positive slides	40	(a) 39	(b) 1	$(b/[a+b])$ 2.5% [false positives]
Negative slides	40	(c) 2	(d) 38	$(c/[c+d])$ 5% [false negatives]

MAINTAIN AN ADEQUATE SUPPLY OF REAGENTS AND OTHER MATERIALS

The STLS is responsible for determining the amount of reagents and other materials the microscopy centres will need every quarter. He will also make sure these supplies are distributed in a timely manner, usually on a monthly basis. Because the RNTCP depends on the microscopy centres, you should work closely with the STLS to make sure there is an adequate supply of reagents and other materials.

Make sure there is an adequate stock of reagents and other materials in the laboratory

It is very important for the laboratory to maintain an adequate stock of reagents and other laboratory materials. Visit each microscopy centre with the STLS. Ask the laboratory technicians if they have enough supplies. If the laboratory has less stocks of any items, bring or make sure supplies are sent to the laboratory from the district or sub-district stock. Remind them to exhaust the old supplies before starting to use the new supplies.

During the visit, you and the STLS should also make sure the reagents are in good condition. Re-filter carbol fuchsin if particles have formed. Laboratory workers cannot perform proper sputum smear examinations with reagents that are not in good condition. Also, ask the laboratory technicians if the binocular microscope is in good working condition and inspect and use the microscope. If it is not working properly, arrange for appropriate maintenance. If the microscope is still under warranty, get the supplier to repair it.

The following is a list of reagents which should always be available in the laboratory:

- Carbol fuchsin
- Methylene blue
- Sulphuric acid
- Immersion oil
- Xylene

- Phenol
- Methylated spirit.

The following is a list of other materials that should always be available in the laboratory:

- Microscope slides, and separate boxes for storing smear-positive and smear-negative slides
- Marking pencils, diamond pencils and grease pencils
- Broomsticks (wooden/bamboo sticks for making smears)
- Plastic bottles for reagents
- Universal glass containers
- Glass (or metal) rods for holding slides during the staining process
- Sputum containers
- Spirit lamp or bunsen burner
- Weighing balance (if reagents are prepared at the centre)
- Bleaching powder
- Foot-operated bin for disposal.



EXERCISE 3

1. The following is a list of reagents and supplies for the microscopy centre:

Carbol fuchsin	Sputum containers
Methylene blue	Boxes of microscope slides
Sulphuric acid	Boxes of grease pencils
Xylene	Wooden sticks
Phenol liquid	Universal glass containers
Methylated spirit	

What, if anything, is missing from the laboratory's stock?

2. How should you make sure the microscopy laboratory has an adequate supply of reagents and other materials?

**Let your facilitator know when you have completed the exercise.
He will review the answers with you.**

ENSURE THAT CONTAMINATED MATERIALS ARE DISPOSED OF SAFELY

Sputum specimens examined in the laboratory are potentially infectious and after examination they must be disinfected and destroyed so that the risk of infection is avoided. **All disposable containers must be used only once.**

After the sputum smears are examined, all sputum cups should be kept in a bucket containing 5% hypochlorite or 5% phenol solution. The cups should be fully submerged in the solution. Similarly, used wooden sticks should be put into the same bucket. This bin/bucket should have a lid which is foot operated.

Sputum cups which contain sputum can be disposed of by any of the following methods:

- (i) Incineration—wherever incinerators exist; this is the preferred method.
- (ii) Autoclaving in an autoclave or in a pressure cooker. At the end of each day's laboratory work the sputum cups and lids, with the lids removed, along with wooden sticks, can be placed in a pressure cooker of approximately 7 litre capacity containing adequate amount of water and boiled using any heating source, electrical or non-electrical. Penetration of steam must be allowed. The autoclave cycle should be 15 minutes at 121 °C HTAT (holding time at temperature), 10 minutes at 126 °C HTAT or 3 minutes at 134 °C HTAT. The material can be discarded with other waste after proper cooling.
- (iii) If neither of the above is available, use 5% hypochlorite solution (10% if using household bleach) or 5% phenol freshly prepared each day. Caps of the sputum cups must be removed and the cups and caps and wooden sticks completely submerged in the solution in a secure place for at least 18 hours. After this, the solution, cups, caps and wooden sticks can be discarded with other waste.
- (iv) As a last resort, if none of the above is available, sputum cups, caps and wooden sticks can be burnt in a pit at a safe distance away from inhabited areas, and the burnt material buried in a special landfill site.

CONDUCT VISITS TO MICROSCOPY CENTRES

Microscopy centres are supervised by an STLS from the sub-district. You will work with the STLS to make sure that tuberculosis-related laboratory services are properly performed. Before you visit the microscopy centres, plan your visit thoroughly. During the visits, you will check to see that laboratory activities related to tuberculosis detection and sputum smear examinations are being correctly performed and recorded by the laboratory technicians.

In this section, you will learn how to prepare for visits to microscopy centres. You will also review the items to check when visiting a laboratory. Then you will develop a checklist to use during a visit to a laboratory.

Prepare for visits to microscopy centres

1. Decide **when to visit** each microscopy centre in the district.
Each microscopy centre in your district should be visited for supervision at least once every month.
2. Decide **what** to check.
The specific items you check will depend on the size of the laboratory. Some important items to check are listed under point 4. Review recommendations made during previous visits and bring these with you.
3. Decide **when to check** each item.
Some items, such as the Tuberculosis Laboratory Register, should be checked at each visit. Other items including stocks of sputum containers, slides and reagents may be checked periodically.
4. Decide **how** to check each item.
Depending on the time available for your visit and the items you have decided to check during the visit, decide which are the best ways to collect the information:
 - (i) **Review the Tuberculosis Laboratory Register.** Check the Tuberculosis Laboratory Register to make sure it is filled completely and accurately. Make sure that all smear-positive patients in the

Tuberculosis Laboratory Register are also registered in the Tuberculosis Register. Verify that New patients had their sputum examined the correct number of times.

- (ii) **Talk with the laboratory technicians.** Make sure they understand the importance of limiting administrative errors and accurately recording the results of sputum smear examinations on the Laboratory Form for Sputum Examination. Also, make sure the laboratory technicians keep the examined sputum smear slides of all patients until the next supervisory visit by an STLS.
- (iii) **Examine supplies.** Check to see if there are adequate numbers of sputum containers, slides, reagents, forms and other laboratory supplies.

5. Develop a **checklist**.

Once you have decided what you want to look for when you go to the microscopy centre and how to check each item, it will be helpful to organize the information into a 'checklist'. In general, your checklist should be:

- just long enough to remind you of the important items/activities you need to check
- easy to use.

Include important general information, such as the name of the centre and STLS, and date of the visit. A more comprehensive checklist is in the Annexure (see page 74). Turn to the Annexure and review the checklist now. This checklist is longer than the one which you would be likely to use, but is provided for reference.

Conduct the visit

Inform the STLS in advance that you are planning to visit the microscopy centre. If possible, he should be there during your visit. When you go to the microscopy centre, use the checklist you have prepared. If you face problems, work with the STLS to solve them.

CHECKLIST FOR LABORATORY SUPERVISION

	Yes	No	Not assessed
<p>Knowledge: Does the laboratory technician know:</p> <ul style="list-style-type: none"> ■ How to properly complete the Tuberculosis Laboratory Register and the Laboratory Form for Sputum Examination? ■ How information from the Tuberculosis Laboratory Register is used in the Tuberculosis Register? ■ How to limit administrative errors (for example, keeping sputum specimens with the proper Laboratory Form for Sputum Examination and slides)? 			
<p>Activities: Does the laboratory technician:</p> <ul style="list-style-type: none"> ■ Examine 3 sputum samples for patients diagnosed as smear-negative? ■ Examine at least 2 slides of cases which were read as smear-positive? ■ Maintain an accurate and complete Tuberculosis Laboratory Register? ■ Use red ink to record all positive results in the Laboratory Register? ■ Maintain separate boxes of all smear-positive and smear-negative slides to be checked by an STLS during supervisory visits? 			
<p>Are the Tuberculosis Laboratory Register and the Tuberculosis Register consistent?</p> <ul style="list-style-type: none"> ■ Does the Tuberculosis Register contain all the smear-positive patients recorded in the Tuberculosis Laboratory Register? If the Tuberculosis Laboratory Register contains names of smear-positive patients which are not found in the Tuberculosis Register, make efforts to bring these patients under treatment and register them in the Tuberculosis Register. ■ Are the sputum smear examination results for follow-up patients in the Tuberculosis Laboratory Register the same as the results recorded in the Tuberculosis Register? 			
<p>Logistics</p> <ul style="list-style-type: none"> ■ Is there an adequate supply of sputum containers, slides, reagents, forms, and other laboratory materials? ■ Is the binocular microscope in good working condition? 			



EXERCISE 4

Part A

In this part of the exercise you will prepare for a visit to a microscopy centre. You will develop a checklist to use during the visit. Include items in your checklist which actually can be checked at the microscopy centre you will visit.

Use the blank page (p. 72) to prepare your checklist for the unit. Be sure to include the following information:

- the date
- a space for the name and location of the laboratory
- key recommendations of the previous visit
- the procedures you will check and whether they are correctly or incorrectly performed
- the method to be used to check each item/procedure
- a short list of the questions to ask when you are speaking to the laboratory technician(s)
- a space for comments about any problems identified and possible causes
- a space for recommendations, and a space for your signature

Part B

A site visit to a microscopy centre may occur during this training. If so, your facilitator will give the details of the visit. Use the checklist you have developed. After the site visit, there will be a group discussion about any problems your group found and the solutions you recommend.

WORKSHEET FOR CHECKLIST

Annexure**Laboratory supervision****Items to monitor on supervisory visits**

1. Is every smear-positive patient recorded in the Tuberculosis Register?
2. Is patient information on the Laboratory Forms, including patient's address and reason for sputum smear examination, complete and legible?
3. Are patients having follow-up sputum smear examinations at recommended intervals?
4. Are there sufficient reagents for the expected number of slides to be prepared and examined in the next quarter?
5. Are the Medical Officers and other staff of the centre aware of the importance of sputum smear microscopy for all chest symptomatics?
6. Are three sputum samples being examined for diagnosis of chest symptomatics?
7. Are two sputum samples being examined for follow-up of diagnosed patients?
8. Are laboratory safety precautions maintained correctly?
9. Are sputum containers and other potentially infectious materials disposed of properly?
10. Are sputum smear examination results reported promptly to the referring facility?
11. Is the Tuberculosis Laboratory Register being properly and completely filled?

Observe the laboratory technician during the sputum-collection procedure

1. Did the laboratory technician check to ensure that the Laboratory Form for Sputum Examination was complete?
2. Is the address listed clearly on the Laboratory Form for Sputum Examination?
3. Is the sputum container clearly labelled on the side and not on the lid?
4. Is the Laboratory Serial Number entered correctly, starting with 1 on 1 January of the year and continuing until 31 December?

5. Are each set of sputum samples from a single patient given a single Laboratory Serial Number?
6. Is the Tuberculosis Number written in the space provided for all patients whose Reason for examination is Follow-up of chemotherapy?
7. Does the laboratory technician demonstrate to patients how to bring up sputum?
8. Does the laboratory technician supervise patients when they provide spot sputum specimens?
9. Does the laboratory technician visually examine the sputum provided to determine if it is sputum or saliva only?

Observe the laboratory technician preparing smears for examination

1. Does the laboratory technician use only new slides?
2. Does the laboratory technician either engrave each slide or label it with a grease marker?
3. Does the laboratory technician use a different bamboo stick for each sputum smear?
4. Are the sputum smears made on the slide of the correct size (2 cm × 3 cm) and thickness?
5. Does the laboratory technician wait for the slide to dry before heating the slide to fix it?
6. When the laboratory technician fixes the slide by heating, does he do it for the proper duration of time?
7. Is the carbol fuchsin free of particles and properly filtered?
8. When the laboratory technician heats the carbol fuchsin, does he do it properly, avoiding boiling and allowing the slides to stand for 5 minutes after heating?
9. Does the laboratory technician tilt the slides after rinsing with water to remove excess water?
10. Is the sulphuric acid allowed to stand on the slide for the appropriate time period (2–4 minutes)?
11. Is the methylene blue allowed to stand on the slide for the appropriate time period (30 seconds)?

Observe the laboratory technician examining slides under the microscope

1. While placing immersion oil on the slide, does the laboratory technician take care to avoid touching the slide with the applicator?
2. While examining the slide with the $\times 100$ lens, does the laboratory technician take care to make sure that the lens does not touch the slide?
3. Does the laboratory technician examine negative sputum smear slides for at least 5 minutes?
4. Does the laboratory technician correctly complete the Laboratory Form for Sputum Examination and Laboratory Register?
5. Does the laboratory technician clean the $\times 100$ lens with cotton after completing the examination?
6. Are slides correctly cleaned and maintained for review by the supervisor?
7. Are all smear-positive results recorded in red ink in the Laboratory Register?
8. After examining the slides, does the laboratory technician put the sputum containers and lids (with lids removed) along with the bamboo sticks, into a foot-operated bucket containing either 5% phenol or 5% hypochlorite?
9. Does the laboratory technician break all smear-positive slides after they have been reviewed by his supervisor?
10. Does the laboratory technician ensure that smear-negative slides are not being re-used for AFB microscopy?

4 ADMINISTERING TREATMENT

INTRODUCTION

Each patient who begins treatment for TB must have a Tuberculosis Treatment Card. This card contains important information about a patient, such as:

- name, age, sex and address of the patient
- type of disease
- regimen prescribed
- duration of treatment
- amount of drugs to be given
- results of sputum smear examinations before and during treatment
- drugs administered during the intensive and continuation phases of treatment.

Before a patient begins chemotherapy, it is very important to find out from the patient whether he has **previously taken drugs** for TB. Treatment regimens differ in type and number of drugs as well as duration. A patient who has never taken anti-TB drugs (or has taken these drugs for less than one month) will start on a different treatment regimen as compared to a patient who has taken anti-TB drugs in the past for one month or more.

During your initial contact with a patient, discuss **health education** issues with him, and, if possible, with his family. Communicate health education messages including the infectious nature of TB, the treatment prescribed to cure him, the type of drugs he will be taking, and screening of symptomatic contacts of smear-positive cases. Also emphasize the importance of close supervision of the initial intensive phase of treatment, and the necessity of sputum smear examinations during treatment and of completing the full course of prescribed chemotherapy. Since health education is an important part of treatment administration, make sure that health workers properly communicate with the patients on a continuous basis, particularly during the intensive phase of treatment.

Studies throughout the world and in India have shown that at least one third of the patients do not take medicines as prescribed. Therefore, all efforts should be made to ensure that every dose of medicine in the intensive phase and one dose every week in the continuation phase are

directly observed to be ingested. Treatment observation should be done by someone who is accessible and acceptable to the patient and accountable to the health system.

One of your most important responsibilities is to ensure that during the intensive phase of treatment (which is 2 to 4 months of directly observed administration of drugs) patients are **swallowing every dose** of their drugs under the direct observation of a health worker. To ensure proper drug administration, observe health workers administering drugs to the patients and speak directly to patients to determine whether they have been receiving the correct number and type of drugs. After the patients swallow their drugs in the presence of a health functionary, those receiving streptomycin should be given the injections with **sterile syringes and needles**.

Patients should be administered drugs from a health unit close to their home. During supervisory visits to the health units, review the Tuberculosis Treatment Cards to determine whether these patients are **regularly coming to the health units to take their drugs**. Make sure any patient who has stopped taking drugs is traced and brought back under treatment.

Use of non-DOTS regimens in some RNTCP areas has been noted. Since patients who receive non-DOTS treatment are more likely to default and to die, all efforts should be made to phase out non-DOTS treatment, as has already been done in many areas. This is important to ensure the success of the RNTCP. For this to occur, convenient, patient-centred treatment observation is essential.

As part of your responsibilities in administering treatment, make sure that **children** under the age of 6 years with a family member who is sputum smear-positive are tested for TB and are getting **proper preventive treatment** if they do not suffer from the disease. If they have TB, make sure they receive the appropriate treatment.

COMPLETE TUBERCULOSIS TREATMENT CARDS

It is very important for the hospital or health unit where the patient is receiving treatment to maintain a Tuberculosis Treatment Card (see Annexure I, page 135) for that patient. A Tuberculosis Treatment Card can help ensure that the patients:

- were correctly classified as having either pulmonary or extra-pulmonary TB;
- were correctly recorded as either New, Relapse, Transfer in, Other, Failure or Treatment After Default;
- were prescribed the correct treatment regimen and dosages;
- had sputum smear examinations at the scheduled times;
- were regularly administered drugs; and
- collected drugs on time.

In some RNTCP areas, non-DOTS treatment is still given; non-DOTS treatment should be phased out. To facilitate registration of patients started on non-DOTS regimen, the Tuberculosis Treatment Card for non-DOTS treatment in DOTS areas should be filled. In the initial stages of implementation, up to 10% of patients may get non-DOTS treatment, particularly the mobile population when surrounding areas are not covered. In this case give Streptomycin, Isoniazid, Ethambutol (SHE) or Isoniazid, Ethambutol (HE). However, this is an admission of failure of the programme to ensure convenient, effective treatment observation and should be phased out.

Record general patient information

It is important that the Tuberculosis Treatment Card contains all relevant and up-to-date information about the patient and his disease. Make sure that data are accurate. General information about a patient that is entered in the top section of the Tuberculosis Treatment Card is as follows:

State/City/District and Code district/sub-district

These are all self-explanatory. A code will be assigned by the national level to each district.

Patient TB No./year

Write the Tuberculosis Number (**TB No.**) assigned to the patient when he was registered in the Tuberculosis Register. (You will learn more about the Tuberculosis Register in the *Registering Cases* module.)

Health Unit

Write the name of the unit (Peripheral Health Institution [PHI]) where the patient will be treated by a Medical Officer (MO).

Name

Write the patient's full name.

Complete Address

Write the patient's detailed address with description of nearby landmarks.

Sex

Tick the box marked 'M' if the patient is a male. Tick the box marked 'F' if the patient is a female.

Age

Write the age of the patient at the time of diagnosis. If the patient does not know his age, write an estimated age.

Name and address of contact person

Write the name and address of a person, identified by the patient, who is close to the patient (e.g. a family member, tribal leader, village doctor, community volunteer) who can be contacted in case the patient cannot be located. Also indicate the relationship of the contact person to the patient.

Record disease classification

Tuberculosis cases are classified as either **pulmonary** or **extra-pulmonary**. Pulmonary TB is characterized by the formation of lesions mainly in the lungs. Extra-pulmonary TB is tuberculosis of organs other than the lungs. If a patient has both pulmonary and extra-pulmonary TB, the patient is classified as having pulmonary TB and the site of extra-pulmonary TB is written as well.

Cases of pulmonary TB are subdivided into *smear-positive* and *smear-negative*. Pulmonary smear-positive TB is highly infectious. One untreated smear-

positive case may infect approximately 10–15 people per year.

Patients with pulmonary smear-negative TB are ill and need treatment; however, they are much less infectious than smear-positive patients.

The following guidelines are used to define the patient's disease classification as pulmonary TB or extra-pulmonary TB.

Pulmonary tuberculosis

Smear-positive patient

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

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

Or: TB in a patient with one sputum specimen positive for AFB and culture positive for *M. tuberculosis*.

Smear-negative patient

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

Or: Diagnosis based on culture positive for *M. tuberculosis* but sputum smear examinations negative for AFB.

Extra-pulmonary tuberculosis

Tuberculosis of organs other than the lungs, such as the pleura (pleurisy), lymph nodes, abdomen, genito-urinary tract, skin, joints and bones, meninges of the brain, tuberculoma of the brain, etc.

Diagnosis should be based on one culture-positive specimen from an extra-pulmonary site, or histological evidence, or strong clinical evidence consistent with active extra-pulmonary TB followed by an MO's decision to treat with a full course of anti-TB therapy.

Pleurisy is classified as extra-pulmonary TB. A patient diagnosed with both pulmonary and extra-pulmonary TB should be classified as a case of pulmonary TB.

The following records which may accompany the patient's file will indicate whether the patient has pulmonary or extra-pulmonary TB:

- report of physical examination
- medical records
- results of X-ray examination
- results of sputum smear examinations
- report from MO.

Classify the patient and tick the appropriate box on the Tuberculosis Treatment Card. If the patient has extra-pulmonary TB, write the site affected in the appropriate space on the card.

Record type of patient

Determine whether the patient who has pulmonary or extra-pulmonary TB should be considered a **New, Relapse, Transfer in, Failure, Other or Treatment After Default** case and tick the appropriate box on the Tuberculosis Treatment Card. If the patient comes under the category '**Other**', specify the type.

Guidelines to determine the type of patient

New

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

Relapse

A patient declared cured of TB by a physician, but who reports back to the health service and is found to be bacteriologically positive.

Transfer in

A patient who has been received into a Tuberculosis Unit/District, after starting treatment in another unit where he has been recorded.

Failure

A smear-positive patient who remains smear-positive at 5 months or more after starting treatment. Failure also includes a patient who was initially smear-negative but who becomes smear-positive during treatment.

Treatment After Default

A patient who received anti-TB treatment for one month or more from any source and who returns to treatment after having defaulted, i.e. not taken

anti-TB drugs consecutively for two months or more.

Other

Patients who do not fit into the above-mentioned types. Reasons for defining a patient as 'Other' must be specified.

If a patient is either a **Relapse, Transfer in, Failure or Treatment After Default** case, a *new Tuberculosis Treatment Card must be started*. The patient's old Tuberculosis Treatment Card has to be kept in the health unit where the patient was originally treated.

If a patient is a 'Transfer in' case, a Tuberculosis Transfer Form (see page 139) and a duplicate copy of the Tuberculosis Treatment Card will be sent from the referring health unit to the health unit where the patient will receive treatment. This form contains information about the patient and his disease. The information should be used to complete a new Tuberculosis Treatment Card for the patient. When the patient has reported to the new health unit, the bottom part of the form is completed by the health unit to which the patient is referred and returned to the referring unit.

A copy of the Tuberculosis Treatment Card should be sent to the District Tuberculosis Officer (DTO) of the district to which the patient is transferred. A Tuberculosis Identity Card is completed for each patient who has a Tuberculosis Treatment Card. It is kept with the patient. Information from the Tuberculosis Treatment Card is used to complete the card. The patient's appointment dates for sputum smear examinations, clinical examinations and drug collection for self-administered medications can be recorded on the back of the patient's Tuberculosis Identity Card.

Record results of pretreatment sputum smear examinations of patients who will begin treatment for tuberculosis

When a health worker or an MO suspects a patient of having symptoms of pulmonary TB, the patient's sputum must be collected and examined. The Laboratory Form for Sputum Examination is the record you will use to obtain information on the results of a patient's sputum smear examination. This form should be kept at the treatment unit. Look at the **Date** column. Write the date when the first sputum specimens were collected and the Laboratory Serial Number on the patient's Tuberculosis Treatment Card under the appropriate columns.

Look at the **Smear result** column of the form. This column contains the results of the sputum smear examinations. There should be 3 sputum specimens collected for every patient for the pretreatment examination.

If all 3 results are **negative**, the laboratory will write NEG under the **Smear results** column. If the patient's results are **positive**, write the highest grade of positivity in the **Smear** column in red ink.

Record the patient's weight

The weight of the patient is written next to the appropriate month.

Determine the category of treatment

Treatment is given according to categories. These categories must be strictly adhered to. Please review the table carefully.

Category of Treatment	Type of Patient	Regimen*
Category I	New sputum smear-positive Seriously ill sputum smear-negative Seriously ill extra-pulmonary**	2(HRZE) ₃ 4(HR) ₃
Category II	Sputum smear-positive Relapse*** Sputum smear-positive Failure*** Sputum smear-positive Treatment After Default	2(HRZES) ₃ 1(HRZE) ₃ 5(HRE) ₃
Category III	Sputum smear-negative, Extra-pulmonary, not seriously ill	2(HRZ) ₃ 4(HR) 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. H: Isoniazid (600 mg), R: Rifampicin (450 mg), Z: Pyrazinamide (1500 mg), E: Ethambutol (1200 mg), S: Streptomycin (750 mg). Patients who weigh more than 60 kg receive additional rifampicin 150 mg. Patients more than 50 years old and those who weigh less than 30 kg receive streptomycin 500 mg. 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.

** Examples of seriously ill extra-pulmonary TB cases are meningitis, disseminated TB, tuberculous pericarditis, peritonitis, bilateral or extensive pleurisy, spinal TB with neurological complications and intestinal and genito-urinary TB.

*** 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 'Other' and given Category II treatment.

Most patients with smear-negative TB should be given Category III (CAT III) treatment. If more than 20% of patients given Category I (CAT I) treatment are smear-negative, then too many patients are being placed on CAT I treatment and diagnostic practices should be reviewed and corrected.

Patients who have been previously treated are at an increased risk for having isolates of *M. tuberculosis* which are resistant to anti-TB drugs. For this reason, they are given a more intensive regimen. Experience in India and elsewhere has shown that Category II (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 generally respond well to treatment, provided they take it regularly.

Treatment is extended for an additional month if sputum smears are positive at the end of the intensive phase (2 months for CAT I patients, 3 months for CAT II patients). If a patient receiving CAT III regimen has a positive sputum smear at the end of month 2, he should be recorded as a Failure and re-registered and treated with the CAT II regimen afresh. CAT I and CAT II patients who have positive sputum smears at the end of the intensive phase and who, therefore, receive one additional month of intensive phase treatment, receive the same duration of treatment in the continuation phase—4 months for CAT I patients and 5 months for CAT II patients. 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 after the start of treatment. If this is positive, the patient is considered a treatment Failure and put on CAT II treatment afresh.

Category I: New cases who are sputum smear-positive, or seriously ill patients with smear-negative or extra-pulmonary disease.

Treatment. Treatment is given in two phases. The intensive phase consists of isoniazid, rifampicin, pyrazinamide and ethambutol given under direct observation thrice a week on alternate days and lasts for 2 months (24 doses). This is immediately followed by the continuation phase, which consists of 4 months (18 weeks; 54 doses) of isoniazid and rifampicin given thrice a week on alternate days—the first dose every week being directly observed. If the sputum smear is positive after 2 months of treatment, the 4

intensive phase drugs are continued for another one month (12 doses) before starting the 4-month (18 weeks) continuation phase. If the sputum smear is positive after 5 or more months of treatment, the patient is declared as a Failure and is placed on CAT II treatment afresh.

Category II: Retreatment cases including patients with Relapse, Failure, Treatment After Default and others. Such patients are generally sputum smear-positive.

Treatment. Treatment is given in two phases. The intensive phase consists of two months (24 doses) of isoniazid, rifampicin, pyrazinamide, ethambutol and streptomycin all given under direct observation thrice a week on alternate days, followed by one month (12 doses) of isoniazid, rifampicin, pyrazinamide and ethambutol, all given under direct observation thrice a week on alternate days. This is immediately followed by the continuation phase, which consists of 5 months (22 weeks; 66 doses) of isoniazid, rifampicin and ethambutol given thrice 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 4 oral intensive phase drugs are continued for another one month (12 doses) before starting the 5-month continuation phase.

Category III: Patients who are smear-negative, or who have extra-pulmonary TB and are not seriously ill.

Treatment. Treatment is given in two phases. The intensive phase consists of isoniazid, rifampicin and pyrazinamide given under direct observation thrice a week on alternate days and lasts for 2 months (24 doses). This is immediately followed by the continuation phase, which consists of 4 months (18 weeks; 54 doses) of isoniazid and rifampicin given thrice a week on alternate days, the first dose of every week being directly observed. If the sputum smear is positive after 2 months of starting treatment, the patient is considered a treatment failure and begun afresh on CAT II treatment.

Drugs are supplied in patient-wise boxes containing the full course of treatment, and packaged in blister packs. For the intensive phase, each blister pack contains one day's medication. For the continuation phase, each blister pack contains one week's supply of medication. The combipack

drugs for extension of the intensive phase are supplied separately.
Information on dosage is provided in the chart given on the next page.

Medication	Dose (thrice a week)	Number of pills in combipack
Isoniazid	600 mg	2
Rifampicin	450 mg*	1
Pyrazinamide	1500 mg	3
Ethambutol	1200 mg	3
Streptomycin	0.75 g**	—

* Patients who weigh 60 kg or more are given an extra 150 mg dose of rifampicin

** Patients over 50 years of age and those who weigh less than 30 kg are given 0.5 g of streptomycin

Dosages for children are given below. Treatment regimens for children with active TB are similar to those of adults. Children are rarely sputum smear-positive, and thus generally receive CAT III treatment. Ethambutol should not be given to children who are too young to have their visual acuity assessed or report reduced vision.

Dosages for children

Drugs	Therapy per dose (thrice a week)
Isoniazid	10–15 mg/kg
Rifampicin	10 mg/kg
Pyrazinamide	35 mg/kg
Streptomycin	15 mg/kg
Ethambutol*	30 mg/kg

*Should not be given to children below 6 years of age

Regimen for non-DOTS treatment in DOTS areas

The prescribed regimen and dosages are presented below.

Treatment	Type of patient	Regimen
Regimen 1	Smear-positive new seriously ill Smear-negative pulmonary seriously ill Extra-pulmonary seriously ill	2HSE 10HE
Regimen 2	Smear-negative cases not seriously ill Extra-pulmonary not seriously ill	12 HE

Regimen 1 (R₁): 12-month conventional chemotherapy regimen, with streptomycin given in the first 2 months. This is given to patients who are:

- (i) New cases of smear-positive pulmonary TB; and
- (ii) Seriously ill cases of extra-pulmonary TB (meningitis, disseminated TB, tuberculous pericarditis, peronitis, bilateral or extensive pleurisy, spinal TB with neurological complications, intestinal and genito-urinary TB).

The treatment consists of 12-month conventional chemotherapy. The initial intensive phase lasts for 2 months and the continuation phase 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 (300 mg) and one tablet ethambutol (800 mg) every day. The dosage for streptomycin injection is 0.75 g per day (0.5 g for those over 50 year of age and those who weigh less than 30 kg).

Regimen 2 (R₂): 12-month conventional chemotherapy regimen, without streptomycin for:

- (i) All patients with smear-negative pulmonary TB who are not seriously ill; and
- (ii) All patients with extra-pulmonary TB who are not seriously ill

The treatment consists of 12-month conventional chemotherapy. Isoniazid and ethambutol are self-administered by the patient daily for 12 months. The dosage for adults is isoniazid (300 mg) along with ethambutol (800 mg) per day.

Table 1: Symptom-based approach to evaluation of possible side-effects of anti-TB drugs used in the RNTCP

Symptom	Drug (abbreviation)	Action to be taken
Drowsiness	Isoniazid (H)	Reassure patient
Red–orange urine/tears	Rifampicin (R)	Reassure patient
Gastrointestinal upset	Any oral medication	Reassure patient Give drugs with less water Give drugs over a longer period of time (e.g. 20 minutes) Do not give drugs on empty stomach If the above fails, give anti-emetic if appropriate
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) for evaluation	STOP ethambutol, refer patient
Ringing in the ears	Streptomycin (S) patient for evaluation	STOP streptomycin, refer
Loss of hearing	Streptomycin (S) patient for evaluation	STOP streptomycin, refer
Dizziness and loss of	Streptomycin (S) patient for evaluation	STOP streptomycin, refer balance
Jaundice	Isoniazid (H) Rifampicin (R) Pyrazinamide (Z)	STOP treatment, refer patient or evaluation

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

Intermittent treatment

It has been proved by clinical trials that thrice a week, alternate-day treatment is as effective as daily treatment. The doubling time of *Mycobacterium tuberculosis* is about 18 hours, compared with 10–20 minutes for most bacteria. In animal models, intermittent treatment is *more* effective than daily treatment, presumably because intermittent dosage allows organisms to re-enter the active metabolic phase, in which the bactericidal agents of isoniazid and rifampicin are more effective. Dozens of clinical trials have demonstrated that intermittent treatment is at least as effective as daily treatment. No differences in the number or severity of side-effects has been found, although patients receiving intermittent treatment had less arthralgia in one trial. However, **alternate-day treatment should only be used in a programme of directly observed treatment (DOT)** so that it can be ensured that the patient completes the full course of treatment and is cured.

Special situations

Hospitalization

Generally, patients with TB do not need hospitalization. Those who are extremely ill can be hospitalized during the initial phase of treatment. In addition, all patients with significant haemoptysis, pneumothorax or large accumulation of pleural fluid leading to breathlessness should be referred to the hospital.

Tuberculous meningitis

Tuberculous meningitis is fatal if untreated. Patients should generally be referred to the hospital. Treatment should be started as soon as possible. The continuation phase should be given for 6–7 months (total treatment 8–9 months). Steroids should be given initially to reduce meningeal inflammation and reduced gradually over 6–8 weeks.

Treatment of tuberculosis during pregnancy

Streptomycin should not be given during pregnancy; other drugs used in the RNTCP are safe during pregnancy. **Breast-feeding should continue regardless of the mother's TB status.** If the mother is smear-positive for AFB, the child should be given chemoprophylaxis for 3 months and then vaccinated with BCG if the tuberculin test is negative. If the tuberculin test

is positive at the end of 3 months, the child should not be vaccinated with BCG and chemoprophylaxis should be continued for 6 months. If the mother is smear-negative for AFB, the child is vaccinated with BCG and chemoprophylaxis is not given.

Breastfeeding should continue regardless of the mother's TB status.



There are often questions about regimens and dosages. Discuss as a group any questions or doubts you may have about anti-TB treatment as recommended in the RNTCP.

Record prescribed regimens, tablets and dosages

There are two sections where the prescribed regimen and dosages of drugs for the patient in the Tuberculosis Treatment Card is to be written: one for the intensive phase of treatment on the front of the card, and one for the continuation phase of treatment on the back of the card.

Usually, an MO will decide which treatment regimen a patient should be prescribed. He will tick the appropriate box on the patient's Tuberculosis Treatment Card indicating the prescribed regimen. He will then write the number of tablets/capsules (and dosage of streptomycin) to be given during the initial intensive phase and the continuation phase of treatment.

During visits to the health units, make sure the correct regimen box was ticked on the Tuberculosis Treatment Card. Compare this with the patient's **Disease Classification, Type of Patient** and sputum smear examination results. For example, if a patient was diagnosed as New pulmonary smear-positive, he should be prescribed CAT I treatment regimen. Discuss with an MO any discrepancies you find.

It is also important that you make sure the correct number of tablets/capsules and the amount of streptomycin are recorded on the patient's Tuberculosis Treatment Card. Base the dosage of rifampicin on the patient's **pretreatment** weight, which should be recorded on his card. If a patient's weight increases to more than 60 kg during the course of treatment, the dosage of his treatment regimen **should not be modified**.

Intensive phase (front of card)

Prescribed regimen and dosages

Determine whether the patient should be prescribed CAT I, CAT II or CAT III treatment, and tick the appropriate box. Write the number of tablets/capsules and the amount of streptomycin the patient will receive thrice a week during the intensive phase of treatment below the appropriate category. If a dose is not given as scheduled, circle the date it was scheduled to be taken.

For non-DOTS treatment in DOTS areas

Determine the regimen to be prescribed R_1 or R_2 and tick the appropriate box.

Continuation phase (back of card)

Prescribed regimen and dosages

Write the number of tablets/capsules the patient will receive thrice a week during the continuation phase of treatment in the box next to the appropriate regimen.

For non-DOTS treatment in DOTS areas

Tick the appropriate regimen on this part of the Tuberculosis Treatment Card.

Management of the tuberculosis patient

Patient flow

The MO of the Peripheral Health Institution (PHI) explains to the patient about the disease, informs him about the dosage schedule, duration of treatment, examination of contacts and frequency of monitoring of progress until cure whenever required. The MO also determines the DOTS centre most easily accessible to the patient after discussing with him and arranges for his treatment there. Health education and motivation of the patient should be reinforced periodically during follow-up visits. The Tuberculosis Treatment Card is maintained at the PHC or CHC where the patient was diagnosed.

If the patient is to be treated by a Peripheral Health Worker (PHW), a duplicate card will be prepared and given to the PHW to record when treatment was directly observed. The MO of the PHI will give the patient's

medicine box for the entire duration of treatment to the PHW. Issue of this medicine box to the PHW will be duly recorded in the special register maintained at the PHC/CHC. The PHW visits the house of the patient (in no case more than a week later) and has a detailed dialogue with the patient and other members of the family, emphasizing the treatment schedule, importance of regular uninterrupted drug intake, completion of the course of treatment, possible intolerance, etc., as well as the need for evaluation of symptomatic contacts and treatment of child contacts (if the patient is smear-positive). Treatment should be started immediately but only after the visit has been made by the PHW (MPW, Anganwadi worker, Dai, Village Health Guide) or community volunteer. A convenient location for drug administration is decided mutually by the PHW and the patient. Medicines are delivered at the home of the patient only in exceptional circumstances when the patient is unable to attend the observation centre. In such situations the entry is circled on the Tuberculosis Treatment Card and the reason for the same stated in the **Remarks** column. **During the intensive phase of treatment each and every dose of medicine is to be taken under direct observation of the PHW or community volunteer.**

Patients should be visited by the health staff for confirmation of the address before commencement of treatment. This opportunity should also be used for screening of contacts and motivating the patient to take regular and complete treatment.

The PHW (or PHC staff) records the days the drugs are administered in the Tuberculosis Treatment Card at the time of intake, and refers the patient to the microscopy unit when follow-up sputum examinations are due. He also enquires about drug reaction and, if necessary, refers the patient to the MO.

The policy regarding the administration of streptomycin injections at the peripheral level, will be to entrust this responsibility to the Auxillary Nurse Midwife (ANM) at the sub-centre level or to any registered allopathic doctor at the place agreed to with the patient for his DOT. If the same is not possible, the patient has to come to the PHC/CHC and may even be hospitalized for the initial intensive phase during which streptomycin injection is to be given. Disposable or sterilized syringes and needles should be used for this as detailed in the *Technical Guidelines*.

During the continuation phase the patient collects drugs from the centre (or from the PHW) on a weekly basis, and must present the empty strip/blister pack of the drugs consumed at the time of the next week's collection. The PHW should collect the empty blister pack and keep it in the patient's patient-wise box. When the patient comes for drug collection, the first dose of the continuation phase must be administered under direct observation.

Sputum smear microscopy is much more informative than radiology in following 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.

Action for patients who interrupt treatment

If a patient does not present as scheduled during treatment, visits to his home should be made to bring him back under treatment. This should be done by the health staff or community health worker no later than the day after the patient was due to come for treatment in the intensive phase, and within a week of the missed dose in the continuation phase. It is important to take action on defaulters immediately after knowing that the patient has defaulted and missed the doses.

The health worker should discuss problems with the patient and find ways of preventing him from defaulting, convince him that cure depends on regular drug intake and convey the same message to relatives so that they can take an interest in ensuring regular intake of drugs by the patient. The health worker should discuss with the patient where he would prefer to take his treatment. The patient should not be blamed. Try to understand his or her difficulties and then motivate accordingly. It is best to negotiate a plan for cure with the patient.

Follow-up

Follow-up is not required for a patient who has completed treatment and has been declared cured. He should be advised to report only if symptoms suggestive of TB recur.

Pulmonary tuberculosis patients who interrupt treatment

If a patient in the intensive phase does not take medication as scheduled, he should be traced and given the medication on the next day. The

medication for the following day is then given as scheduled. For example, if a patient is receiving DOT on Mondays, Wednesdays and Fridays, but does not take medication on Wednesday, the patient should be found on Thursday and given medication, and should take the next dose of medication on Friday, returning to the previous schedule.

If a patient completely misses any dose of medicine, these doses must be made up at the end of the scheduled period. CAT I and CAT III treatments consist of 24 doses in the intensive phase, followed by thrice a week dosage on alternate days for 18 weeks of the continuation phase. CAT II treatment consists of 36 doses in the intensive phase, followed by thrice a week dosage on alternate days for 22 weeks of the continuation phase. Thus, CAT I and CAT III treatments each consist of 78 doses, and CAT II treatment consists of 102 doses. CAT I and CAT II patients whose sputum smears are positive at the end of the intensive phase receive an additional 4 weeks (12 doses) of medication. The number of doses must be strictly adhered to. Patients should complete the 24 scheduled doses (36 in case of CAT II) within 3 months (4–5 months for CAT II). In case the intensive phase is extended by one month because of a positive smear at the end of the initial intensive phase, this should be completed within 6 weeks.

Where DOT is given, Tuberculosis Treatment Cards should be organized according to the day of scheduled observation and the phase of treatment (i.e. one box for intensive phase and one box for continuation phase). When the patient swallows the medication under direct observation, the Tuberculosis Treatment Card should be placed after the divider for the next scheduled observation (e.g. from Monday to Wednesday during the intensive phase). In this manner, the Tuberculosis Treatment Cards of patients who do not present for treatment will be apparent on the same day, facilitating appropriate action for retrieval of patients.

Sometimes a patient may stop taking his drugs. This can happen when a patient does not understand that he needs to take ALL his drugs for the full duration of treatment. When such a patient returns to the treatment unit, the health worker must get the patient back under treatment. The treatment prescribed depends on the type of patient, the duration of treatment taken, the length of interruption, and whether he is smear-positive or smear-negative when he returns for treatment.

At any time during treatment, if a patient who was *smear-negative* at the time of diagnosis interrupts treatment for 2 months or more, sputum smear examination should be repeated. If the sputum smears are negative, the patient should continue and complete the regimen he was on before he interrupted treatment. If one or more sputum smears are positive and the patient was on treatment for:

- less than one month, the patient should start CAT I treatment afresh;
- more than one month, the patient is considered a default case, re-registered as **Treatment After Default**, and started on CAT II treatment.

To determine the type of treatment that should be prescribed to patients who were smear-positive at the time of diagnosis and who interrupt treatment, refer to the following tables. *You do not have to memorize these tables.* They can be used as tools in unusual circumstances when patients interrupt treatment and need to be placed on treatment again. The tables will become easier to understand if you need to determine treatment after interruption for a specific patient, and may be kept as reference for this purpose. In the rare case of a patient who, according to the table, should ‘start again’ but who should not be re-registered (smear-positive patients who receive less than 1 month treatment and who interrupt treatment for 2–7 weeks), additional drugs should be provided by the DTO/MO-TC/STS (e.g. from prolongation packs).

Record results of follow-up sputum smear examinations

Two sputum specimens are taken for follow-up sputum smear examinations at three specified intervals: at the end of the intensive phase, two months into the continuation phase and at the end of treatment. Results must be available by the end of the intensive phase and end of treatment. For example, give a CAT I patient a sputum container at the time of the 22nd dose, collect the container with the early morning specimen and a spot specimen at the time the 23rd dose is given, and have results available when the patient comes to take the 24th dose. Similarly, collect 2 sputum samples (early morning—spot) two weeks before the end of treatment, so that the patient can be told of the results when he comes to collect the medicine for the last week and take his last directly observed dose.

If 2 specimens are taken and 1 is positive, the patient is considered to have a positive smear. If both specimens are positive, the highest number

Table 2: 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

The information provided in the table above is presented as a flow chart on the following page.

Management of patients who were *smear-negative* at the time of diagnosis and who interrupt treatment for more than 2 months

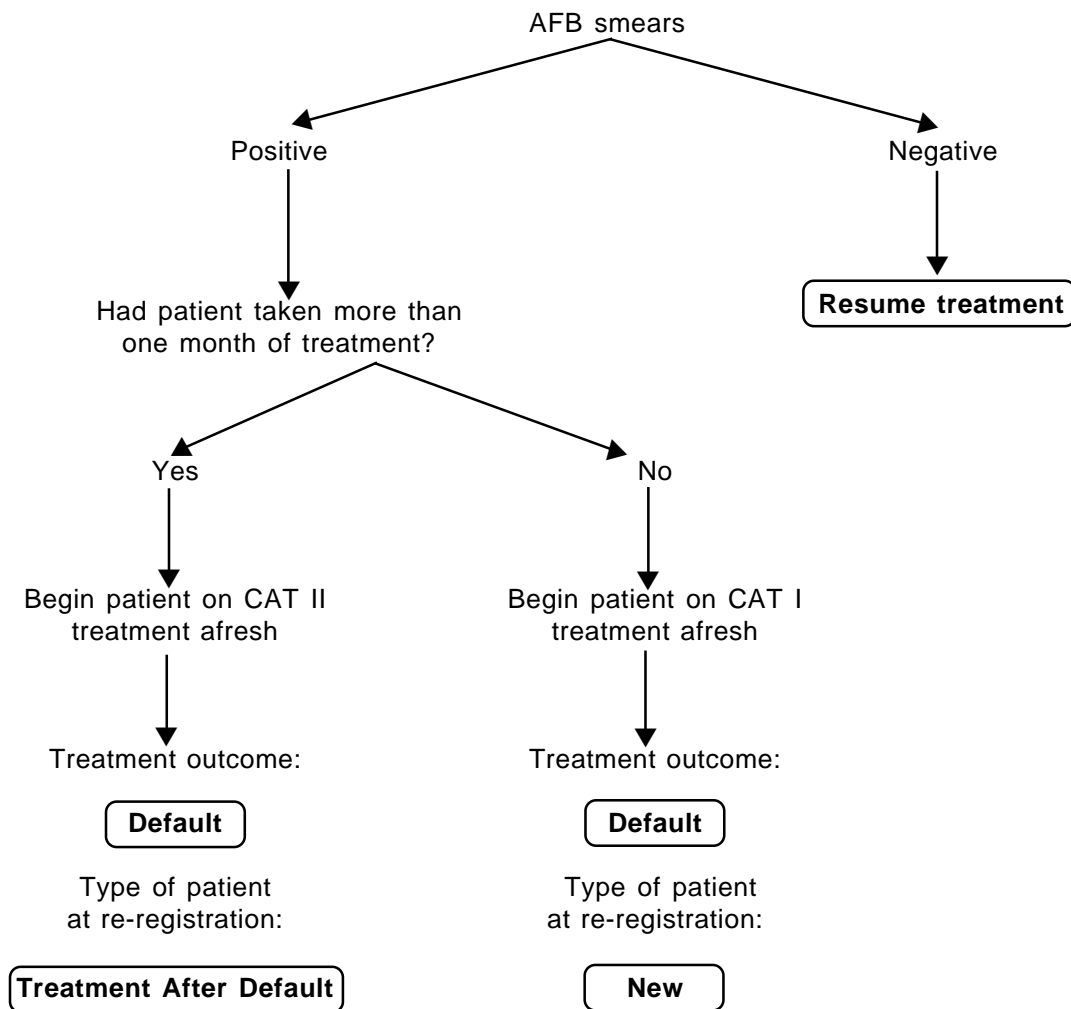


Table 3: Treatment for New smear-positive cases who interrupt treatment (Category I)

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 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 categorized as 'Other'.

Table 4: 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.

** 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 categorized as 'other'.

associated with the positive smear results (for example 3+) is written on the patient's Tuberculosis Treatment Card next to the appropriate month. If both specimens are negative, the patient is smear-negative and NEG is recorded next to the appropriate month. The schedule of sputum examinations is given in the table on page 58.

A patient who is diagnosed as a *New pulmonary smear-positive* case will have his sputum examined at the end of 2 months of treatment. If the patient is smear-negative after 2 months of treatment, the date, sputum smear result and Laboratory Serial Number of the sputum smear examination should be recorded next to **month 2** on the Tuberculosis Treatment Card.

If the patient is smear-positive after 2 months of treatment, forward slashes (/) should be drawn on the Tuberculosis Treatment Card in the **Date**, **Smear result** and **Lab No.** columns next to **month 2**. The date of the sputum smear examination should be recorded above the slash under the **Date** column. The number associated with the positive sputum smear results (for example 2+) should be written above the slash under the **Smear result** column. The Laboratory Serial Number should also be recorded above the slash under the **Lab No.** column. The initial intensive phase of drug treatment (HRZE)₃ should continue for another 4 weeks. At the end of the additional 4 weeks of the intensive phase of treatment (i.e. at the end of 3 months of treatment), a sputum smear should be examined. The date, result and Laboratory Serial Number of the sputum smear examination should be recorded below the forward slash under the appropriate columns. Sputum will then be examined at the end of 5 months, and at the end of treatment. The date, sputum smear result and laboratory serial number should be recorded in the same way.

Month	Date	Lab No.	Smear result	Weight
2/3	17/3 16/4	164 234	1+ NEG	45 kg

A patient who is diagnosed as a *pulmonary smear-positive Relapse, Failure or Treatment After Default* case will have his sputum smear examined at the end of 3 months of start of treatment.

If the patient is smear-positive after 3 months of treatment, forward slashes (/) should be drawn on the Tuberculosis Treatment Card under the **Date**, **Smear result** and **Lab No.** columns. The date of the smear examination should be recorded above the forward slash under the **Date** column. The number associated with the positive results (for example 1+) should be written above the slash under the **Smear result** column. The Laboratory Serial Number should also be recorded above the slash under the **Lab No.** column. The initial intensive phase of drug treatment (HRZE)₃ should continue for another 4 weeks. At the end of the additional 4 weeks of the intensive phase of treatment (i.e. at the end of 4 months of treatment), sputum smear should be examined. The date, result and Laboratory Serial Number of the sputum smear examination should be written below the forward slash under the appropriate columns.

A patient who is diagnosed as a *pulmonary smear-negative case* (not seriously ill) will have his sputum examined after 2 months of treatment and at the end of treatment. The date, result and Laboratory Serial Number of the sputum smear examination should be recorded next to **Month 2** on the Tuberculosis Treatment Card. If a smear-negative patient is found to be smear-positive at the end of 2 months, the patient should be placed on the retreatment regimen (CAT II) and re-registered as **Failure**.

Record drug administration (intensive phase)

The months that the patient will be administered drugs during the intensive phase are written under the **Month** column in the drug collection table on the bottom at the Tuberculosis Treatment Card. The appropriate day (1–31) is ticked (✓) after the drugs are administered thrice a week to the patient.

For non-DOTS treatment in DOTS areas

Tick (✓) the appropriate regimen. Write C on the date when drugs were collected by the patient and draw a horizontal line (C) on the date when drugs were collected by the patient and draw a horizontal line (C——) to indicate the period for which drugs were supplied for self-administration.

Record drug collection (continuation phase)

The months that the patient will be collecting his drugs during the continuation phase are written under the **Month** column in the table at the back of the Tuberculosis Treatment Card. An 'X' is entered on the day (1–31) the drugs were swallowed under direct observation. 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.

For non-DOTS treatment in DOTS areas

Tick (✓) the appropriate regimen. Write C on the date when drugs were collected by the patient and draw a horizontal line (C) on the date when drugs were collected by the patient and draw a horizontal line (C ———) to indicate the period for which drugs were supplied for self-administration.

Record remarks

Any comment about the patient can be written in this space. Remarks can be regarding the:

- reason for discontinuation of drug collection (for example patient transferred to another district)
- efforts to trace patients who interrupted treatment
- results of X-ray examination
- tuberculin test result in children
- histology report (such as report on lymph node examination) for extra-pulmonary TB
- names and treatment details of children under the age of 6 years in contact with a smear-positive case who are prescribed preventive chemotherapy.

COMMUNICATE WITH PATIENTS

Good communication between a TB patient and the staff who treat him is very important. For a patient to be cured, he needs to:

- be prescribed the correct treatment regimen, and
- take all his prescribed drugs regularly for the total prescribed treatment period.

It is very important for the patient to know the duration of his treatment and understand the necessity of taking *all* his prescribed drugs regularly. Tell him that he will continue to spread TB if he does not take all his drugs. Inform the patient that although TB is a life-threatening disease, if the prescribed treatment is taken for the complete duration, it is curable. Explain to him that TB treatment is only effective if he takes all his drugs for the entire period prescribed. It is dangerous to take only part of the prescribed drugs because in such cases the disease may become incurable.

It is therefore very important that health education is provided to the patient so as to make him understand the importance of taking complete treatment. Health education should be imparted when the TB Treatment Card is completed or when the patient is first registered and should be given periodically during the course of treatment. You and the other staff should stress to the patient the necessity of direct observation of every dose of drugs taken during the intensive phase and the first dose of the weekly blister pack during the continuation phase. Also explain the importance of sputum smear conversion at the end of 2(3) months and at the completion of treatment.

Reassure the patient that anti-TB drugs are generally safe. Counsel him that the urine and tears may turn orange-red as a result of one of the pills, but that this is harmless and normal and is not permanent.

Always speak respectfully to patients. Reassure them frequently that TB is curable. Emphasize that direct observation of treatment is as important as the drugs themselves. The real purpose of direct observation is to develop a human bond with the patient and not to mechanically watch the patient swallow the drugs. Remember that patients are in need of a friend; reassure

them that they are being provided effective, high-quality curative care. Constantly during treatment, remind patients of how much weight they have gained, how much their cough has decreased, and how well they are looking now. Spend time getting to know patients' problems. Encourage patients by telling them what proportion of the treatment they have finished. Always remind patients of the next appointment. Patients who are treated respectfully develop trust not only in their treatment observer but also in the health system as a whole and are much less likely to default. In the RNTCP, the patient should be the VIP in practice and not only in theory.

Determine if a patient has been previously treated for tuberculosis

It is very important for you to determine if the patient has been previously treated for TB. If the initial interview of the patient does not provide enough information on his medical history, he could be prescribed the wrong regimen. For example, a pulmonary smear-positive patient who was previously treated for TB might omit information about his past treatment if he does not understand why it is important to tell this to the interviewer. Then, instead of being prescribed the required retreatment regimen (CAT II), he could be incorrectly placed on a regimen for new patients (CAT I), thus receiving a weaker regimen instead of the required stronger retreatment regimen.

The **Type of Patient** (New, Relapse, Transfer in, Other or Treatment After Default) should be ticked on the patient's Tuberculosis Treatment Card. It is very important to verify with the patient that he has been correctly recorded so that you can make sure he has been prescribed the correct treatment regimen.

To do this, ask the patient if he has been treated for TB in the past. Ask every patient if he has ever taken injections for more than one or two weeks (streptomycin is likely) or taken a medicine which turned the urine orange-red (rifampicin is likely). If you think a patient is hiding his past treatment for TB, explain that New patients do not receive *better* drugs than retreatment patients. When a previously diagnosed and partially treated smear-positive patient begins treatment again, he must take the drugs prescribed under the retreatment regimen to be cured. The retreatment patient needs a stronger regimen than a New patient to be cured.

Provide health education to patients

During initial contact

During your first contact with a patient, which is usually when you register him, you will give the patient essential information about his disease. Make sure he feels comfortable enough to ask you what he does not understand. Keep in mind that the patient is probably very sick and might still be feeling disturbed about having the disease. Ask the patient essential questions throughout the discussion to make sure he understands what is being said. During later discussions with the patient, you will explain more details.

The topics to be discussed initially with the patient are as follows:

■ **What is tuberculosis**

Explain in simple terms what TB is and what type of TB the patient has (for example TB of the lungs). Reassure the patient that if the prescribed treatment is taken for the complete period, TB *is* a curable disease.

■ **Treatment of tuberculosis**

Explain general information about the TB treatment, such as:

- duration of treatment
- frequency of the patient's visits to the health unit for taking treatment
- where the patient will receive treatment
- treatment is free of charge at government centres.

■ **Necessity of directly observed treatment (DOT)**

Explain the importance of taking DOT. This means that the health worker watches the patient swallow all his drugs. Ensure that drugs, including streptomycin injections, are properly given. Explain that diet and rest have limited impact on outcome of treatment, but that regular drug-taking is essential.

■ **How tuberculosis spreads**

Explain in simple terms that TB can spread when a patient sneezes or coughs. People in close contact with the patient can become infected when they breathe in these germs (tubercle bacilli). **Stress the**

importance of taking all family members exposed to the disease (contacts) and who have symptoms of TB to the closest health unit for screening of TB. In particular, children under 6 years of age should be screened because they are at risk of developing severe forms of the disease. Also explain how to prevent TB from spreading (for example covering the mouth when coughing and sneezing and avoiding spitting in public).

■ **Looking for symptoms of tuberculosis**

Describe the following symptoms of TB of the lungs to the patient so that he can recognize whether a family member might be a TB suspect:

- A cough which lasts for 3 or more weeks. Usually, the person also has one or more of the symptoms listed below:
 - weight loss;
 - tiredness;
 - fever, rise in temperature especially in the evening;
 - night sweats;
 - chest pain;
 - shortness of breath;
 - loss of appetite; and
 - coughing up of blood-stained sputum.

During registration

In this example, the designated Medical Officer-Tuberculosis Control (MO-TC) is registering a patient who has just been diagnosed with pulmonary smear-positive TB.

Role Play

MO-TC: *“Hello, Mrs Khurana. How are you feeling this morning?”*

Patient: *“I am very tired. My chest hurts and I have been coughing.”*

MO-TC: *“I am sorry to hear you are not feeling well, but you will get better. Do you know what disease you have?”*

Patient: *“I have tuberculosis of the lungs.”*

MO-TC: *“Yes, you have tuberculosis of the lungs. Tuberculosis is also called TB. TB can occur anywhere in the body, but most people who have TB have*

*TB of the lungs. However, your disease **is curable** if you take all the drugs given to you for the recommended time period. Have you ever been treated for TB before?"*

Patient: *"No, I have not been treated for TB before. My brother had TB last year and had to stay in the hospital, but I never had TB. Do I have to stay in the hospital to get better?"*

MO-TC: *"No, only people who are very sick from TB have to stay in the hospital. But you can walk to the health centre. To get better, you need to take all the drugs given to you for 2 months under the MPW's direct observation at this health centre. You will only have to come to the health centre to take 24 doses of medicine during the first two months. The MPWs are well trained and will watch you swallow your drugs. They will make sure you are getting better.*

After 2 months, you will go once a week to the health centre to swallow the first dose of the week and to collect the drugs for the rest of the week. You will swallow several drugs thrice a week for 4 months for which you will have to come to the health centre 18 times. In all, you will have to come to the health centre 42 times during six months."

Patient: *"So, I will have to take drugs for 6 months?"*

MO-TC: *"Yes, you must take the drugs prescribed to you thrice a week for 6 months to get cured. Do you know how TB spreads?"*

Patient: *"No, I do not know how TB spreads."*

MO-TC: *"TB spreads when a person who has TB of the lungs and has not taken drugs to cure it sneezes or coughs in front of others. Very small germs are released and can be breathed in by someone standing near that person. At this time, there are a few germs. But after some weeks, the inhaled germs reproduce producing more germs which attack the lungs. If you cover your mouth when you cough or sneeze, and do not spit in front of others, you may prevent TB from spreading. Another way of preventing TB from spreading is to encourage all people with whom you are in close contact and who have symptoms of TB to come to the health centre for a sputum smear examination. Do you know what the symptoms of TB are?"*

Patient: *"I do not know the symptoms. What are the symptoms of TB?"*

MO-TC: *"The most common symptom of TB is cough for more than 3 weeks. Other symptoms are weight loss, tiredness, fever, night sweats, chest pain, shortness of breath, loss of appetite, and/or coughing up of blood."*

Patient: *“My oldest daughter has been coughing for several weeks. I will make sure she goes to the health centre for examination.”*

MO-TC: *“That is very good. Do you have any questions about your disease or your treatment?”*

Patient: *“No, I do not have any questions right now.”*

(The MO-TC then registers the patient and arranges to see her again in a few days.)

On a continuous basis

There are several things to discuss with the patient about TB after the patient has been in the intensive phase for approximately one week. Then, either you or a health worker should repeat this information to the patient at least once a week during the intensive phase and once a month during the continuation phase. (This is done in privacy or within a group setting.)

When you meet with the patient, spend the first few minutes checking if he remembers what was previously discussed regarding the treatment. Ask the patient questions, such as ‘How long will your treatment last?’

Health education topics should be discussed with the patient on a continuous basis. It is important to ask the patient questions throughout this discussion to make sure he understands what is being said.

■ Type and colour of prescribed drugs/injection

Explain the different types of drugs the patient will be taking. Also, discuss the colours of the drugs so that the patient can identify whether he is being given the correct drugs.

■ Amount and frequency of drugs/injection

Tell the patient the number of tablets and dosages of each drug he will be taking from the blister pack, how often he will be taking them, and for how long.

■ Possible side-effects of drugs/injection

Explain to the patient the following common side-effects of the anti-TB drugs he is taking:

- skin rashes
- skin and/or eyes turn yellow

- flu-like symptoms (fever and chills)
- pain and swelling of joints, particularly ankles and wrists
- difficulty with vision (in patients taking ethambutol)
- imbalance (in patients taking streptomycin).

Tell the patient that if he experiences *any* of these side-effects, he must go to the nearest health unit immediately.

■ **Frequency and importance of sputum smear examinations/Meaning of positive and negative results of sputum smear examinations**

Explain to each pulmonary TB patient that he will be required to bring up sputum and collect it in a container several times during the treatment of TB. Tell him the importance of bringing up sputum from deep within the lungs for examination by a laboratory technician. The laboratory technician uses a special instrument called a microscope to see whether there are TB germs in the sputum. Tuberculosis germs cannot be seen with the naked eye. If the laboratory technician sees TB germs in the sputum during microscopy after the intensive phase of treatment, the patient is still sick. If the technician does not see TB germs in the sputum during microscopy, the patient is getting better, **but he must continue to take the drugs.**

Inform the patient when he will have to bring up sputum. Explain the importance of finding out the results of sputum smear examinations. These results can affect the remaining treatment, its duration as well as quantities of drugs. In simple terms, *also stress the importance of sputum conversion at the end of 2(3) months and at the end of treatment.*

■ **What happens if the patient takes only selected drugs**

Tell the patient that he needs to take *all* his prescribed drugs together to be cured. Tell him *if he does not take all his drugs, the germs might produce more germs again. After a while, the germs will be back in large numbers and the patient will become sick again.* Explain that during the continuation phase also, the patient must take all his drugs for the entire prescribed period because his disease is not yet cured even though he might feel better.

During the first week of the intensive phase

In the following example, the patient is classified as a New pulmonary smear-positive case. A nurse is providing health education to the patient

after one week of registration. The patient is 35 years old and weighs 52 kilograms.

Role Play

- Nurse: *“Hello, Mr Singh. How are you feeling this morning?”*
- Patient: *“I am not feeling very well. I have been coughing and I get night sweats. I am very tired.”*
- Nurse: *“Well, you will be feeling much better in a week or two. The drugs you are taking are very strong. Do you remember for how long you will be treated?”*
- Patient: *“I think I will come here thrice a week on alternate days for 2 months so that the nurses can give me my drugs and injections.”*
- Nurse: *“Yes. These nurses will make sure you are getting better. We will give you one red capsule and 8 white tablets. After the 2 months of DOT, you must continue treatment and collect your drugs once a week from the health centre. At the time of weekly collection, you must take the first dose directly observed. Do you remember how long you will continue taking drugs?”*
- Patient: *“I do not remember how long I must take the drugs.”*
- Nurse: *“After the 2 months of DOT, you will collect the drugs every week for 4 months. Although you might feel better, you must still take all your drugs. Do you have any questions?”*
- Patient: *“I do not have any questions.”*
- Nurse: *“Now tell me what type of drugs and how many of them you are given?”*
- Patient: *“I am getting 1 red capsule and 8 white tablets at each visit thrice a week.”*
- Nurse: *“That is correct. Sometimes, some of these drugs may cause a reaction such as skin rash, yellowness of the skin or eyes, fever, chills, pain and swelling of joints, particularly ankles and wrists, or difficulty in seeing. If you get any of these reactions, tell me or any of the nurses immediately. Do you understand what you need to do if you get any kind of reaction to the drugs?”*
- Patient: *“Yes, I understand that if I have any of the symptoms you mentioned or I feel more ill from the drugs I should tell you or another nurse right away.”*
- Nurse: *“Good. Now, you have been diagnosed with tuberculosis of the lungs. You*

will take strong drugs so you will get better. After 2 months, we will ask you to bring up your sputum and collect it in a container which we will give you so we can find out if you still have TB germs in your lungs. The container will be sent to a laboratory technician who will examine the sputum under a microscope. These germs cannot be seen with the naked eye. Only through the microscope we can see whether the sputum has TB germs.

If no germs can be seen through the microscope, the treatment has been effective so far. You will continue your treatment for an additional 4 months, as we have previously discussed. However, if TB germs are seen through the microscope, you will have to continue closely supervised treatment for 1 more month. This is to make sure that the drugs are working and that you get cured. After the additional month, you will receive treatment for another 4 months. In that case, your complete treatment would last for 7 months.

At the end of 4 months of treatment, you will be asked to bring up your sputum again and collect it in a container. This sputum examination is to make sure you still do not have any TB germs in your lungs. Then, the last time you come to collect the drugs, toward the end of 6 months of treatment, you will bring up sputum one last time into the container. We will check your sputum for the last time. Then we can know whether you have been cured.”

Patient: *“What can I do to get rid of the TB germs?”*

Nurse: *“As you know, we give you drugs thrice a week for 2 months. You must swallow all the drugs you are given in front of us. If you do this, you will get rid of most of the TB germs after 2 months. However, after this period you must also take your drugs thrice a week for 4 months even if you feel better. If you do not take the drugs for all 6 months, you might not be cured. You must **not** sell any of your drugs. The drugs are worth more to you than money because they can cure you. Do you have any questions?”*

Patient: *“No, I do not have any questions. I will take all my drugs so that I get better.”*

Nurse: *“Good. I hope you feel better soon.”*

MONITOR DRUG ADMINISTRATION

For patients to be cured, they not only need to be prescribed the correct regimen, but they must also take all their drugs for the full duration of treatment. This is especially important during the intensive phase of treatment when the patient's sputum should convert from smear-positive to smear-negative.

During the intensive phase of treatment, health workers must directly observe intake of drugs. They should make sure that each patient swallows the drugs. Once patients swallow their drugs, those patients who receive streptomycin should be given the injections with *sterile syringes* and *needles*. This is called directly observed treatment (DOT).

When you visit the health units that provide DOT, observe that health workers administer drugs to the patients and make sure sterile syringes and needles are used. In addition, talk with the patients privately to determine whether they have been receiving the correct number and type of drugs.

Ensure proper drug administration

Periodically, during supervisory visits, look at a patient's Tuberculosis Treatment Card to see the drugs he should be getting, and then observe the health workers administer the drugs. Health workers must give tablets to the patient according to what is written on his Tuberculosis Treatment Card. They must observe intake of drugs to make sure that the patient has swallowed the drugs. After distributing drugs to each patient, streptomycin injections should be given to the patients on CAT II treatment (except for pregnant women). By giving the injection **after** the drugs, it is ensured that the patient has swallowed all his drugs.

If the health worker does not administer the drugs properly, inform him of the correct procedure.

Since it is likely that the health worker will administer the drugs properly in your presence, another option is to meet with the patient privately to determine if he is receiving the correct number and type of drugs. To do this, refer to the patient's Tuberculosis Treatment Card to determine the drugs he should be taking. Then, in private, ask the patient to describe

how he is receiving the drugs. If you cannot determine from the patient's response whether the health worker is administering the drugs properly, ask the patient specific questions, such as:

- How many drugs are you receiving?
- What do the drugs look like?
- When are you given the drugs?
- How are you given the drugs?
- Do you have to pay for the drugs?
- (If hospitalized) Is there anyone in the ward who does not receive drugs?

It is very important to make sure that each patient receives the correct number and type of drugs, especially, during the intensive phase of treatment when the patient's sputum should convert from smear-positive to smear-negative. There are many reasons why patients may not receive the correct number and types of drugs. Some of them are:

- health workers may not have directly observed the drug intake;
- health workers may have forgotten to give patients all their tablets or may have given them the wrong number of tablets;
- injections may not have been given to patients who were prescribed streptomycin;
- health workers may not have given the tablets to the patients before the injection;
- health workers may have given only certain drugs to patients they like, for whatever reason; and
- health workers may be making their patients pay for their drugs, and therefore, the patients without money do not receive all the prescribed drugs.

If you discover that some patients are not receiving their drugs properly, speak with the health worker who is responsible for administering the drugs. Stress the importance of patients receiving the correct number and types of drugs during the intensive phase of treatment so that they can convert from smear-positive to smear-negative.

Monitor drug collection and recording

A chart on the front of the Tuberculosis Treatment Card is used to indicate the days (1–31) on which a patient takes his drugs during the intensive phase of treatment. A health worker ticks the appropriate box on the chart after the patient takes his drugs and streptomycin injection (if applicable) under direct observation.

On the back of the Tuberculosis Treatment Card there is a chart to indicate when a patient collects his drugs during the continuation phase of treatment. During the continuation phase of treatment, all patients collect drugs once a week on a designated collection day; their medicines are directly observed on this day and the next two doses are self-administered. A health worker writes an 'X' in the appropriate box to indicate the day the drugs are collected. A horizontal line (—) is drawn to show the number of days for which the supply was given.

The **Remarks** section on the Tuberculosis Treatment Card can be used by a health worker to suggest the reason the patient did not come to take or collect his drugs (for example, 'patient moved to . . . district').

Patients must take all of the doses of treatment in both intensive and continuation phases. For example, if a patient 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:

April	22		○	23	24		S	X							S
	✓			✓	✓										

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:

April	22		○		23		S	24							S
	✓				✓			✓		X					

Refer to the tables on pages 99–102 for management of patients who interrupt treatment for longer periods of time.

If the patient is to be treated by a PHW, a duplicate card will be prepared and given to the PHW to record the direct observation of treatment.

If a patient on ambulatory treatment in the intensive phase has not taken his drugs for **two consecutive doses**, look at the back of the Tuberculosis Treatment Card. See if there are any remarks health workers might have written (in the **Remarks** section) to suggest why the patient has not taken his drugs. If there is no indication of the reasons for the patient's absence, a health worker should go to the patient's residence to trace and get him back under treatment. If the health worker cannot find the patient, he might try to locate the patient's contact person whose name and address is listed on the patient's Tuberculosis Treatment Card. The contact person might know where the patient is at present.

After administering drugs, health workers should look through the Tuberculosis Treatment Cards of all the patients who were due to come that day and put aside the Tuberculosis Treatment Cards of those patients who did not come for treatment. A health worker should trace these patients immediately and try to get them back under treatment.

During supervisory visits to the health units, review the back of the Tuberculosis Treatment Cards of all patients in the continuation phase of treatment. Verify that each patient came to the health unit to collect his drugs on time. If a box next to the drug collection period is blank, determine whether it has been **one week** since the patient was supposed to collect his drugs. Look for any remarks health workers might have written (in the **Remarks** section). They may suggest why the patient has not collected his drugs. A health worker should trace this patient if there is no indication of a reason for the patient's absence.



EXERCISE WORKBOOK E2

Completion of Tuberculosis Treatment Cards

Use a calendar for 1996 and 1997. Treatment begins in 1996. Neither diagnosis nor treatment is done on Sundays. Use your own state, district and sub-district names on the Tuberculosis Treatment Card. Be sure to indicate outcome and date on side II of the Tuberculosis Treatment Card. **Remember that you must make up for missed doses.** For this exercise, names and addresses of contact persons are not given. In practice, the names and addresses of contact persons must be filled up to aid in retrieving patients who have interrupted treatment. **Use the Laboratory Forms for Sputum Examination you completed in Exercise Workbook E1 to complete the Tuberculosis Treatment Cards.**

Parvathi Sinha (Patient B) is a 16-year-old female who weighs 41 kg. She has never been treated for tuberculosis before. She has pulmonary and extra-pulmonary (lymph node) tuberculosis. She started treatment on 7 September. The first 24 doses were all observed as scheduled except for dose 21 which was given one day late.

On follow-up at two months, she is smear-negative (29 October, Lab No. 712), weighing 45 kg. She then defaulted on 16 November.

Lakshmi Kumari (Patient C) is a 46-year-old woman who weighs 62 kg. She has never been treated for tuberculosis before. She started treatment on 16 September and her sputum is negative at the end of 2 months (6 November, Lab No. 111, 64 kg), 4 months (30 December, Lab No. 398 66 kg) and 6 months (3 March, Lab No. 314, 70 kg). She takes every dose as prescribed, under direct observation thrice a week in the intensive phase and once a week under direct observation in the continuation phase.

Lakshmi Pati Rao (Patient D) is a 50-year-old man who weighs 46 kg. He has had cough for years. When asked, he reports that he had received treatment for 'pneumonia' several times in the past. He remembers receiving shots once for a few months, and taking a medicine which made his urine turn orange. He recalls that these medicines helped him feel better.

He starts treatment on 16 September.

Doses 3, 9, 15 and 30 were missed entirely (count from doses actually given).

His sputum was positive (2+) at the end of 3 months (6 December, Lab No. 118, 45 kg).

Doses 44 and 47 were missed.

His sputum was positive (2+) at the end of 4 months (15 January, Lab No. 148; 43 kg). Sputum was negative at the end of 6 months (10 March, Lab No 879; 43 kg) and positive (3+) at the end of 9 months (23 June, Lab No. 978; 40 kg). The patient attended all weekly collections except the 12th and 14th, which he missed entirely. When should his sputum be sent for culture and sensitivity testing, if available?

Kailash Nath (Patient F) is a 35-year-old man who weighs 39 kg. He has never been treated for tuberculosis before. He starts treatment on 16 September. His drugs are administered under direct observation in the intensive phase, but doses 12 and 16 were given one day late. His sputum is positive (1+) at the end of 2 months (4 November, Lab No. 223, 42 kg). What is the correct treatment?

Dose 30 was given one day late.

His sputum is negative at the end of 3 months (2 December, Lab No. 289). He received all weekly collections in the continuation phase of treatment, except the fourth week which he missed.

His sputum is negative at the end of 5 months (27 January, Lab No. 35, 45 kg) and 7 months (7 April, Lab No. 883, 50 kg).

Ghanshyam Singh (Patient I) is a 16-year-old male with extra-pulmonary tuberculosis of the knee. He has never been treated for tuberculosis previously. He weighs 38 kg. Treatment began on 4 September. He was directly observed for all doses as prescribed. Orthopaedic follow-up examination was done and no further recommendations for orthopaedic follow-up were given.

Bhola Ram (Patient J) is a 32-year-old man who weighs 44 kg. He started treatment on 10 September. He misses doses 13 and 16 in the intensive phase. His sputum smear was negative at the end of 2 months (2 November, Lab No. 736, 46 kg), positive (1+) at the end of 4 months (18 January, Lab No. 12, 48 kg) and negative at the end of 5 months (8 February, Lab No. 889) and 6 months (22 March, Lab No. 997, 49 kg). He misses weeks 2, 5 and 8 of the continuation phase of treatment.

Lallan Prasad Parmar (Patient L) is a 52-year-old man. He was treated with short-course chemotherapy for smear-positive TB at this centre for 8 months one year ago and had completed the treatment prior to the implementation of the RNTCP. He now has cough and fever for the past month. One sputum sample out of three is positive. X-ray shows right upper lobe cavity. He begins treatment on 17 September. His initial weight was 38 kg. He did not take doses 31 and 34 as scheduled, but these were made up on the next day. His sputum smear was negative at the end of 3 months (5 December, Lab No. 742, 40 kg). After 5 weeks of the continuation phase he is transferred to District Y.

Kiran Kumar (Patient O) is a 37-year-old man with three negative sputum smear examinations, living at 15 Gulmohar Park, who did not improve after a 10-day course of co-trimoxazole. Chest X-ray showed infiltrates in the left lower and right upper lung fields and it is decided that he should receive a full course of anti-TB treatment. His initial weight was 45 kg. He began treatment on 23 September. He missed doses 12 and 18 entirely. His sputum smear is negative at the end of 2 months (18 November, Lab No. 861, 48 kg) and 6 months (14 March, Lab No. 842, 50 kg). No collections were missed during the continuation phase.

Srinivasa Rao (Patient T) is a 36-year-old man with three sputum specimens negative for AFB who did not improve after a 14-day course of co-trimoxazole. Chest X-ray showed right upper lobe and left lower lung infiltrates. He is given CAT III treatment. His initial weight was 38 kg. He began treatment on September 28. At month 2, his weight was still 38 kg and sputum smear was positive (2+) (22 November, Lab No. 798). No doses were missed.

What are the possible causes of this?

How would you classify this patient? Upon re-registration, what type of patient would he be and what would be the treatment?

Note: Upon further questioning, the patient revealed that he had taken anti-tuberculosis treatment several times in the past, stopping when he felt better after a few weeks or months each time. The initial smears were reviewed, and found to be truly negative, containing only epithelial cells. If this patient initially had resistance to isoniazid alone, the regimen given would have probably produced rifampicin resistance and caused the failure of the CAT III treatment initially given, and of the CAT II retreatment regimen given subsequently, both attributable to poor history-taking.

Nanda Kumar (Patient W) is a 24-year-old man with three negative sputum smear examinations who did not improve after a 7-day course of co-trimoxazole. He has become increasingly weak, with fever for the past six months, and the sputum is blood-streaked. X-ray showed extensive bilateral interstitial infiltrates and blunting of both costophrenic angles. He started treatment on 12 September. His initial weight was 55 kg. His sputum was negative at the end of 2 months (2 November, Lab No. 801) and 6 months (27 February, Lab No. 910). His weight increased to 61 kg and then to 62 kg. No doses were missed.

Niranjan Kumar (Patient X) is given 10 days treatment with co-trimoxazole. The symptoms resolve.

Meena Kumari (Patient Y) is given a 10-day course of co-trimoxazole. There is no resolution of symptoms. Chest X-ray is taken and shows no abnormalities. Patient is given bronchodilators and the symptoms resolve.

Ammani Amma (Patient Z) is given a 10-day course of co-trimoxazole. There is no resolution of symptoms. Chest X-ray is taken and shows no abnormalities. Fever was not documented.

ENSURE ALL HEALTH WORKERS USE STERILE SYRINGES AND NEEDLES

During supervisory visits to the hospitals and health units within your district, make sure the health workers are using sterile needles and syringes. When health workers give patients streptomycin injections during the intensive phase of treatment, they must use sterile syringes and needles **every day** for each patient. **Unsterile syringes and needles may transmit infection.**

In areas where HIV infection is prevalent, a high proportion of tuberculosis patients are infected with HIV. Because most of the tuberculosis patients receive 24 injections of streptomycin, **if syringes and needles are not properly sterilized, the risk of the transmission of the deadly HIV infection is high. In such areas, preference should be given to the use of disposable needles and syringes.**

Health workers should know why sterilization is important and how to sterilize their instruments. You must observe them to make sure they follow the basic rules of sterilization.

Sterilization of syringes and needles for streptomycin injections

It is essential to avoid transmission of blood-borne diseases (especially HIV infection) while giving streptomycin injections. Recommended procedures for sterilization of needles and syringes must be strictly enforced. Disposable syringes and needles should be used, if available.

To ensure that transmission of blood-borne diseases is minimal, streptomycin injections should be given by qualified personnel only.

Rules for sterilization

1. Health workers must use a separate sterile syringe and a separate sterile needle for every patient for each injection.
2. Needles and syringes should be thoroughly cleaned before sterilization. Sterilization by autoclave/hot air oven is preferred wherever feasible. A properly washed syringe wrapped in paper should be kept in a hot air

oven at 160 °C for one hour. Sterilization in an autoclave is achieved at 121 °C at 15 lbs for 15 minutes when pressure builds up to 15 lbs after the whistle.

3. When using a **steam sterilizer**, remember:

- Place instruments in the steam arising from boiling water for 15 minutes.
- Do not cover instruments within the steam sterilizer with water.
- Do not use it on an open wood fire. (It might not produce enough heat.)
- In high altitudes sterilize the instruments for a longer period of time.

4. Sterilization using a **pressure cooker**:

- fill the pressure cooker (7 litre capacity) with water up to the mark below the perforated platform. The water level should be just below the platform.
- place syringes and needles which have been cleaned thoroughly on the perforated platform inside the pressure cooker. The water should not immerse the syringes and needles.
- cover the pressure cooker with lid properly as per the instructions given.
- heat the pressure cooker until steam jets out of the hole at the top of the lid.
- allow steam to jet out for 10 minutes. This is to make sure all air inside the pressure cooker is removed. If air is allowed to remain inside the pressure cooker, the temperature attained inside the pressure cooker will not be sufficient to sterilize the syringes and needles.
- place the weight on the pressure cooker.
- when maximum pressure is reached, the cooker starts whistling.
- wait for 20 minutes after the whistling starts and then remove the source of heat.
- do not open the lid or remove the weight of the pressure cooker until the cooker becomes cold.

5. Sterilization by **boiling**:

This method should be used only where there is no other alternative for sterilization. Use a special boiling pan. If this is not available use a saucepan. Fill it with water. Heat over the stove. Glass syringes should be placed in the container while the water is still cold. Needles and forceps should be placed when the water is boiling. Leave these articles to boil for 20 minutes (count the time after the water has started boiling).

6. Sterile syringes and sterile needles should be kept in a sterile covered container.
7. Use sterile forceps to take sterile instruments out of the sterile covered container.
8. When holding a sterile syringe, touch only the safe parts of the syringe, i.e. the outside of the barrel or the top of the plunger.
9. Wash your hands when you come in contact with body fluids or any infected material.



EXERCISE 1

In this exercise you will read about two health workers taking care of patients in two different hospitals. Assume that you are a DTO observing these health workers administer streptomycin. You must make sure they use sterile needles and sterile syringes for each patient. When you finish reading each case, answer the exercise questions in the space provided.

Case 1: Vivek

Read the case information below:

Vivek is a nurse at Naka hospital. At 10:00 a.m. he begins to administer streptomycin injections after the patients have swallowed their drugs. Vivek removes the cover from the boiling pan. He carefully puts together the syringe and needle using sterile forceps to pick up the barrel, plunger and needle.

He places some of the syringes and needles on a table which he has just cleaned with a wet cloth. He is then ready to give the injections. Since he does not have enough sterile syringes, he injects two patients with the same syringe. However, he does change the needle.

At the end of the day, Vivek places the used syringes and needles into the boiling pan and sterilizes them for 20 minutes. He keeps the cover on the pan until he uses the syringes and needles again in the morning.

1. Was the syringe still sterile after Vivek placed it on the clean table? Explain.

2. What did Vivek forget to do after having completed giving the streptomycin injections before placing the syringes and needles into the boiling pan?

3. How many patients should Vivek have injected with the same syringe? Explain.

Case 2: Meena Kumari

Read the case information below:

Meena Kumari is a nurse at Napala hospital. At 9:00 a.m. she begins administering streptomycin injections to patients after they have swallowed their drugs.

She opens the steam sterilizer and takes out a sterile barrel, plunger, and needle from the steam sterilizer with a towel. She is careful to touch only the shaft of the needle and the shaft of the plunger. Next, she puts together the syringe and places it on the sterile rack cover. Then, she puts together several more syringes until she has one for each patient.

After briefly talking to the patients, she begins giving injections. Meena Kumari washes her hands often—before and after she uses a sterile syringe and needle. At 9:30 a.m. she has finished giving injections to these patients.

ADMINISTER PREVENTIVE TREATMENT TO CHILDREN

Since tuberculosis is an infectious disease, children who have family members suffering from tuberculosis can frequently catch the infection. The infection may develop later into tuberculosis. Some children may develop a very serious form of the disease (such as meningitis), and may die if they are not diagnosed and treated.

In children, tuberculosis is most severe in those under the age of 6 years, and in particular, for those who are 0 to 3 years of age. Make sure that all children under the age of 6 years who have a family member with smear-positive tuberculosis are screened for symptoms and receive either full treatment or preventive chemotherapy.

The patient should be told that if any of the persons in his family have complained of symptoms of tuberculosis, especially children, they should be brought to the nearest health centre for examination.

A child should be brought into a health unit to be screened for symptoms of tuberculosis. If the child **has symptoms** of tuberculosis, an MO will examine him. If the MO diagnoses that the child is suffering from tuberculosis, he will decide the child's treatment regimen according to the site of the disease and the results of sputum smear examinations, regardless of whether the child has received BCG vaccination.

If the child **does not have symptoms**, he should receive preventive chemotherapy, regardless of whether he has been vaccinated with BCG. This consists of administration of isoniazid daily—5 mg per kg body weight for 6 months.

If a *tuberculin test is available*, the test will be given after 3 months of INH (isoniazid) preventive chemotherapy.

- If the induration from the tuberculin test is less than 6 millimetres in diameter, preventive chemotherapy is stopped and the child is vaccinated with BCG (if he has not previously been vaccinated).
- If the induration is 6 millimetres or more in diameter, continue isoniazid preventive chemotherapy for another 3 months.

Use the table given below to decide on how to proceed with preventive chemotherapy in children under the age of 6 years who were in contact with a smear-positive case. A paediatrician should preferably be consulted.

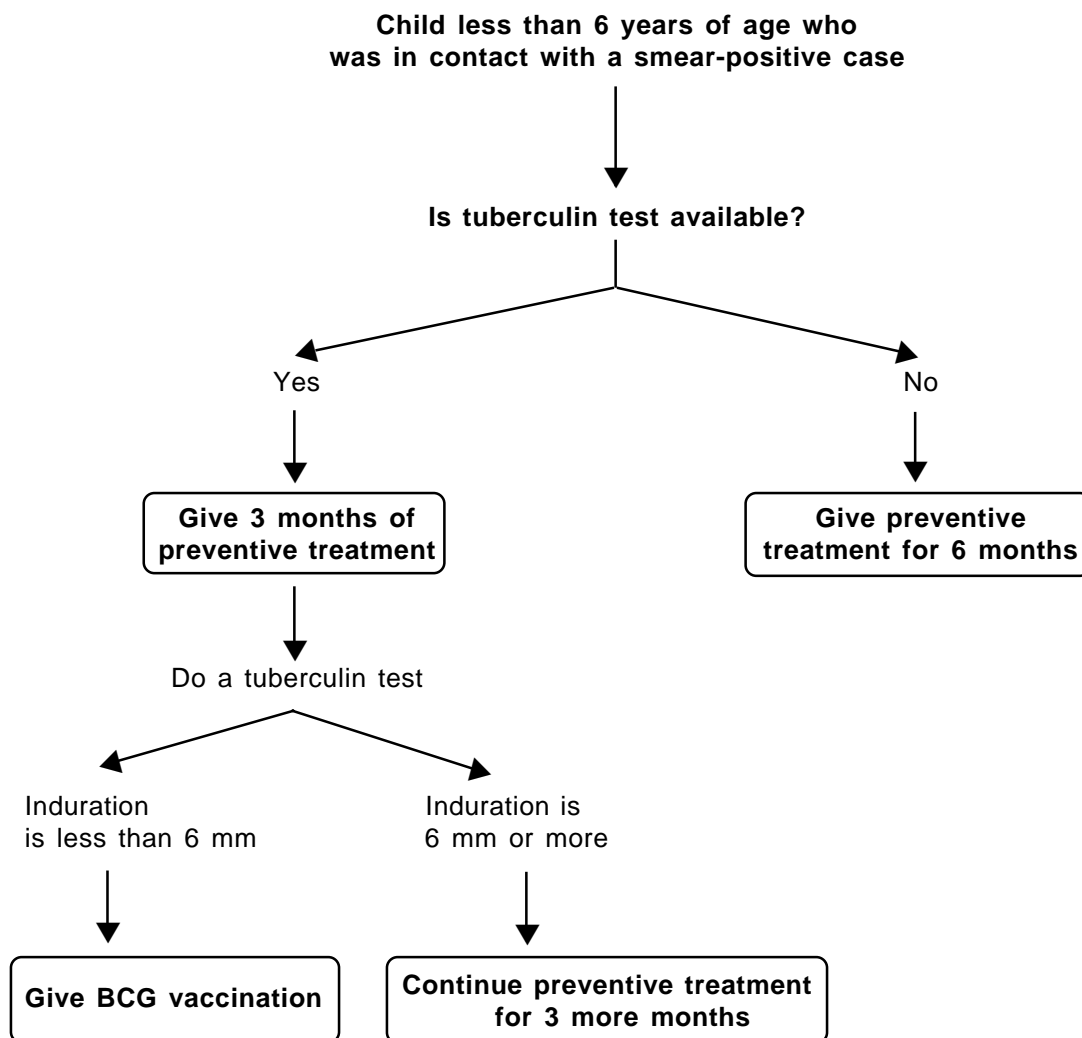
To ensure that proper preventive chemotherapy is given to children, enquire (or have the health workers enquire) from all the tuberculosis patients under treatment if they have children under 6 years of age. If they do, ask them if the young family members have been screened for tuberculosis. Explain to them how children can catch the infection which may later develop into tuberculosis. Make sure that the children are brought to a health unit for screening.

Table 6: How to proceed with preventive chemotherapy in children under 6 years of age who were in contact with a smear-positive case

If:	And:	Then:						
The child has symptoms of tuberculosis	an MO determines (preferably in consultation with a paediatrician) that the child has tuberculosis	a full course of anti-tuberculosis treatment (CAT III) should be given.						
The child does not have symptoms of tuberculosis	a tuberculin test is not available	the child should receive preventive chemotherapy for 6 months (isoniazid daily—5 mg per kg body weight).						
The child does not have symptoms of tuberculosis	a tuberculin test is available	the child should receive 3 months of INH preventive chemotherapy and a tuberculin test should then be done.						
		<table border="1"> <thead> <tr> <th>If:</th> <th>Then:</th> </tr> </thead> <tbody> <tr> <td>The child's induration to the tuberculin test is less than 6 millimetres in diameter</td> <td>stop the preventive chemotherapy and give him a BCG vaccination (if he has not previously been vaccinated).</td> </tr> <tr> <td>The child's induration to the tuberculin test is 6 millimetres or more in diameter</td> <td>continue isoniazid preventive chemotherapy for another 3 months.</td> </tr> </tbody> </table>	If:	Then:	The child's induration to the tuberculin test is less than 6 millimetres in diameter	stop the preventive chemotherapy and give him a BCG vaccination (if he has not previously been vaccinated).	The child's induration to the tuberculin test is 6 millimetres or more in diameter	continue isoniazid preventive chemotherapy for another 3 months.
		If:	Then:					
The child's induration to the tuberculin test is less than 6 millimetres in diameter	stop the preventive chemotherapy and give him a BCG vaccination (if he has not previously been vaccinated).							
The child's induration to the tuberculin test is 6 millimetres or more in diameter	continue isoniazid preventive chemotherapy for another 3 months.							

The table on the previous page is presented in the form of an algorithm below.

**Preventive treatment of children under 6 years of age
who were in contact with a smear-positive case**





EXERCISE 2

Case 1: Salim Khan

Salim Khan, a 4-year-old child, has a mother who is staying in the hospital where she is undergoing treatment for smear-positive tuberculosis. Salim's father brings him to a health centre to be screened for symptoms of tuberculosis. Salim does not have any symptoms suggestive of tuberculosis.

1. What action should be taken for Salim?

2. What should be done if his induration to the tuberculin test has a diameter of less than 6 millimetres?

3. What should be done if his induration to the tuberculin test has a diameter of 6 millimetres or more?

Case 2: Suresh Kumar

Suresh is 2 years old and weighs 10 kg. His mother has smear-positive tuberculosis and is undergoing the intensive phase of treatment from a health centre near their home. A health worker at the facility tells Suresh's mother to bring him so that he can be screened for symptoms of tuberculosis. Suresh does not have symptoms of tuberculosis. A tuberculin test is not available.

1. What type of treatment should Suresh receive?



When you have completed the exercise, let the facilitator know you are ready for a group discussion.

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME — NON-DOTS TREATMENT IN DOTS AREAS
Treatment Card

State: _____ City/District: _____ Code district: _____
 Name: _____ Patient TB No./Year: _____
 Complete address: _____ Health Unit: _____
 Sex: M F Age: _____
 Name and address of Contact Person: _____

Disease Classification

Pulmonary
 Extra-pulmonary
 Site: _____

Type of Patient

New
 Relapse
 Transfer in
 Failure
 Treatment after default
 Other (specify) _____

Month	Date	Lab No.	Smaier result	Weight
0				
2				
6				
12				

I. INITIAL INTENSIVE PHASE—Prescribed regimen and dosages:

Tick (✓) the appropriate Regimen below.

- Regimen 1 [2HSE 10HE or 2HST 10HT]
 Regimen 2 [12HE or 12HT]

H: Isoniazid E: Ethambutol S: Streptomycin T: Thioacetazone

Write C on date when the drugs were collected by the patient and draw a horizontal line (C—) to indicate the period for which medications were supplied for self-administration.

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

Annexure II

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Transfer Form

(Fill in triplicate with carbon paper between the sheets. Send one copy to the Unit where the patient is referred, give one copy to the patient and retain one copy for records.)

Name of Transferring Unit: _____

Name of Unit to which patient is transferred (if known): _____

Name of patient: _____ Age: _____ Sex: M F

Complete address: _____

TB No.: _____ Date of starting treatment: _____

<p>Disease Classification</p> <p><input type="checkbox"/> Pulmonary</p> <p><input type="checkbox"/> Extra-pulmonary</p> <p>Site: _____</p>

<p>Category of Treatment</p> <p><input type="checkbox"/> Category I</p> <p><input type="checkbox"/> Category II</p> <p><input type="checkbox"/> Category III</p>

<p>Type of Patient</p> <p><input type="checkbox"/> New <input type="checkbox"/> Relapse</p> <p><input type="checkbox"/> Transfer in <input type="checkbox"/> Treatment after default</p> <p><input type="checkbox"/> Other (specify) _____</p>

<p>Most Recent Sputum Status</p> <p>Date _____ Month _____ Year _____</p> <p><input type="checkbox"/> Positive <input type="checkbox"/> Negative</p>
--

Drugs the patient is receiving: _____

Remarks: _____

Signature: _____

Date transferred: _____ Designation: _____

For use by the District where the patient's treatment ended. Date of outcome: _____

Name of patient: _____

Old TB No. (given at transferring unit): _____ New TB No. (given at receiving unit): _____

Treatment outcome: Cured Treatment completed Died
 Failure Defaulted Transferred

Date: _____ Signature: _____

(At the end of treatment send this form to the TB Unit where the patient was registered.)

For use by the TB Unit where the patient has been transferred.

Name of patient: _____

Old TB No. (given at transferring unit): _____ New TB No. (given at receiving unit): _____

Age: _____ Sex: M F Date of transfer: _____

Name of TB Unit: _____ Area: _____

The above-named reported at this TB Unit on: _____

Signature: _____ Designation: _____ Date: _____

(Send this part back to the Transferring Unit as soon as the patient has reported and has been registered.)

TREATMENT CATEGORIES AND SPUTUM EXAMINATION SCHEDULE

TREATMENT REGIMEN			SPUTUM EXAMINATIONS FOR PULMONARY TB			
Category of treatment	Type of patient	Regimen [†]	Pre-treatment sputum	Test at month	IF: result is	THEN:
Category I	New sputum smear-positive	2(HRZE) ₃	+	2	-	Start continuation phase, test sputum again at 4 and 6 months [‡]
	Seriously ill sputum smear-negative				+	Continue intensive phase for one more month, test sputum again at 3, 5 and 7 months [‡]
		Seriously ill extra-pulmonary ^{††}	4(HR) ₃	-	2	-
	+					Continue intensive phase for one more month, test sputum again at 3, 5 and 7 months [‡]
Category II	Sputum smear-positive Relapse ^{†††}	2(HRZE) ₃	+	3	-	Start continuation phase, test sputum again at 5 and 8 months
	Sputum smear-positive Failure ^{†††}				+	Continue intensive phase for one more month, test sputum again at 4, 6 and 9 months
Category III	Sputum smear-negative, not seriously ill	2(HRZ) ₃	-	2	-	Start continuation phase, test sputum again at 6 months [‡]
	Extra-pulmonary, not seriously ill				+	Re-register the patient and begin Category II treatment [‡]

† 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. H: Isoniazid (600 mg), R: Rifampicin (450 mg), Z: Pyrazinamide (1500 mg), E: Ethambutol (1200 mg), S: Streptomycin (750 mg). Patients who weigh more than 60 kg receive additional rifampicin 150 mg. Patients more than 50 years old and those who weigh less than 30 kg receive streptomycin 500 mg. 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.

†† Examples of seriously ill extra-pulmonary TB cases are meningitis, disseminated TB, tuberculous pericarditis, peritonitis, bilateral or extensive pleurisy, spinal TB with neurological complications and intestinal and genito-urinary TB.

††† 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 tuberculosis. In these cases, the patient should be categorized as 'Other' and given Category II treatment.

‡ Any patient treated with Category I or Category III who has a positive smear at 5, 6 or 7 months of treatment should be considered a Failure and started on Category II treatment afresh.

Modules 1–4