REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Technical and Operational Guidelines for Tuberculosis Control

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October 2005

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New Delhi - 110 011.

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Abbreviations

AIDS	Acquired Immuno-Deficiency Syndrome
ANM	Auxiliary Nurse Midwife
ARTI	Annual Risk of Tuberculous Infection
ASHA	Accredited Social Health Activist
AWW	Anganwadi Worker
BPHC	Block Primary Health Centre
CDHO	Chief District Health Officer
CDMO	Chief District Medical Officer
CGHS	Central Government Health Scheme
CHC	Community Health Centre
CIDA	Canadian International Development Agency
CMO	Chief Medical Officer
CTD	Central TB Division
DDG (TB)	Deputy Director General, TB
DEO	Data Entry Operator
DFID	Department for International Development, of the United kingdom
DGHS	Directorate General of Health Services
DM	District Magistrate
DMC	Designated Microscopy Centre
DOT Centre	Directly Observed Treatment Centre
DOT	Directly Observed Treatment
DOTS	Directly Observed Treatment, Short-course
DPM	Deputy Programme Manager
DRS	Drug Resistance Surveillance
DST	Drug Sensitivity Testing
DTC	District Tuberculosis Centre
DTCS	District TB Control Society
DTO	District Tuberculosis Officer
EPTB	Extra pulmonary Tuberculosis
EQA	External Quality Assessment
ESI	Employees State Insurance
ESR	Erythrocyte Sedimentation Rate
FNAC	Fine Needle Aspiration Cytology
GDF	Global Drug Facility
GFATM	Global Fund for AIDS, TB and Malaria

HA	Health Assistant
HIV	Human Immuno-Deficiency Virus
HRD	Human Resource Development
IEC	Information, Education and Communication
IRLs	Intermediate Reference Laboratories
LQAS	Lot Quality Assurance Sampling
LRS	Lala Ram Sarup Institute of Tuberculosis and Respiratory Diseases, New Delhi.
LT	Laboratory Technician
MDG	Millennium Development Goal
MDR-TB	Multi Drug Resistant Tuberculosis
MO	Medical Officer
MoHFW	Ministry of Health & Family Welfare
MO-TC	Medical Officer –Tuberculosis Control
MPHS	Multi-purpose Health Supervisors
MPW	Multi-purpose workers
NGOs	Non Governmental Organizations
NRLs	National Reference Laboratories
NTF	National Task Force
NTI	National Tuberculosis Institute, Bangalore
NTP	National Tuberculosis Programme
OPD	Out Patient Department
OR	Operational Research
OSE	On-site Evaluation
PCC	Pollution Control Committee
PHC	Primary Health Centre
PHIs	Peripheral Health Institutions
PHW	Peripheral Health Worker
PPM	Public Private Mix/ partnership
PPs	Private Practitioners
PRIs	Pachayati Raj Institutions
PTB	Pulmonary Tuberculosis
PWBs	Patient-wise Boxes
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement

RBRC	Random Blinded Rechecking
RNTCP	Revised National Tuberculosis Control Programme
SA	Statistical Assistant
SPCB	State Pollution Control Board
STCS	State Tuberculosis Control Society
STDC	State Tuberculosis Training and Demonstration Centres
STF	State Task Force
STLS	Senior Tuberculosis Laboratory Supervisor
STO	State Tuberculosis Officer
STS	Senior Treatment Supervisor
TB	Tuberculosis
TH	Taluk Hospital
TO	Treatment Organizer
TRC	Tuberculosis Research Centre, Chennai
TU	Tuberculosis Unit
USAID	United States Agency for International Development
VCTC	Voluntary Testing and Counseling Centre
WHO	World Health Organization
ZTF	Zonal Task Force

INTRODUCTION 1

Tuberculosis

Tuberculosis (TB) is an infectious disease caused by *Mycobacterium tuberculosis*, and rarely by other organisms of the "tuberculosis complex".

Tuberculosis is most commonly transmitted by inhalation of infected droplet nuclei which are discharged in the air when a patient with untreated sputum positive TB coughs or sneezes. If the bacillus succeeds in infecting a person, only about 5%–10% of such infected persons (primary infection) develop active disease. In the remaining 90% to 95 % of infected persons, initial infection usually goes unnoticed. Tuberculin sensitivity appears within a few weeks of infection and initial lesions commonly heal leaving no residual changes except occasional pulmonary or tracheo-bronchial lymph node calcifications (primary complex). Infection occurs almost exclusively through the respiratory route. The infection may then spread from the primary lung lesion to any part of the body via the blood stream, lymphatic and bronchial systems.

Post primary TB (active TB disease) arises from endogenous reactivation of latent foci which remained dormant since the initial infection or exogenous re-infection. Post primary TB usually affects the lungs (more than 85%) but can involve any part of the body. Pulmonary TB which is sputum smear-positive is highly infectious and should receive topmost priority for treatment. Cases which are smear-negative are much less infectious than those which are smear-positive. Extra-pulmonary TB can affect the lymph nodes, pleura, bones and joints, the genito-urinary tract, the nervous system (meningitis), intestines, etc. The precise diagnosis of some of the severe forms is a challenge to physicians as they present a symptom complex with extraordinary diversity. However, patients with extra-pulmonary TB (without concomitant pulmonary TB) hardly ever spread the disease to others. If untreated, TB leads to death within 2–3 years in at least half the patients. About 20 to 25% have natural healing and 25 to 30% remain positive and continue to spread the disease in the community.

Extent of the Tuberculosis Problem

One third of the global population is estimated to be infected with TB bacillus. The annual incidence of new cases of all forms of TB (pulmonary and extra-pulmonary) worldwide is estimated to be approximately 8.8 million, of which about 95% occur in developing countries. Globally, it is estimated that 1.8 million people die from TB each year—the majority of them in developing countries.

Tuberculosis (TB) remains a major public health problem in India. About 40% of the population in India is estimated to be infected with TB bacillus. Every year approximately 1.8 million people develop TB and nearly 400,000 die from it. The annual incidence of smear positive TB is estimated to be 75 per 100,000 population (based on

Annual Risk of Tuberculous Infection (ARTI) study done for the four zones of the country from 2000 to 2003. India accounts for one fifth of global incidence of TB and tops the list of 22 high TB burden countries.

TB kills more adults in India than any other infectious disease.

In India, every day:

- more than 5000 develop TB disease
- more than 1000 people die of TB (i.e. 1 death every 1.5 minutes)

Tuberculosis is a barrier to socio-economic development. It is estimated that the annual cost to society and the country due to TB amounts to nearly US$ 3 billion in indirect costs and US$ 300 million in direct costs. The greatest burden of tuberculosis incidence and mortality in India is in adults aged 15 to 60 years, which include the most productive members of society. TB affects more men than women, but still kills more women than all causes of maternal mortality put together.

Every year due to TB (as per estimates made in 1997):

- More than 170 million work-days are lost
- nearly 300,000 school children dropout from the schools
- more than 100,000 women are rejected by their families

The HIV epidemic has the potential to worsen the TB situation, increasing the number of TB cases and accelerating the progression of TB infection to active disease. It is estimated that 50 to 60 % of HIV infected people will develop TB disease in their lifetime when compared to 10% of HIV negative persons infected with TB.

Another challenge to TB control in India is multi-drug resistant TB (MDR-TB). Fortunately the data available to date shows that levels of MDR-TB remain relatively low, at around 3%, amongst new patients and 12% in re-treatment cases. However these relatively low percentage figures translate into large absolute number of MDR-TB cases, who can transmit their drug resistant disease to others and require effective treatment.

Childhood TB is a reflection of the prevalence of sputum smear-positive pulmonary tuberculosis (PTB) and the extent of transmission of TB infection in the community. The incidence of TB in children is less compared to adults, but they are likely to suffer from more serious forms of TB and may die if not treated properly.

TB Control in India

The National Tuberculosis Programme of India (NTP) was initiated in 1962, based on research by Tuberculosis research centre, Chennai and National TB Institute, Bangalore. The National programme was designed for domiciliary treatment using self administered standard drug regimens. A large network of District TB centers were created with trained staff and infrastructure. Despite the existence of the NTP, there was little impact on the TB burden till 1992. A combined review of the programme in 1992 concluded that the NTP could not achieve the objectives because of low priority, managerial weaknesses, over dependence on X-rays for diagnosis and inadequate funding. Incomplete treatment was the norm rather than exception due to low rates of treatment adherence and lack of supervision.

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 thereafter increased in phased manner. A full-fledged programme was started in 1997 and rapidly expanded with excellent results. This Revised National Tuberculosis Control Programme (RNTCP) uses the DOTS (Directly Observed Treatment, Short-course chemotherapy) strategy, which is based on results of tuberculosis research done in India. By June 2005 the RNTCP had covered more than 1 billion population (more than 90% of the country was covered) and whole of the country was expected to be covered by 2005 end. Since the inception of RNTCP and up to June 2005, more than 4.5 million patients were initiated on treatment and about 750,000 additional lives were saved[1].

Objectives of the Revised National Tuberculosis Control Programme (RNTCP)

The Goal of the RNTCP is to decrease mortality and morbidity due to TB and reduce the transmission of infection until TB ceases to be a major public health problem. The goal is achieved through the following objectives.

The Objectives of the RNTCP are

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

Effort should be made to first achieve the objective 1 and then make additional efforts to meet the objective 2.

[1] To estimate the number of lives saved, best available data from both the RNTCP and the NTP are used. A systematic evaluation of outcomes in the NTP indicated that 29% of the smear-positive patients died and approximately 10%-12% of smear-negative patients die under programme conditions in the NTP. In the RNTCP, no more than 4% of all patients die. Thus, taking a weighted average of smear-positive and smear-negative patients, the differential mortality is at least 18%. That is, for every hundred patients treated under the RNTCP, at least eighteen lives are saved. For details refer to ‘www.tbcindia.org/calculation.asp.’

TB can be controlled by early detection and effective treatment of infectious pulmonary TB cases who act as the sources of infection. Thus the basic curative as well as preventive strategy is the treatment of infectious TB patients until cure. The priority for treatment are newly diagnosed, sputum-positive pulmonary tuberculosis cases, as they are the main sources of infection and are more likely to die unless effectively treated.

The RNTCP is based on the Directly Observed Treatment, Short-Course (DOTS) strategy, which is the internationally recommended strategy of choice for TB control. The DOTS strategy has the following five components:

- **Sustained political commitment** to increase human and financial resources and make TB control a nation-wide activity integral to national health system;
- **Access to quality-assured TB sputum microscopy** for case detection among persons presenting with, or found through screening to have, symptoms of TB (most importantly prolonged cough).
- **Standardized short-course chemotherapy** to all cases of TB under proper case-management conditions including direct observation of treatment – proper case management conditions imply technically sound and socially supportive treatment services;
- **Uninterrupted supply of quality-assured drugs** with reliable drug procurement and distribution systems
- **Recording and reporting system enabling outcome assessment** of each and every patient and assessment of the overall programme performance.

Directly Observed Treatment (DOT), in which a trained peripheral health worker or community volunteer watches as patients swallow all medicines, is fundamental to ensuring cure. DOT should be ensured for every dose in the intensive phase of treatment and at least the first dose of the week in the continuation phase. DOT is one of the five components of the DOTS strategy.

The diagnosis and treatment of TB are functions of the general health services and hence a part and parcel of Primary Health Care. At the District Level, the District Tuberculosis Centre (DTC) acts as the nodal centre for planning, training, logistics, quality control, monitoring and supervision.

Early detection of disease should be done in all symptomatic patients reporting to the general health services with cough of duration of 3 weeks or more by examination of 3 sputum smears for AFB. Contacts of smear-positive cases should also be evaluated. Sputum examination and treatment of TB including anti-TB drugs are provided free of charge under the Programme. The outcome of treatment is evaluated by analysis of the results of quarterly cohorts of all registered cases.

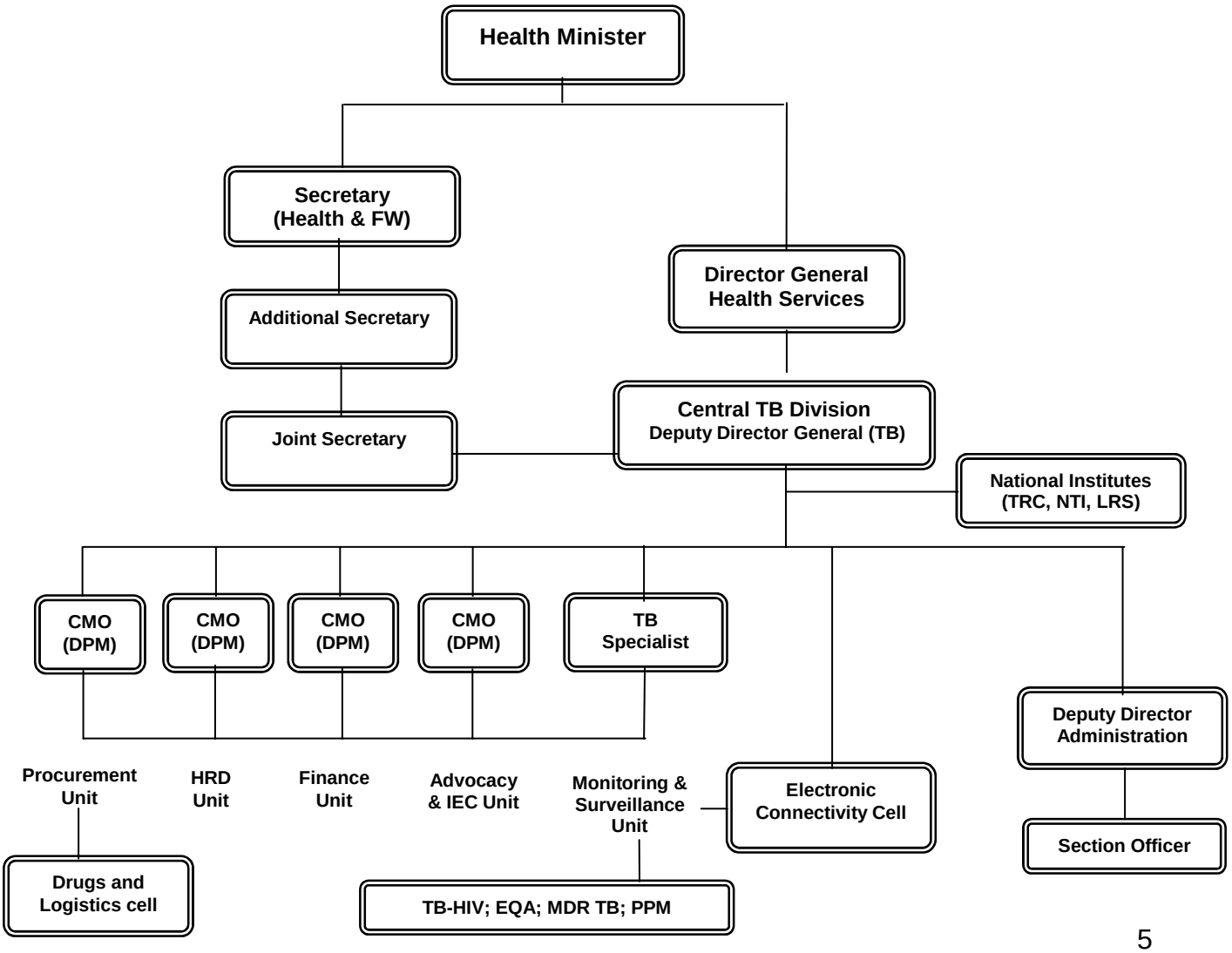
ORGANIZATIONAL STRUCTURE AND FUNCTIONS 2

The structure of RNTCP comprises of five levels: National level, State level, district level, sub-district level and peripheral health institution level.

National Level

At the central level the Revised National TB Control Programme is managed by Central TB Division of Directorate General Health Services, the technical arm of the Ministry of Health and Family Welfare (MoHFW). A National Programme manager, Deputy Director General TB (DDG TB), is in charge of the tuberculosis programme for the entire country. The Joint Secretary from the administrative arm of the MoHFW looks after the financial and administrative control of the programme. The CTD is assisted by 3 national tuberculosis institutes, namely, National Tuberculosis Institute, Bangalore, Tuberculosis Research Centre, Chennai, and Lala Ram Sarup Institute of Tuberculosis and Respiratory Diseases, New Delhi.

Organizational Structure: Central Level



Central TB Division has five units to manage various programme activities. These units are headed by the Chief Medical Officer (CMO) of the rank of Deputy Programme Manager (DPM) and assisted by other technical and secretarial staff. The five units are as mentioned below:

1. Supervision, monitoring and epidemiological surveillance unit
2. Human resource development unit
3. Procurement, supply and logistic unit
4. Finance unit
5. Advocacy and IEC unit

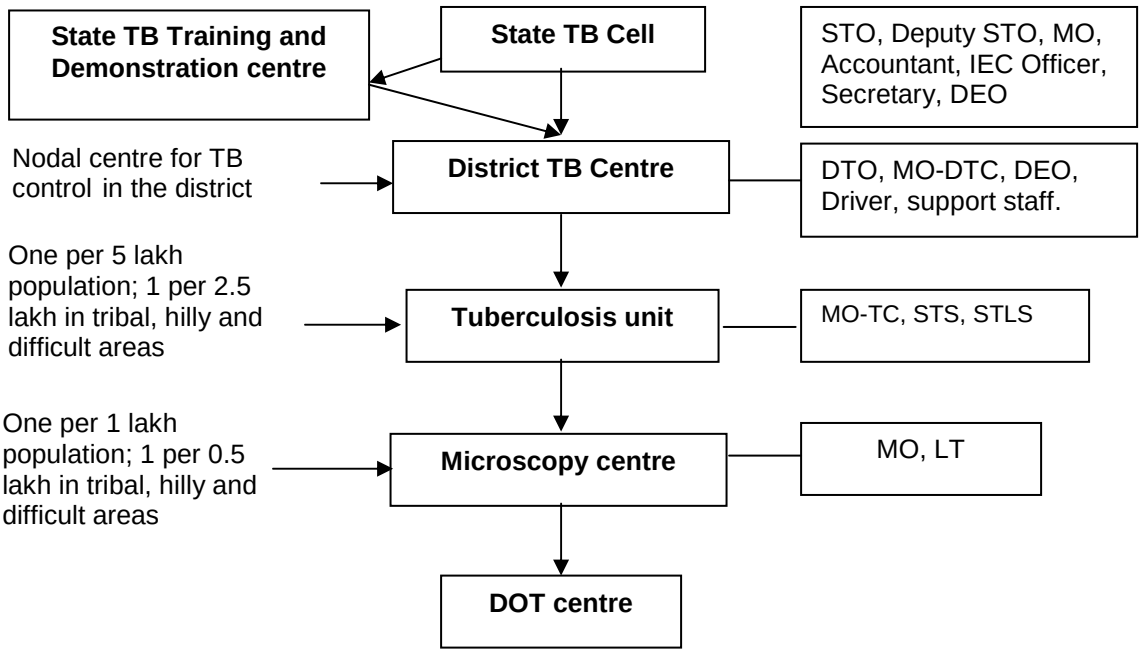
The functions of CTD are described in Annex 1A (page 74).

State Level

At the State level, the State Tuberculosis Officer (STO) is responsible for planning, training, supervising and monitoring the programme in their respective states as per the guidelines of the State TB Control Society or its equivalent (STCS or its equivalent). The STO based at the State TB Cell is administratively answerable to the State Government and technically follows the instructions of the CTD, and coordinates with CTD and the districts for executing the duties mentioned above. There should be a full-time STO trained in RNTCP for each state.

With the rapid expansion of the programme, MoHFW has re-structured and strengthened the functions of the STCS or its equivalent. The States have increased ownership and accountability for implementation. Capacity building and de-centralization are taking place in the technical, financial as well as logistic aspects of the programme. The States, via the STCS or its equivalent, are now directly responsible for monitoring and supervising the work of District TB Control Societies (DTCS) or its equivalent.

Structure of RNTCP at the state level:



Functions of the State TB Cell are listed in Annex 1B (page 76).

In major states of the country, a State TB Training and Demonstration Centre (STDC) support's the State TB cell. The STDC has three units – A training unit, Supervision and monitoring unit and an Intermediate Reference Laboratory (IRL) supporting an effective Quality Assurance system of the RNTCP Sputum smear microscopy network in the State.

Functions of the STDC are listed in Annex 1C (page 78).

The **State TB Cells** have been provided with equipment, infrastructure and contractual staff to carry out its activities. The staffs at the STC are the State TB Officer, Deputy State TB Officer, Medical Officer STC, State IEC Officer, State Accountant, Secretarial Assistant, Pharmacist and Data Entry Operator.

Responsibilities of staff of State TB Cell (State IEC Officer and State Accountant) are given in Annex 1D (page 80).

State Drug Stores (SDS) for anti-TB drugs are essential for effective management of drugs logistics. For the long-term sustainability of the programme, decentralization of many aspects of drug management to the states has been done. One SDS (@ 1 per 50 million population) is established in all major states and in those states where management of drug logistics is difficult e.g. hilly areas, difficult to access areas and areas prone to natural calamities.

District Level

The district is the key level for the management of primary health care services. The district level (or municipal corporation level) performs functions similar to those of the state level in its respective area. The Chief District Health Officer (CDHO) / Chief District Medical Officer (CDMO) or an equivalent functionary in the district 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. In RNTCP, the primary role of the DTC has shifted from a clinical one to a managerial one. The District TB Officer (DTO) at the DTC has the overall responsibility of management of RNTCP at the district level as per the programme guidelines. The DTO is also responsible for involvement of other sectors in RNTCP 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 RNTCP at a central level institution.

Functions of the CDMO/CDHO, District TB Officer and other staff of the DTC are listed in Annex 1E (page 82).

Sub-District Level (Tuberculosis Unit Level)

A major organizational change in RNTCP is the creation of a sub-district level (Tuberculosis Unit). The Tuberculosis unit (TU) will consist of a designated Medical Officer-Tuberculosis Control (MO-TC) who does tuberculosis work in addition to his/her 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). TUs are generally based in a Community Health Centre (CHC), Taluk Hospital (TH) or Block Primary Health Centre (BPHC). The team of STS and STLS at the Tuberculosis Unit level (TU level) are under the administrative supervision of the DTO / MO-TC. The TU covers a population of approximately 500,000 (250,000 in tribal, desert, remote and hilly regions). The TU will have one Microscopy Centre for every 100,000 population (50,000 in tribal, desert, remote and hilly regions) referred to as the Designated Microscopy Centre (DMC). DMCs are also provided in Medical Colleges, Corporate hospitals, ESI, Railways, NGOs, private hospitals, etc, depending upon requirements. The TU is responsible for accurate maintenance of the Tuberculosis Register and timely submission of quarterly reports to the district level. The TU is the nodal point for TB control activities in the sub-district.

MOTC at the TU has the overall responsibility of management of RNTCP at the sub-district level and is assisted by the STS and STLS. The MO-TC is trained in RNTCP at a state level institution, preferably State TB Training and Demonstration Centre (STDC). MOTC is expected to undertake supervisory visits in the TU for seven days in a month.

The functions of the TU team are given in Annex 1F (page 85).

Peripheral Health Institutions (PHIs)

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

Case-finding and treatment of TB are integrated into the functions of the medical staff of government health services. The staff in specialized services which support the programme (DTC) has these functions in addition to supporting the DTO in the management of the Programme. In situations where more than one MO is posted in any of the peripheral health centres, one of them may be identified and entrusted with the responsibilities of the RNTCP.

The categories of staff involved in TB control at PHI level and their principal responsibilities are given in Annex 1G (page 90).

TB Laboratory services

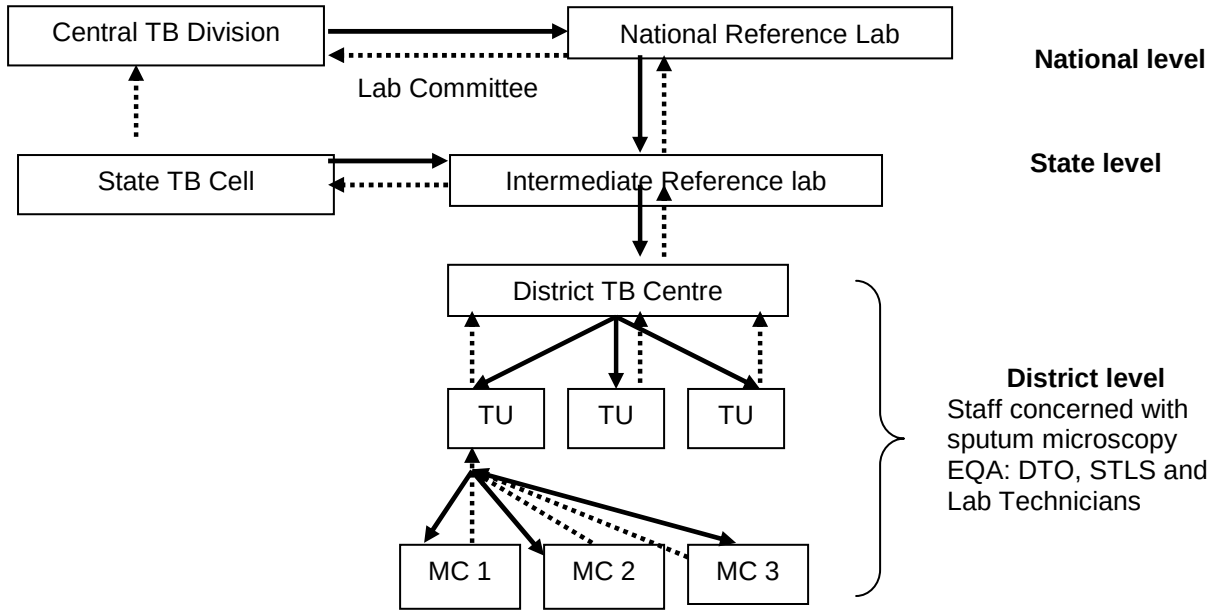
The aims of the laboratory service are: (i) the diagnosis of cases, and (ii) monitoring of treatment.

The Laboratory network for RNTCP in India consists of three designated National Reference Laboratories (NRLs) namely Tuberculosis Research Center, Chennai, National Tuberculosis Institute, Bangalore and LRS Institute of Tuberculosis and Respiratory Diseases, Delhi; about 24 Intermediate Reference Laboratories (IRLs) at state level; and about 10,000 Microscopy Centres or peripheral laboratories. A nodal laboratory in each state will be designated as IRL. Usually the STDCs (State TB Training and Demonstration Centres) would be designated as IRL provided that they have a well functioning laboratory. Else, the state is to identify a Public Health Laboratory or Medical College Laboratory and designate that as the IRL after the laboratory is assessed by a visit from the NRL. The RNTCP Microscopy Centers in each district are the peripheral laboratories. Roles of NRL and IRL are described in Annex H (page 95).

A Central Laboratory Committee has been constituted with the Microbiologists of the three NRLs and CTD representatives as members. This committee works as a task force to guide Laboratory related activities of the programme.

Structure of RNTCP Laboratory network:

The different levels of laboratories under RNTCP are as follows:



National Reference Laboratory: Each NRL will supervise sputum microscopy EQA of 8 to 11 states designated under them. The NRLs are internationally accredited laboratories as their EQA is being performed by a WHO reference laboratory for anti-tuberculous drug susceptibility testing.

Intermediate Reference Laboratory: The states will designate one Intermediate Reference Laboratories in the STDC or Medical College or in any Public Health Laboratory of the state. The IRL should be a facility deemed fit for accreditation by the respective NRL looking after the state. The designated IRL will conduct sputum microscopy EQA for the state and occasionally for a neighbouring state or union territory based on an understanding between the two concerned STCSs or its equivalent/ CTD. The IRL will ensure proficiency of RNTCP staff for carrying out good quality diagnosis by providing technical training to district and sub-district technicians and STLS.

Designated Microscopy Centre: Sputum microscopy diagnostic services under RNTCP are provided by Designated Microscopy centres (DMC) established for every one lakh population (50,000 population in tribal and hilly areas). In addition the DMCs are also established at Medical colleges, Corporate hospitals, ESI, Railways, NGOs, large private hospitals, and other major hospitals.

The DMCs should satisfy the following criteria

1. RNTCP trained Laboratory technician should be present [1]
2. Binocular Microscope should be present in the laboratory
3. Physical infrastructure in Laboratory should meet RNTCP guidelines.
4. Daily new adult OPD of at least 60-100 and/ or workload of at least 3-5 sputum smears per day for the Laboratory Technician in the laboratory.

DMCs in the public sector, at the onset of the programme, were provided with funds to undertake minor civil works to build up their physical infrastructure and were provided with binocular microscopes.

In addition, before designating a DMC in other sectors, there should be a formal agreement by the hospital/laboratory to take part in the external quality assurance and to allow the concerned RNTCP staff for supervision as per RNTCP guidelines

If the above criteria are met by any private laboratory it can be considered for establishing as a DMC. However, the population norms for DMCs (one DMC per 100,000 population in the usual cases and 50,000 population in remote and difficult areas) should not prevent from designating a private hospital/laboratory as DMC if the decision is based on programme needs and fulfillment of the above citeria.

Any laboratory/ private health facility not fulfilling the above criteria may be considered for referral/ sputum collection centre.

There is no provision from RNTCP for civil works, Binocular Microscope and LT for laboratories in private and NGO sectors. For such DMCs, the logistics including Laboratory consumables, registers and forms may be supplied from RNTCP as per guidelines. In exceptional cases provision of BMs may be considered for DMCs in other sectors by CTD.

Sputum collection Centres:

To improve access to diagnostic services in areas such as the tribal, hilly, difficult to reach areas of the country sputum collection centres may be established. Collection and transport of sputum samples should be as per the RNTCP guidelines (refer section on ‘Diagnosis of Pulmonary Tuberculosis’). Each district shall identify such areas and plan for establishment of the sputum collection centres.

Private practitioners in urban and rural areas can also collect sputum samples and send to the nearest DMC as per PP scheme 1 (Refer guidelines on “Involvement of Private practitioners in RNTCP”).

[1] In the public sector, laboratory technicians are from the state health system. However, there is a provision for contractual LTs if required, under the programme. Refer to Financial guidelines and PIP for details.

DIAGNOSIS OF PULMONARY TUBERCULOSIS 3

Tuberculosis (TB) affects the lungs in more than 85% of cases. This form of the disease is called pulmonary tuberculosis. Pulmonary tuberculosis is an infectious disease and spreads mainly by droplet infection. Sputum positive pulmonary TB patients are the main source of infection. It is estimated that an untreated smear positive pulmonary TB patient infects 10-15 persons annually. Therefore, it is very important to identify TB suspects and diagnose them early in order to effectively treat and make them non infectious.

Identification of tuberculosis suspects

Most patients with TB visit health facilities promptly after symptoms occur. Hence, every adult patient with respiratory symptoms attending the health facility must be asked about symptoms suggestive of tuberculosis.

The most common symptom of pulmonary TB is a persistent cough for 3 weeks or more, usually with expectoration. It may be accompanied by one or more of the following symptoms such as weight loss, chest pain, tiredness, shortness of breath, fever, particularly with rise of temperature in the evening, in some cases there will be blood in the sputum, loss of appetite and night sweats

About 2-3% of new adult outpatients in a general health facility are expected to have cough for 3 weeks or more and on an average 10% of the suspects are expected to have sputum positive pulmonary TB.

Case finding tools

The main tools for diagnosing pulmonary TB are sputum smear microscopy, chest X-ray, and culture of Mycobacterium tuberculosis bacilli.

- **Sputum smear microscopy:** This is the primary tool for diagnosing TB as it is easy to perform at the peripheral laboratories, not expensive and specific with low inter and intra reader variation. It is simple and requires minimum training. Can be used for diagnosis, monitoring and defining cure. Therefore, this is the key diagnostic tool used for case detection in RNTCP. If good diagnostic practices are followed, it is expected that at least 50% of the new pulmonary TB patients diagnosed will be smear-positive.

- **Chest X-ray:** X-ray as a diagnostic tool is sensitive but less specific with large inter and intra reader variations. No shadow is typical of TB, 10-15% culture-positive cases remain undiagnosed and 40% patients diagnosed as having TB by X-ray alone may not have active TB disease. It is supportive to microscopy.

- **Culture:** Culture of Mycobacterium tuberculosis bacilli is very sensitive and specific but is expensive as it requires a specialized laboratory set-up and results are available only after several weeks. If available, culture of tubercle bacilli may be helpful, although in sputum-negative cases a clinical decision to treat for TB based on X-ray findings and lack of response to broad-spectrum antibiotics would be more practical and also ensure prompt treatment. Culture and sensitivity testing is valuable for diagnosis and management of drug resistant tuberculosis, besides epidemiological surveillance and planning.

- **Tuberculin test:** Tuberculin test may be useful as an additional tool for diagnosing pediatric TB, in whom a positive test is more likely to reflect recent infection with TB and indicates a much higher risk of developing disease. However, the tuberculin test has no role in diagnosing adult pulmonary TB disease in India.

Case-finding methods

- Examination of sputum of patients with symptoms suggestive of TB, who present on their own initiative at health facilities;

- Promotion of awareness in the community, amongst the medical professionals and all medical staff regarding respiratory symptoms, notably persistent cough for 3 weeks or more, and the need to obtain and examine 3 sputum specimens for the diagnosis of TB;

- Examination of household contacts of smear-positive TB patients; irrespective of the duration of cough

- Examination of extra-pulmonary TB cases with cough of any duration.

Diagnosis by Sputum Microscopy

A medical practitioner at a health facility screens patients and advises those who are suspected of having TB (cough for three weeks or more) to undergo sputum smear examination at the nearest RNTCP designated microscopy centre. A laboratory form for sputum examination has to be filled and sent to the laboratory with the patient. The sputum specimen may be collected and transported to the laboratory if the patient is unable to travel to microscopy centre.

Microscopic examination of sputum is, as a rule, the only way by which the diagnosis of pulmonary TB can be confirmed. Whenever TB is suspected, atleast 3 specimens of sputum should be collected over 2 consecutive days and examined by microscopy. Only one laboratory form needs to be filled for all the three specimens of the patient.

Guidelines for collecting sputum for smear microscopy

- **First visit to the microscopy centre**: When a TB suspect reports to the laboratory a specimen is collected on the spot. S/he is given a sputum container with the

laboratory serial number written on its side and is instructed to inhale deeply two to three times with his/her mouth open, cough out deeply from the chest, open the container, spit out the sputum into it and close the container tightly. This specimen is called a spot specimen. The patient is then given a similarly marked empty sputum container to collect a specimen early next morning and bring it to the laboratory. This specimen is called an early morning specimen.

- **Second visit to the microscopy centre**: The early morning specimen brought by the patient is received and a further spot specimen is collected.

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

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

- **Tasks performed before sputum collection:** Before a health worker collects a sputum specimen, the reasons for sputum collection have to be explained to the patient. The Laboratory technician/ health worker must ensure that the patient's full address is entered in the laboratory form.

- **Tasks performed during sputum collection:** A specimen collected under the proper guidance of a health worker is likely to yield more conclusive results than one produced by a patient without any guidance. Sputum should preferably be collected in open air or in a vacant room with open windows. The health worker or the laboratory technician should stand behind the patient. The health worker should also ensure that no-one stands in front of the patient. If a patient coughs out only saliva, s/he should be asked to try again to bring out sputum. Patient must be asked to rinse the mouth before bringing out the sputum samples.

- **Tasks performed after sputum collection:** Sputum specimens should be examined on the same day. In cases where sputum needs to be transported to a DMC it must be examined within a week after collection. Storage of sputum samples should be in cool place/ refrigerator. A smear is made, fixed and stained using the Ziehl-Neelsen staining technique.

If the first spot specimen is positive by microscopy and the patient does not return for the second sputum test, an immediate search must be made to find the patient to prevent dissemination of infection in the community. In the interest of the patient, second and third specimens of sputum must be collected and examined. To facilitate this it is important to note down the complete address of all symptomatic patients.

Smear preparation, Staining and Reading

All specimens should be examined in the nearest designated microscopy centre, as a rule, by the Ziehl–Neelsen method.

ZIEHL-NEELSEN STAINING PROCEDURE

1. A new unscratched slide is selected and the slide is labeled with the Laboratory Serial Number with a diamond marking pencil.
2. A smear is made from yellow purulent portion of the sputum using a broom stick. A good smear is spread evenly, 2 cms x 3 cms in size and is neither too thick nor too thin. The optimum thickness of the smear can be assessed by placing the smear on a printed matter. The print should be readable through the smear. Smear preparation should be done near a flame. This is required, as six inches around the flame is considered as a sterile zone which coagulates the aerosol raised during smear preparation.
3. The slide is allowed to air dry for 15–30 minutes.
4. The slide is fixed by passing it over a flame 3–5 times for 3–4 seconds each time.
5. 1% filtered carbol fuchsin is poured to cover the entire slide.
6. The slide is gently heated with carbol fuchsin on it, until vapours rise. Do not boil.
7. Carbol fuchsin is left on the slide for 5 minutes.
8. The slide is gently rinsed with tap water until all free carbol fuchsin stain is washed away. At this point, the smear on the slide looks red in colour.
9. 25% sulphuric acid is poured onto the slide and allowed to stand for 2–4 minutes.
10. The slide is gently rinsed with tap water and tilted to drain off the water.
11. A properly decolourised slide appears light pink in color .If the slide is still red, sulphuric acid is reapplied for 1–3 minutes and then rinsed gently with tap water. The back of the slide is wiped clean with a swab dipped in sulphuric acid,
12. 0.1% methylene blue is poured onto the slide and left for 30 seconds. Then the slide is rinsed gently with tap water and allowed to dry.
13. The slide is examined under the binocular microscope using x40 lens to select the suitable area and then examined under x100 lens using a drop of immersion oil.
14. The results are recorded in the Laboratory Form and the Laboratory Register.
15. The slides are inverted on a tissue paper till the immersion oil is completely absorbed. Xylene is not to be used for cleaning the slides, as it may give false results at repeat examination after storage.
16. All positive and negative slides are stored serially in the same slide-box until instructed by the supervisor.
17. All contaminated materials are disinfected as per guidelines before discarding. (Refer to section on ‘Infection Control and Hospital Waste Management’)

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

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

** Record exact number seen in 100 fields*

Classification of tuberculosis cases

It is important to classify cases of TB in order to determine the correct combination of drugs and duration of treatment. Classification of pulmonary cases should be based on at least 3 sputum smear examinations. Sputum should also be examined for cases of suspected extra-pulmonary TB if pulmonary symptoms are present.

Pulmonary tuberculosis

a. Smear-positive patient

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

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

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

b. Smear-negative patient

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

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

Extra-pulmonary tuberculosis

Extra-pulmonary tuberculosis (EPTB) is tuberculosis of organs other than the lungs, such as the pleura (pleurisy), lymph nodes, intestines, genito-urinary tract, skin, joints and bones, meninges of the brain, etc.

Diagnosis should be based on one culture-positive specimen from an extra-pulmonary site, or histological or radiological, or strong clinical evidence consistent with active extra-pulmonary TB followed by the treating 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 sputum smear positive pulmonary TB and extra-pulmonary TB should be classified as a case of pulmonary TB.

Diagnostic algorithm of RNTCP

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

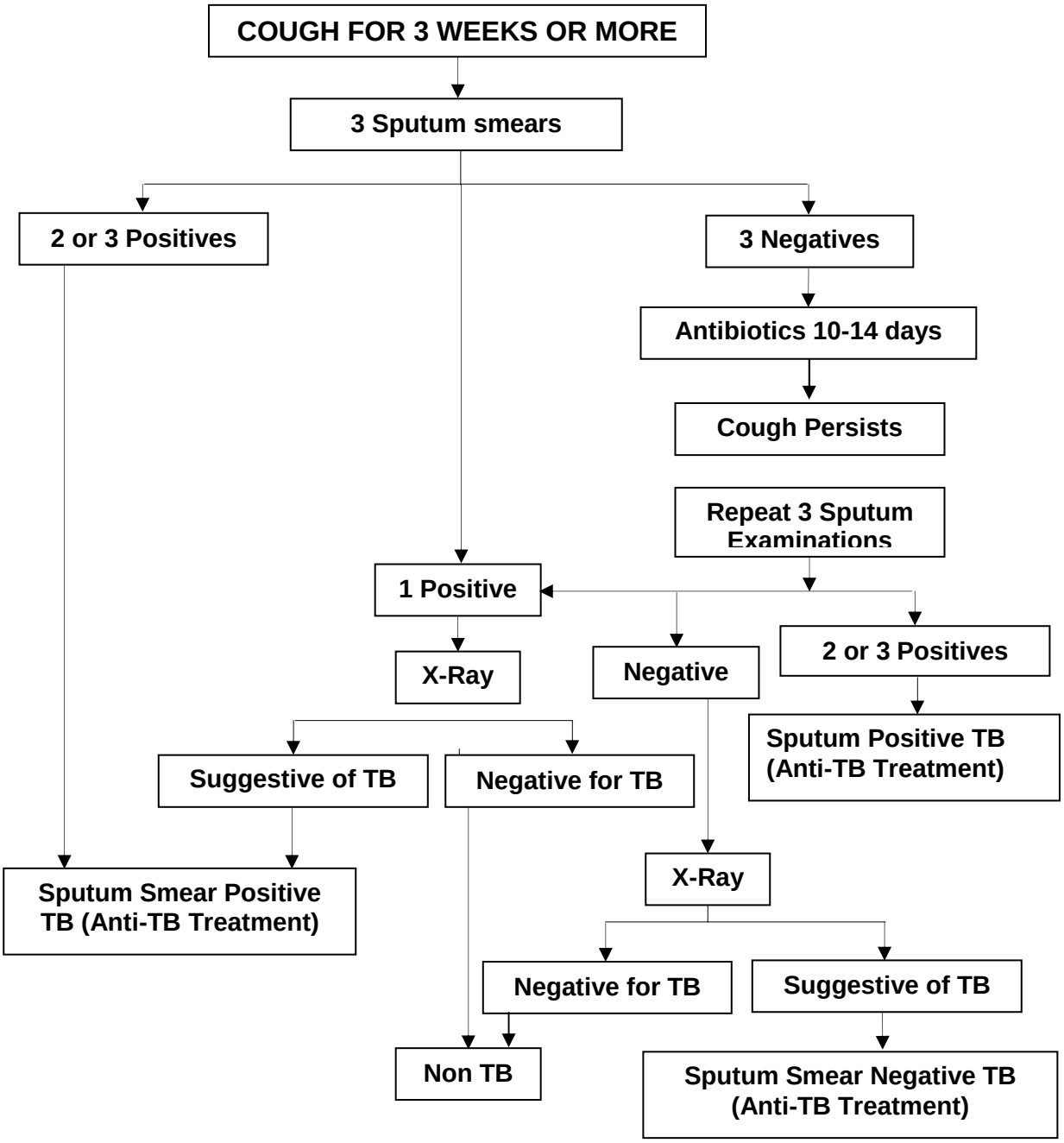
For patients with only one sputum positive result on smear examination, chest X-ray is taken. If findings of the X-ray are consistent with pulmonary tuberculosis patient is diagnosed by the physician as a case of sputum positive pulmonary TB.

Patients in whom all 3 samples are negative on sputum smear examination are prescribed symptomatic treatment and broad spectrum antibiotics (such as cotrimoxazole, doxycycline, amoxycillin) for 10-14 days. In such cases antibiotics such as fluoroquinolones (ciprofloxacin, ofloxacin, etc.), rifampicin or streptomycin, which are active against tuberculosis, are not to be used. Most patients are likely to improve with antibiotics if they are not suffering from TB. If the symptoms persist after a course of broad spectrum antibiotics, repeat sputum smear examination (3 samples) must be done for such patients.

If two or more smears are positive, the patient is diagnosed as having smear positive pulmonary TB. If only one sputum sample is positive, chest X-ray is taken. If findings of the X-ray are consistent with pulmonary tuberculosis, patient is diagnosed by the physician as a case of sputum positive pulmonary TB.

If the results for all the three sputum samples of repeat examination are found negative then a chest X-Ray is taken. If findings of the X-ray are consistent with pulmonary tuberculosis, patient is diagnosed by the physician as a case of sputum negative pulmonary TB.

DIAGNOSTIC ALGORITHM FOR PULMONARY TB



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

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

Follow up Smear examination

During follow-up two sputum samples are to be tested each time. The schedule is as follows:

For smear positive TB patients, 2 sputum samples (Morning - Spot) have to be tested each time on three occasions - At the end of the intensive phase (2 months for new cases and 3 months for re-treatment cases), two months into the continuation phase (at the end of 4 months for new cases / 5 months for re-treatment cases) and at the end of treatment. If the smear is positive at the end of the intensive phase, it should be tested again at the end of extended IP (3 months in new cases and at 4 months in re-treatment cases).

For smear negative patients, two sputum samples have to be tested on two occasions – at the end of IP and at the end of treatment.

Quality Assurance

Effective quality assurance (QA) of the RNTCP sputum smear microscopy network is of crucial importance. QA is a total system consisting of internal quality control (QC), assessment of performance using external quality assessment (EQA) methods, and continuous quality improvement (QI) of laboratory services.

Quality Control (QC): Also called Internal Quality Assurance, includes all means by which the laboratory personnel performing TB smear microscopy, control the processes including checking of instrument, new lots of staining solutions, smear preparation, grading etc. It is a systematic internal monitoring of working practices, technical procedures, equipment, and materials, including quality of stains.

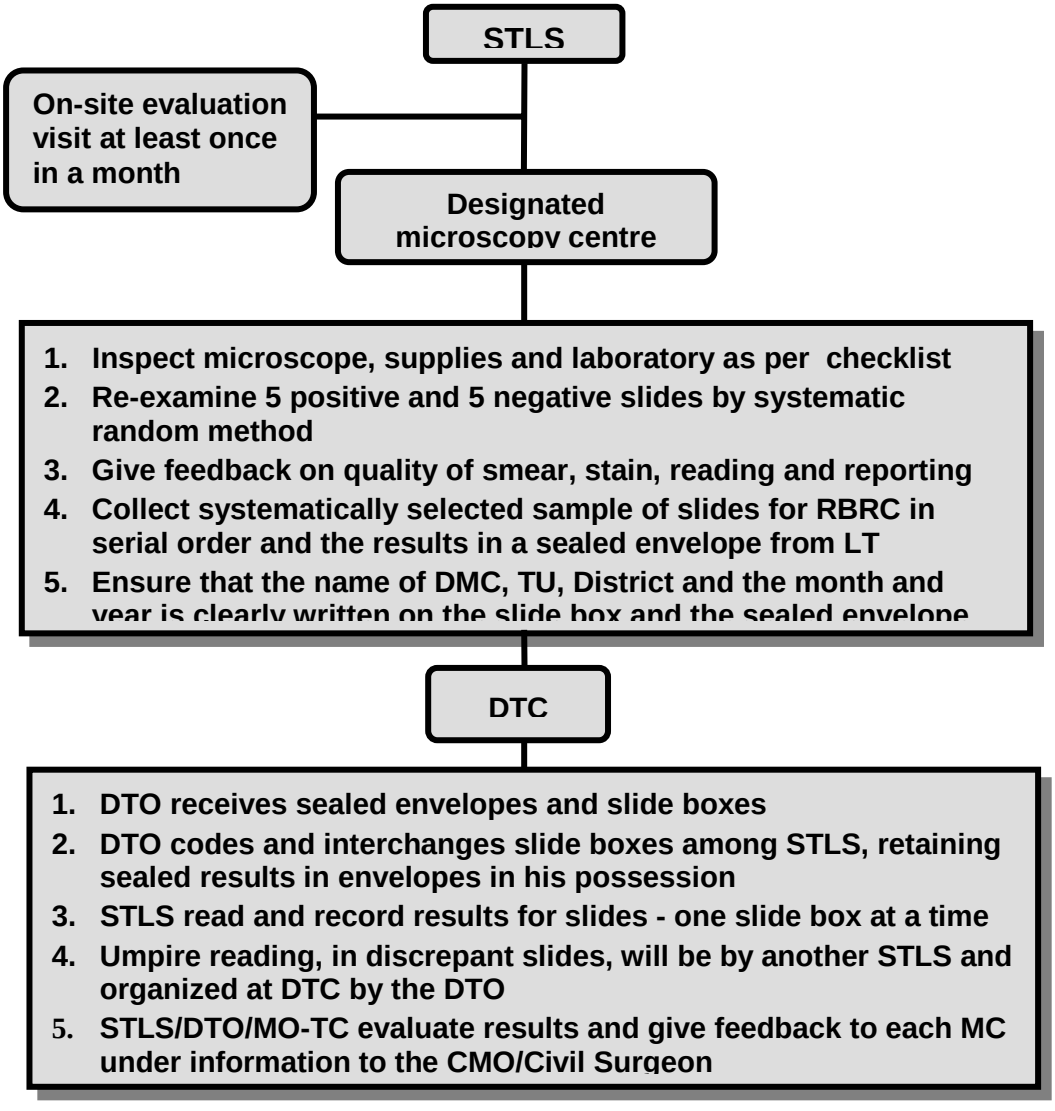
External Quality Assessment (EQA): A process to assess laboratory performance. EQA includes on-site evaluation of the laboratory to review QC and evaluation of entire process of smear microscopy, and random blinded re-checking of routine smears. EQA

also allows participant laboratories to assess their capabilities by comparing their results with those obtained in other laboratories in the network through panel testing and rechecking of patient slides, using both un-blinded and blinded procedures.

Quality Improvement (QI) A process by which all components of smear microscopy diagnostic services are carefully analysed with the aim of looking for ways to permanently remove obstacles to success. Appropriate data collection, data analysis, correct interpretation of the results and creative problem solving, are the key components of this process. It involves continued monitoring, identifying defects, followed by remedial action including retraining when needed, to prevent recurrence of problems. QI mostly relies on effective on-site evaluation visits.

The network of designated microscopy centres (DMCs) is supported and supervised by regional/state laboratories (Intermediate Reference Laboratories or IRLs), and overseen by the National TB Reference Laboratories (NRLs).

Quality Assurance Network in Sputum-smear Microscopy



External Quality Assessment (EQA)

At the district level the activities of DTO, MO-TC and STLS for EQA of RNTCP laboratory network are

- on-site evaluation of DMCs
- blinded re-checking of DMC's slides at DTC, and
- reporting the results of activities to LT and MO of the DMC and to STDC promptly.

The on-site evaluation (OSE) of DMC by the STLS includes a comprehensive assessment of laboratory safety, condition of the binocular microscope, adequacy of supplies as well as the technical components of sputum smear microscopy; including preparation, staining and reading of smears. The frequency of on-site evaluation of any DMC is decided on the basis of its performance. On-site evaluation of every DMC is conducted at least once a month by the STLS of the respective TB Unit.

The DTO/ MO-TC would also be supervising the DMC as per their tour programme and hand over to MO of DMC the summary of observations and recommendations for corrective actions.

Random blinded rechecking (RBRC) at the district level involves selection of a small sample of slides (sample size determined by the LQAS i.e. Lot Quality Assurance Sampling methodology), which is representative of all slides of a DMC (both positive and negative). The original slide examination results by LTs are blinded and read by a STLS not belonging to the same TU to prevent bias.

The STDC / IRL conduct OSE, analyze district reports of RBRC during OSE and Panel testing of the districts. Similarly NRL conduct OSE and Panel testing of the IRLs. (Details of QA activities of the NRL, IRL and district can be obtained from "Guidelines for Quality Assurance of Smear microscopy for diagnosing Tuberculosis").

Checklists have been developed to assist supervisors during the field visit and to allow for the collection and analysis of standard data for subsequent remedial action.

TREATMENT 4

The objectives of Tuberculosis treatment are:

- To decrease mortality and morbidity by ensuring cure, minimizing relapses and preventing development of drug resistance
- To decrease infections and break the chain of transmission of infection
- To achieve the above whilst minimizing side effects due to drugs

These objectives are achieved in RNTCP through intermittent (thrice weekly) treatment regimens given under direct observation for both pulmonary and extra-pulmonary tuberculosis patients. Treatment regimens for tuberculosis have emerged as a result of controlled clinical trials in India and other parts of the world. It has been proven that thrice-a-week (intermittent) treatment is as effective as daily treatment and produces lesser side effects.

RNTCP provides standardized anti-TB treatment in three categories. Once the patient has been diagnosed as having TB, may be pulmonary or extra-pulmonary, the MO is responsible for deciding the treatment regimen under one of the three categories depending on

- Sputum Smear results
- The history of previous anti-TB treatment
- Disease classification (pulmonary/ extra-pulmonary)
- Severity of illness

Definition of types of cases

New

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

Relapse

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

Transferred in

A TB patient who has been received for treatment in a Tuberculosis Unit, after starting treatment in another unit where s/he has been registered.

Treatment after default

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

Failure

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

Chronic

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

Others

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

Seriousness of Illness

The severity of the illness depends on the bacillary load, the extent and the anatomical site of the disease. The involvement of an anatomical site helps in classifying if the disease is severe, depending on whether it is life threatening or has high risk of developing subsequent severe handicap or both. The following forms of extra-pulmonary TB and smear negative pulmonary TB are classified as 'seriously ill'.

Extra-pulmonary TB classified as 'seriously ill'	**Smear-negative pulmonary TB classified as 'seriously ill'**
• meningitis • pericarditis • peritonitis • bilateral or extensive pleural effusion • spinal TB with neurological involvement • intestinal • genito-urinary • co-infection with HIV • All forms of pediatric extra-pulmonary TB other than lymph node TB and unilateral pleural effusion are considered to be seriously ill.	• miliary TB • extensive parenchymal infiltration • co-infection with HIV • cavitary disease • All forms of pediatric sputum smear negative pulmonary TB except primary complex

Treatment regimens

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

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

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

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

Drugs and their dosage

The most important drugs used in the treatment of TB are isoniazid (H), rifampicin (R), pyrazinamide (Z), streptomycin (S) and ethambutol (E). The dosage strengths are as follows:

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

Drugs are supplied in patient-wise boxes (PWB) containing the full course of treatment, and packaged in blister packs. The PWB have a color code indicating the category (Red

for CAT I, Blue for CAT II and Green for CAT III). In each PWB, there are two pouches one for intensive phase (A) and one for continuation phase (B). For the intensive phase, each blister pack contains medicines for one dose. For the continuation phase, each blister pack contains one week's supply of medication. The drugs for extension of the intensive phase (prolongation pouches) are supplied separately.

For adults, drugs will be given in the recommended number of pills/capsules irrespective of body weight. However, for patients weighing more than 60 kilograms an additional capsule of rifampicin 150 mg will be added to the treatment regimen. Patients who are more than 50 years old receive streptomycin 500mg and patients who weigh less than 30 Kg receive drugs as per body weight.

For children, the drugs will be given according to body weight. Patient wise boxes for children is being developed, however until these are available the drugs are given to children as per body weight. The recommended dosages for children are given in section on Pediatric TB.

Regimen for Non-DOTS (ND) treatment in RNTCP areas

In RNTCP areas, all / most patients would be getting DOTS regimen. Unobserved rifampicin should not be given under any circumstance. However, RNTCP non-DOTS treatment (self administered non rifampicin containing regimen) may be needed in exceptionally few cases (e.g. adverse reaction to rifampicin and pyrazinamide). To facilitate registration of patients started on RNTCP Non-DOTS regimens, a Tuberculosis Treatment Card should be filled. Up to a maximum of 5% of patients may get Non-DOTS treatment in an RNTCP area. Every effort should be made to minimize Non-DOTS, so that all patients are provided superior regimen under DOTS. The justification for initiating patient on non-DOTS treatment should be specified in the "Remarks" column of the treatment card and TB register. The prescribed Non-DOTS treatment regimen and dosages are presented below.

Non-DOTS Regimen 1 (ND1): 12-months conventional chemotherapy regimen, with streptomycin given in the first 2 months. This is given to patients who are: cases of sputum smear-positive pulmonary TB and for seriously ill cases of smear negative and extra-pulmonary 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 (300 mg) and ethambutol (800 mg) are self-administered by the patient daily for 12 months. Streptomycin 0.75 g per day (0.5 g for those over 50 year of age) is administered daily in the initial intensive phase for 2 months. Those who weigh less than 30kg receive dosages calculated as per body-weight.

Non-DOTS Regimen 2 (ND2): 12-months conventional chemotherapy regimen, without streptomycin for patients with smear-negative pulmonary TB who are not seriously ill; and for patients with extra-pulmonary TB who are not seriously ill.

The treatment consists of 12-month conventional chemotherapy. Isoniazid (300 mg) and Ethambutol (800 mg) are self-administered by the patient daily for 12 months.

Drug administration

After the Medical Officer decides to treat the patient, the Treatment Card and Patient Identity Card are prepared. The patient is put on treatment only after the verification of address by the Peripheral Health Worker (PHW) within a period of one week of diagnosis. The patient is also registered in the TB register during the supervisory visit of the STS within a period of one month from the start of treatment.

Prior to starting of treatment, the MO of the Peripheral Health Institution (PHI) explains to the patient about the disease, dosage schedule, duration of treatment, the need for examination of contacts and frequency of follow up sputum to monitor progress towards completion / cure. The MO also discusses with the patient to determine a DOT centre which is acceptable and easily accessible to the patient. Health education and motivation of the patient should be reinforced periodically during follow-up visits. The original Treatment Card is maintained at the PHI where the patient was started on treatment.

If the patient is to be treated by a DOT provider located outside the premises of PHI, a duplicate card will be prepared and given to the DOT provider to record all necessary information. The Medical Officer of the PHI will give the patient-wise box (PWB) for the entire duration of treatment to the PHW. Issue of the PWB to the PHW will be duly recorded in the stock register maintained at the health facility. The PHW visits the house of the patient (definitely within a week) 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 check-up of contacts. The treatment is initiated after this visit by PHW or community volunteer. For drug administration, a convenient location is decided mutually between the PHW and the patient.

Either of two cycles - Monday, Wednesday and Friday; or Tuesday, Thursday and Saturday - is fixed as days for drug administration. All doses in the intensive phase must be taken under observation of the DOT provider. The patient must be contacted within one day of missing a dose during the intensive phase. The dose missed on the specified day in the intensive phase can be administered on the following day. In the continuation phase, the first dose of the week should be taken under direct observation and the subsequent doses for the week are self administered. On the next scheduled visit, the empty blister pack should be collected by the DOT provider before giving the next weekly dose. The patient must be contacted and retrieved for treatment within a week of missing a dose in continuation phase. All the empty blister packs (of IP and CP) should be retained in the PWB.

Treatment cards should be organized at DOT centers according to the day of scheduled observation and the phase of treatment (i.e., intensive phase and continuation phase). The cards should be organized in such a manner that the cards of patients who do not present for treatment will be apparent on the same day, and appropriate action for their retrieval can be taken.

As regards the administration of streptomycin injections at the peripheral level, the policy will be to entrust this responsibility to the Auxiliary Nurse Midwife (ANM) or equivalent at the sub-centre level or to any registered medical practitioner who is acceptable and accessible to the patient. If the same is not possible, the patient has to come to the PHC / CHC or any other nearest health institution. The streptomycin injection should be given using disposable or sterilized syringes and needles.

The DOT provider records the drug administration, and refers the patient to the microscopy centre for follow-up sputum examinations. He also enquires about any drug reaction and refers the patient to the MO if needed.

Side effects

Serious side effects of anti-TB drugs are less with intermittent chemotherapy. Drugs should not be administered on empty stomach. DOT providers should identify common side-effects early and report to the medical officer.

The details of anti-TB drugs used in RNTCP, their interactions and symptom based approach to evaluation of possible side-effects are given in Annex 4 (page 135-139).

Special situations

Management of TB patients on DOT in special situations is described below.

Hospitalization

General policy of RNTCP is to treat patients on ambulatory basis. However, occasionally the general condition of the patient may be serious enough to require hospitalization. For example, in patients with pneumothorax or large accumulations of pleural fluid leading to breathlessness; massive haemoptysis etc. These patients can be managed in general hospitals.

All indoor patients are to be treated with RNTCP regimens. The treatment is given using prolongation pouches which will be supplied by District TB Officer through the STS of the TU in which the indoor facility is situated. On discharge, patients may be given a maximum of three doses (1 week drug supply) to cover the intervening period prior to their continuation of treatment at their respective DOT Centre, which may / may not be in the same TU/district, hence ensuring no interruption in treatment. All indoor patients treated under RNTCP, should be registered under the local TU in which the indoor

facility is located. If the patient resides outside the TU/district, on discharge s/he will be transferred out for continuing treatment.

Flow chart for hospitalized patients is given in Annex 6A and 6B (page 142-143).

Treatment of TB during pregnancy and postnatal period

- Streptomycin should not be given; other drugs used in RNTCP are safe
- Breast feeding should continue regardless of the mother's TB status
- Advise the mother to cover her mouth, if she is smear-positive, while breastfeeding the baby
- Chemoprophylaxis for the baby is recommended if mother is sputum smear-positive.

Treatment in patients with renal failure

- Rifampicin, isoniazid and pyrazinamide can be safely given.
- Streptomycin and ethambutol, if given, should be closely monitored with reduced dosage under the supervision of the treating physician.

Treatment in women taking oral contraceptive pills

- Rifampicin decreases the efficiency of oral contraceptives; switch to another method of contraception.

Directly Observed Treatment (DOT)

Directly observed treatment (DOT) is one of the key elements of the DOTS strategy. In DOT, an observer watches and supports the patient in taking their drugs. Direct observation ensures treatment for the entire course with the right drugs, in the right doses and at the right intervals.

DOT is necessary because at least 1/3 of patients on self-administered treatment fail to adhere to treatment and it is impossible to predict which patients will take regular treatment.

The health worker or community volunteer who administers DOT is called the 'DOT Provider'. DOT provider should be acceptable and accessible to the patient and is accountable to the health system. The 'DOT centre' is a place where DOT is given and is convenient to both patient and DOT provider. DOT can be provided by anyone other than the patient's family members.

To ensure treatment success, patients must take all doses of treatment, in both intensive and continuation phases. During the intensive phase of treatment, each and every dose of medicine is to be taken under direct observation of the DOT Provider.

After the patient takes the drugs under direct observation in the IP, the appropriate box in the treatment card is ticked (√) after the drugs are administered. If the patient misses a dose it is recorded 'O' on the treatment card. If a patient does not take medication as scheduled in the IP, s/he should be traced and given the medication on the next day. The medication for the following day is then given as scheduled. If a patient misses any dose of medicine (does not come on two successive days in IP), these doses must be made up at the end of scheduled period and the duration of treatment will get prolonged.

During the continuation phase of treatment, all patients collect drugs from the DOT centre (DOT provider) once a week on a designated day. One dose is administered under direct observation on the day of collection and the next two doses of the week are given to the patient for self- administration. An 'X' is entered in the appropriate box to indicate the day the drugs were swallowed under direct observation. A line is drawn through the remaining days of the week (after the X) to indicate that the drugs for the remaining period of the week have been given (X--------). The patients must present at the time of next week's collection the empty strip/blister pack of the drugs consumed. During the continuation phase, if the patient is late by a single day for drug collection, the dose may be given and other doses taken as scheduled. If the patient is late by two days or more days from the date on which he was scheduled to have the first directly observed dose of the weekly blister pack is given on the day he presents for collect the drug, the missed dose is marked as 'O" on the treatment card. The drugs are given as when s/he returns for treatment and the missed doses must be made up at the end of scheduled period and the duration of treatment will get prolonged.

Patients who miss a dose must be contacted and put back on treatment through home visits. 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 immediately after knowing that the patient missed a dose. The reasons for the same interruption of treatment must be recorded in the treatment card.

Patient flow for DOT

After receiving the sputum results, the MO of the Peripheral Health Institution (PHI) is responsible for the following measures:

- establishing the diagnosis of tuberculosis
- deciding the type of patient and category of treatment
- explain to the patient about:
    - the disease

  - the treatment (dosage schedule, duration, common side-effects and methods to prevent them)
  - the need for examination of contacts (especially, if patient is smear-positive)
  - frequency of monitoring of progress until cure
  - importance of directly observed treatment (DOT)

- determines the DOT Centre and the DOT Provider
- initiates the Tuberculosis Treatment Card (in duplicate when required) and the TB Identity Card
- make the patient-wise box available at the DOT Centre along with the TB treatment Card, TB Identity Card and sputum containers for morning samples of follow-up sputum examinations

For the purpose of identifying a suitable DOT provider and an appropriate DOT Centre, a DOT Directory should be maintained at PHI level. This directory should contain a locality-wise list of DOT Centres / DOT Providers in the area and should be updated regularly. The place identified for DOT (DOT Centre) and name and designation of the DOT provider should be entered in treatment card in the space provided.

If the patient is to be given DOT by a Peripheral Health Worker (PHW) / community DOT Provider, the MO of the PHI where the patient is prescribed treatment, will send a duplicate copy of the treatment card along with the patient's-wise box The PHW visits the house of the patient as soon as possible (in no case later than one week) for confirmation of the address. This opportunity is used for a detailed dialogue with the patient and other members of the family, emphasizing on points similar to the ones mentioned above (for the MO-PHI) and screening of contacts. The initial home visit should be recorded in treatment card in the space provided. A convenient location for drug administration and a suitable DOT provider is decided mutually by the PHW and the patient.

The Community DOT Provider will be provided with the duplicate TB treatment card along with sputum containers (for morning samples of follow-up sputum examinations) and PWB. If untrained, on the spot training has to be done for the community DOT provider regarding directly observed treatment, adverse reactions, follow-up sputum examination and recording drug intake. The DOT provider should also be trained to give health education and motivation messages to the patient. The PHW is responsible for supervising and ensuring DOT and updating of the original card at the PHI on a fortnightly basis.

In case the patient misses any dose, PHW would have to take retrieval actions in case the community DOT Provider fails to retrieve the patient. If the DOT Provider is

unsuccessful in retrieving such patients, it should be reported to next level of supervisors (e.g. MPW, MO-PHI, STS, MO-TC etc.). If the patient misses DOT on two occasions in the intensive phase, DOT Provider should arrange a visit by the MO-PHI to the patient's home, so that the MO-PHI can review the reasons for the same, give intensive counseling to the patient and, if required, ensure that DOT is made more convenient for the patient.

The MO of the PHI (where treatment card was initiated) and the STS should also supervise DOT on a regular basis and support the PHW in patient retrieval. DTO and MO-TC should support them in their efforts through field-visits.

The DOT provider records the days the drugs are administered in the Tuberculosis Treatment Card at the time of drug intake, and refer the patient to the Designated Microscopy Centre (DMC) when follow-up sputum examinations are due. DOT provider also enquires about drug reactions and, if necessary, refers the patient to the MO.

Monitoring of patients

Sputum smear microscopy is much more informative than radiology in monitoring the progress of chemotherapy. Hence, the patient should be referred for follow-up sputum examinations at the prescribed intervals. Other investigations like ESR, antibody detection etc. are unreliable and have no role in diagnosing and / or evaluating the progress or results of treatment.

Follow up Smear examination

Follow-up of the patients is done as detailed below:

New smear-positive patients

Two smears are examined each time during follow-up. The first follow- up sputum examination is done at the end of 2 months of intensive phase. On the 22nd dose in intensive phase, the patient is given a sputum container and instructed to bring the early morning sample. The patient brings the sputum sample when he comes for the 23rd dose in the intensive phase when a spot sample is also collected. The results of both the smear examinations will be available at the next visit of the patient. If both smears are negative, the patient will be put on the continuation phase. If either of the smears is positive, the intensive phase will be extended by one more month, and sputum examination will be repeated at the end of the third month. Thereafter, the patient is put on the continuation phase regardless of his/her sputum status at the end of the extended intensive phase. Subsequent follow-up smear examinations are done after 2 months into continuation phase and if found positive the patient is declared as a treatment failure, re-registered and started on the re-treatment regimen afresh. If the follow-up sputum is negative, the continuation phase is completed and smear examination repeated at the end of treatment. The sputum should generally be collected at the time of collection of the 16^{th} blister so that the results are available at the time of

supply of the last week's blister pack. Results of end of treatment sputum should be available not later than one week of completion of treatment.

Re-treatment patients

The first sputum smear examination is done at 3 months after beginning of the intensive phase. On the 34th dose of the intensive phase the patient is given a sputum container and instructed to bring the early morning sample .The patient brings the sputum sample when he comes for 35th dose in the intensive phase when a spot sample is also collected. The results of both the smear examinations will be available at the next visit of the patient. If both smears are negative, the patient will be put on the continuation phase. If either of the samples is positive, the intensive phase of treatment will be extended by one more month, and another smear examination will be done at the end of the fourth month of treatment. Thereafter, the patient is put on the continuation phase regardless of his sputum status at the end of 4 months of the intensive phase. Subsequent follow-up sputum examinations are done after 2 months into continuation phase. Irrespective of the results of the follow-up smear examinations, the patient continues and completes the treatment when a final follow-up sputum smear is done. The sputum should generally be collected at the time of collection of the 20th blister so that the results are available at the time of supply of the last week's blister pack.

Smear-negative patients

Two smears are examined during the follow-up visit at the end of 2 months of the intensive phase and again at the end of treatment. If the patient becomes sputum smear-positive at the end of IP or at the end of treatment, his outcome is 'failure' and is started on re-treatment Cat II regimen after registration.

Treatment outcome

The patient's treatment outcome is identified by reviewing her/his Tuberculosis Treatment Card. The treatment outcome and the date the patient stopped treatment is written in the appropriate column in the Tuberculosis treatment card. The date on which the patient stopped treatment is the date of the last dose of drugs taken.

The duplicate TB Treatment card and the used / partially used PWB of the patient should be immediately returned by the PHW to the PHI. The MO of the PHI should record the treatment outcome in the treatment card and sign it. The treatment card of the patients whose outcome has been declared and partially used PWBs, if any, should be handed over to the STS during his routine monthly visits.

It is the responsibility of the STS to ensure that

- The Tuberculosis Treatment Cards reach the TB Unit from the treatment centres as soon as the treatment outcome is recorded and within a maximum of one month time.

- The treatment Outcome is recorded in the TB Register within one month of the completion of the treatment in case of cured and treatment completed cases. Similarly the outcomes of patients declared defaulted or died should be recorded within one month of the event.

- Partially used PWBs if any, is returned to the DTC for reconstitution.

Every patient started on treatment has to be given one and only one treatment outcome.

Patients whose outcome is identified as failure should be started on Cat II treatment afresh.

Determination of treatment outcomes

If the patient	Then the treatment outcome is identified as
Was registered as pulmonary smear-positive, completed treatment and had negative smear results on 2 occasions, one of which is at end of treatment	Cured
Was registered as pulmonary smear-positive, completed treatment with negative smears at the end of the intensive phase but none at end of treatment	Treatment completed
Was registered as pulmonary smear-negative or extra-pulmonary, and completed treatment	
Was known to have died from any cause whatsoever while on treatment	Died
Was registered as pulmonary smear-positive CAT I, and was smear-positive at 5 months or later*	Failure
Was registered as pulmonary smear-positive CAT II (retreatment), and was smear-positive at five months or later of CAT II treatment	
Was registered as pulmonary smear-negative or extra-pulmonary on CAT III, but was smear positive any time during treatment*	
Has not taken drugs for more than 2 months consecutively any time after starting treatment	Defaulted
Was transferred to another TU/district and his/her treatment outcome is not available	Transferred out

**Also, re-registered immediately as Category II and started on the re-treatment regimen*

MANAGEMENT OF PEDIATRIC TUBERCULOSIS UNDER RNTCP 5

Introduction

Childhood TB is a reflection of the prevalence of sputum smear-positive pulmonary tuberculosis (PTB) and the extent of transmission of TB infection in the community. Children are likely to suffer from more serious forms of TB and are more likely to die if not treated properly. Reliable data on disease incidence and prevalence is however not available due to the difficulties in diagnosis of pediatric TB under field conditions.

Diagnosis

TB should be suspected among children presenting with fever and / or cough for more than 3 weeks, with or without weight loss or no weight gain; and history of contact with a suspected or diagnosed case of active TB disease within the last 2 years. Diagnosis should be based on a combination of clinical presentation, sputum examination wherever possible, Chest X ray (PA view), Mantoux test (1 TU PPD RT23 with Tween 80, positive if induration >10mm after 48-72 hours) and history of contact. Diagnosis should be made by a Medical Officer and the existing RNTCP case definitions be used for all cases diagnosed. PPD would be supplied by CTD to district headquarters. See Algorithm 1 (Annex 5A, page 140) for the diagnosis of pediatric TB.

Children showing neurological symptoms like irritability, refusal to feed, headache, vomiting or altered sensorium may be suspected to have TB meningitis.

Use of currently available scoring systems is not recommended for the diagnosis of TB among children. Where diagnostic difficulties are faced, the child should be referred to a pediatrician for further management.

Treatment of Pediatric TB

DOTS is the recommended strategy for treatment of TB and all pediatric TB patients should be registered under RNTCP. Intermittent short course chemotherapy given under direct observation should be used in children, as in adults.

RNTCP treatment categories and regimens for children

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

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

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

*** *Prefix indicates month and subscript indicates thrice weekly.*

In patients with TBM on Category I treatment, the four drugs used during the intensive phase should be HRZS (instead of HRZE) due to poor penetration of blood brain barrier by ethambutol. In TBM and spinal TB with neurological complications continuation phase of treatment should be given for 6 - 7 months, thus extending the total duration of treatment to 8 - 9 months.

Steroids should be used initially in hospitalised cases of TBM and TB pericarditis and reduced gradually over 6 - 8 weeks.

In all instances, before starting a child on Category II treatment, s/he should be examined by a Pediatrician or TB expert, wherever available.

As recommended by WHO, and in view of the growing evidence that the use of Ethambutol in young children is safe, Ethambutol is to be used as per RNTCP regimen for all age groups.

To assist in calculating required dosages and administration of anti-TB drugs for children, the medication would be made available in the form of patient wise-boxes, linked to weight bands. The recommended dosages for thrice weekly regimen in

children are as follows: Isoniazid 10-15mg/kg; Rifampicin 10mg/kg; Pyrazinamide 30-35mg/kg; Ethmabutol 30mg/kg and Streptomycin 15mg/kg.

For monitoring treatment, follow-up sputum examinations are to be performed with the same frequency as in adults. Clinical or symptomatic improvement is to be assessed at the end of the intensive phase of treatment and at the end of treatment. Improvement should be judged by absence of fever or cough, a decrease in the size of lymph node(s), weight gain, etc. Radiological improvement is to be assessed by Chest X-ray examination in all smear-negative pulmonary TB cases at the end of treatment. (Algorithm 2, Annex 5B, page 141).

Chemoprophylaxis

Recent infection with tubercle bacilli is one of the risk factors for disease development. The younger the child, the higher is the risk of breakdown of infection into disease. Therefore, household contacts of smear-positive TB cases, especially those below 6 years of age, must be screened for symptoms of tuberculosis. In case of symptoms being present, the diagnostic algorithm for pediatric TB should be followed and the child should be given a full course of anti TB treatment if s/he is diagnosed as a TB case. For asymptomatic children under 6 years, chemoprophylaxis with isoniazid (5 mg per kg body wt) should be administered daily for a period of six months. This is regardless of the BCG vaccination status.

Role of BCG Vaccination

Effective treatment of infectious patients under DOTS protects children against all forms of TB. The most effective way to prevent TB is to ensure that sputum smear positive patients are cured. To protect contacts of smear positive cases should be screened and managed as described above.

BCG vaccine is an attenuated strain of tubercle bacilli. After in depth reviews, it was concluded that though BCG may not protect against TB of lung which occurs mostly in adults, it could provide substantial protection against childhood forms of TB such as tubercular meningitis, miliary TB. In India, it is recommended to give BCG vaccination to all children preferably at birth as part of National Immunization Schedule to give the benefit of protection against the childhood forms of TB (refer to National Immunization Schedule, Govt. of India).

MANAGEMENT OF EXTRA-PULMONARY TUBERCULOSIS 6

Extra-pulmonary TB (EPTB) comprises about 10% to 15% of all new TB cases in our country. Among them, 75% have lymph node or pleural TB.

A person with extra-pulmonary TB may have symptoms related to the organs affected, such as, swelling of lymph nodes, occasionally with discharge of pus; pain and swelling of the joints; headache, fever, stiffness of the neck and mental confusion when the brain or meninges are involved. In addition, the following general symptoms like weight loss, fever, particularly with rise of temperature in the evening and night sweats may be present.

Patients with suspected EPTB should be referred to a competent medical practitioner for expert opinion. Diagnosis of such patients may be made by using appropriate diagnostic procedures (such as FNAC/Biopsy/culture from the site of disease) as well as clinical methods. Patients with EPTB who also have cough of any duration, should have 3 sputum samples examined. If the smear result is positive, the patient is classified as pulmonary TB.

Intermittent short course chemotherapy regimens of 6-9 months are recommended internationally for all forms of extra-pulmonary TB. In cases of TBM, initial hospitalization is recommended. In TBM, ethambutol should be replaced by streptomycin in the intensive phase and continuation phase of the treatment is for 6-7 months. Adjunctive steroids may be useful in pericardial and meningeal TB.

Management of TB lymphadenitis

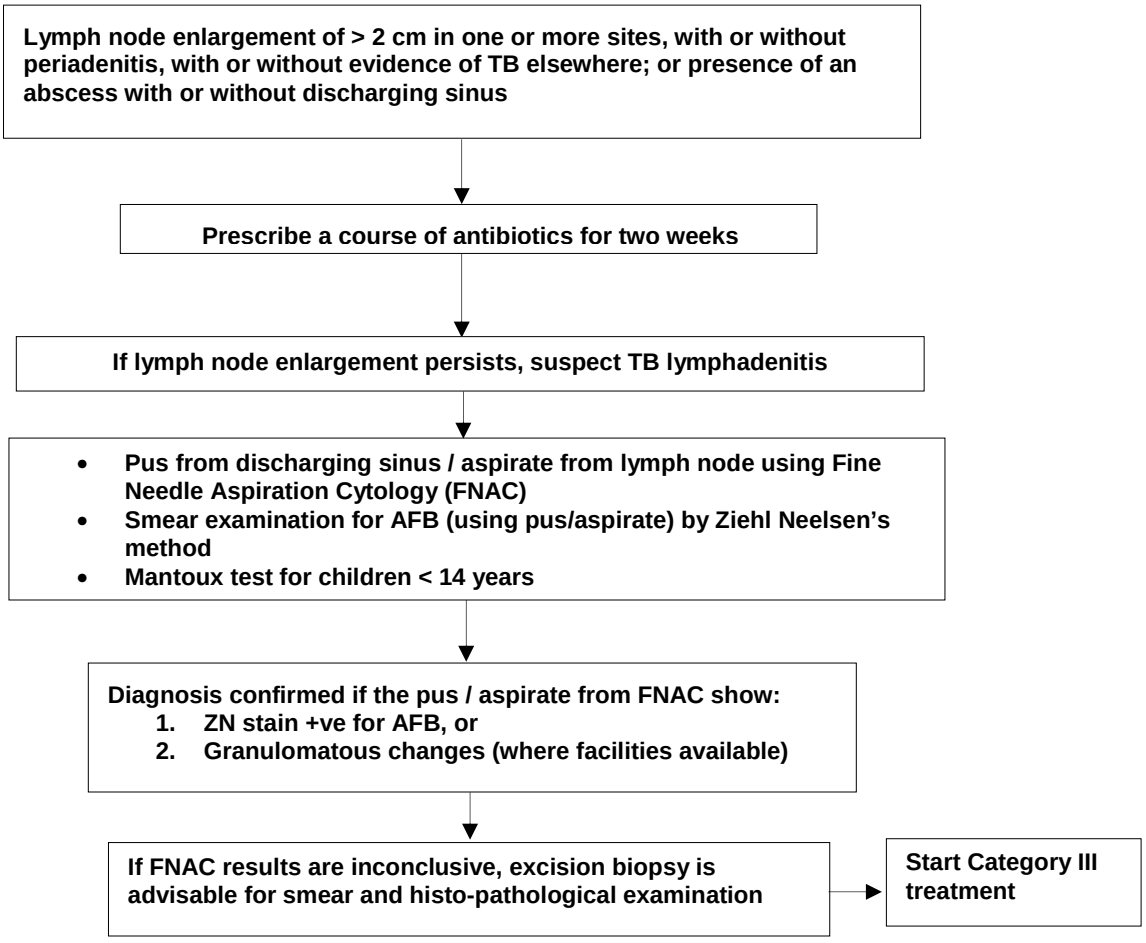
Lymph node TB usually presents as slowly progressive, painless enlargement of the lymph nodes of neck, sometimes of axilla or groin. **Cervical lymph node TB is the most common manifestation of extra-pulmonary form of TB**. Lymph node involvement of more than one group is common. Individual nodes are firm and discrete though matting of nodes may occur and may progress to abscess and sinus formation if left untreated. Tubercular abscess is also called “cold abscess” since inflammation is uncommon. In addition, constitutional symptoms like fever, malaise, weight loss, anorexia, etc. may be present but not invariably. This form of TB is more common in children and adults who are less than 30 years of age.

Diagnosis based on clinical findings alone can lead to over-diagnosis in a high proportion of cases. Therefore, attempt should always be made to confirm diagnosis by undertaking fine needle aspiration cytology (FNAC). This procedure can be undertaken wherever facilities are available. Refer to the diagnostic algorithm on the next page for details. In addition, sometimes chest radiograph may reveal mediastinal widening suggestive of hilar adenitis.

Intermittent 6-month short course chemotherapy regimen has been proven to be very effective in the treatment of superficial TB lymphadenitis.

Paradoxical reactions in the form of persistence or enlargement of existing nodes or appearance of new nodes may occur in about one fourth of cases during treatment as well as after completing treatment, and sometimes even a few months later. These reactions do not indicate treatment failure and probably represent an immune response to the release of mycobacterial products caused by the rapid bactericidal activity of the drug regimens. Therefore, extension or modification of treatment is not warranted as they usually regress spontaneously. Residual lymphadenopathy, after treatment completion has also been reported in about one third of patients. Studies have shown that re-treatment is required only if residual lymph node biopsy is bacteriologically confirmed as positive by culture for Mycobacterium tuberculosis. As culture facilities are not available everywhere, FNAC may be resorted to. However the granulomatous changes may persist for a long time even after adequate treatment. Hence the decision to start re-treatment can not be based on histo-pathological proof alone. The relapse rates after SCC are reported to be quite low.

Diagnostic algorithm for TB lymphadenitis



Management of Pleural TB

Patients presenting with chest pain with or without difficulty in breathing for more than two weeks should be referred for chest radiograph. Constitutional symptoms like fever, anorexia, loss of appetite may be present but not invariably. If chest X-ray is suggestive of pleural effusion, pleural aspiration should be performed for biochemical, cytological and smear examination by Z-N stain for confirmation of diagnosis. Where available, pleural biopsy may be performed.

Patients with unilateral pleural effusion are treated with Category III regimen. Bilateral or extensive effusions are classified as seriously ill forms of extra-pulmonary TB and treated with Category I regimen.

MANAGEMENT OF PATIENTS WITH HIV INFECTION AND TUBERCULOSIS 7

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

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

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

DOTS in TB-HIV

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

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

Anti tuberculosis therapy and antiretroviral therapy (ART)

The antiretroviral drugs, which are used in HIV-positive patients, are effective in slowing down the progress of HIV disease and prolonging life. These drugs are grouped as nucleoside reverse transcriptase inhibitors (NsRTI), non-nucleoside reverse transcriptase inhibitors (NNRTI), nucleotide reverse transcriptase inhibitors (NRTI), protease inhibitors (PI) and fusion inhibitors. The current recommendations on ART are

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

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

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

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

Operationalisation of VCTC-RNTCP Cross-Referral Linkages

Service linkages between VCTC and RNTCP diagnostic and treatment centres are the most important area of co-ordination between the HIV/AIDS and TB Control programme. RNTCP visualizes VCTC as a PHI referring TB suspects irrespective of their sero-status. VCTC's will identify and refer suspected TB cases to the RNTCP Designated Microscopy Centres. TB patients who have other HIV-associated opportunistic infections, or report risk behaviour for HIV, would be offered referral to VCTC for counselling and diagnosis of HIV infection.

Steps for operationalization

- Ensure that the VCTC, DMC and DOT centre are in the same campus so that referral linkages are easily established. In case they are not in the same campus, efforts should be made to establish effective referral linkages between them.

- Ensure that all the VCTC and RNTCP staff are trained in TB/HIV.

- Provide VCTC with RNTCP Laboratory Forms for sputum examination to refer patients to DMCs.
- Provide VCTC with a list of DMCs and DOT centres in the district/state.
- Ensure IEC materials on TB are displayed and available at the VCTCs. IEC material on HIV provided by State AIDS Control Society (SACS) would be displayed at all RNTCP sites.
- Confidentiality of HIV status must be ensured at all levels by all staff. Remember that the HIV status of a patient should not be mentioned in the Treatment card, TB Laboratory Register or any other document. Do not use any symbols/codes for identification of HIV positive persons
- The VCTC Counsellors are to visit the DMCs, and the STSs are to visit the VCTCs to follow-up on referred cases.
- Monthly RNTCP Review meetings are to be attended by the VCTC staff. During this meeting information on cross referral and feedback on the utilization of the services, would be shared.
- State TB Officer, State VCTC Programme Officer, District TB Officer and District Nodal Officers (HIV/AIDS) to review TB/HIV co-ordination activities during their periodic field visits.

For details, refer to guidelines on HIV/TB coordination.

Referral of persons from VCTC to RNTCP

At VCTC

VCTC Counsellors will identify persons with symptoms suggestive of TB disease amongst the clients. The Counsellor will ask each and every client for history of cough for more than three weeks and other associated symptoms of TB. Patients, irrespective of their sero-status, having cough will be referred to a DMC for sputum examinations and in case of symptoms of extrapulmonary TB, the patient should be referred to a competent medical practitioner for expert opinion. The RNTCP sputum examination form will be filled in by the Counsellor. On the sputum examination form, the Counsellor should fill in all the required details including the name of VCTC, and take special care in obtaining and recording correct residential address of the patient. The counsellor will not mention the HIV status of patient on the form or elsewhere, but shall encourage the patient to disclose his HIV status (if known) to the treating physician, in the interest of better case management. The sputum examination form is given to the patient with specific instructions on the location and timings of the DMC. The Counsellor should make a detailed note of the referral in the Counselling Register.

The counsellor should impart information / counselling on TB to all VCTC clients and should document the same in the counselling register, irrespective of whether they have signs or symptoms of TB or not.

At Designated Microscopy Centre

Once the patient reaches the DMC, the same process would be followed as for any other TB suspect, i.e. the diagnostic algorithm of RNTCP would be followed. The Laboratory Technician would enter the details of the patient, including correct residential address and clearly mention the name of VCTC as the referring unit in TB laboratory register. After all the three sputum examinations are done, the results of the test are given to the patient. Patient would then go to the Medical Officer for further management.

In case of Extrapulmonary TB, the VCTC would refer the patient to the Medical Officer for necessary investigations. After obtaining the test results, the Medical Officer would decide further course of management.

If the patient has TB (Pulmonary or Extrapulmonary TB), treatment categorization is done as per the RNTCP treatment algorithm. Voluntary disclosure of the HIV status by the client should be encouraged. All new TB cases with known HIV positive status, would receive RNTCP Category I regimen and retreatment TB cases will receive Category II regimen. Based on patient's area of residence, these patients are referred for treatment to the nearest DOT centre.

Referral of TB patients to VCTC for HIV-Testing

TB patients who have signs / symptoms of other HIV-associated opportunistic infections, or report risk behaviour for HIV would be offered referral by the medical officer to the VCTC. Thus, these diagnosed TB patients may be referred from DMC, DOT Centre, Out-patient clinics, TB ward, TB Clinic etc. Sometimes the patient may simultaneously be investigated for TB and HIV. The doctor should first complete the investigations for TB and then refer for HIV investigations. While referring to the VCTC, the doctor should write a referral note to VCTC in which the TB status of the person is mentioned. The referral of the TB patients to the VCTC for eliciting the HIV status for the sake of categorisation should never be done.

Once the referred TB patient reaches VCTC, the same procedure will be followed as that for any other client attending VCTC. At the VCTC, the patient/client will undergo pre-test counselling. HIV testing is done after obtaining informed consent. The details of the patient/client will be entered into the PID register and Counselling Register. HIV testing is done and the test results are handed over by the Laboratory Technician to the Counsellor. The counsellor reveals the HIV test result to the patient/client with post-test counselling. The HIV test results are not revealed to any other person other than the individual.

For Details of Operationalisation of VCTC-RNTCP cross-referrals linkages separate modules for TB/HIV compiled by the Central TB Division may be referred.

RECORDING AND REPORTING 8

Maintenance of accurate records and registers of patients and programme activities; and reporting data to the state/central unit every quarter, is essential for proper monitoring and management of Revised National Tuberculosis Control Programme (RNTCP). RNTCP records and reports are standardized and provide the required information for managing the programme effectively.

The following standardized records and reports are used in the RNTCP:

Forms

- **Laboratory Form for Sputum Examination** – kept at all the PHIs. It is filled generally by the MO of the referring health facility. Only one form is filled for each patient. Patient will report to the DMC along with the laboratory form. In case PHI is a sputum collection centre, sputum samples are sent to the DMC along with the laboratory form. It is essential to indicate in the laboratory form whether the sputum has been sent for diagnosis or follow-up. In the former case, the patient's detailed address should be given so that if the patient does not return to the health institution and the sputum is found to be smear-positive, the patient can be traced. The Tuberculosis No. of all patients whose sputum is being examined for follow-up must be written in the space provided. (Laboratory form at Annex 3A, page 101)

- **Tuberculosis Treatment Card** is filled at the PHI when patient is initiated on treatment. This card contains important information about a patient, such as: Name, age, sex and address of the patient; Type of disease; history of past anti-TB treatment; 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; Treatment outcome of the patient; Retrieval actions for missing doses; Preventive treatment for children; details of X-ray or other tests for diagnosis of EP TB; and Remarks. It also has information on the DOT provider, person conducting the initial home visit and the signature of the MO.

  It is kept at the peripheral health institution where the patient receives treatment (either at the district hospital, CHC, PHC, Health post, etc). For the patients who do not come to these health institutions and have to be given treatment at the sub-centre or village level by the multi-purpose worker/ anganwadi worker/ ASHA/ community DOT provider, a duplicate card is made and given to the above health functionary who is directly supervising drug administration of the patient. Information regarding administration of drugs during the treatment will be entered on this card and in case a duplicate is used for this purpose, the information is transferred on to the main card kept at the health institution by the most peripheral health functionary/community volunteer, on a fortnightly basis. The STS transfers the

relevant data, particularly the results of bacteriological examinations, from the treatment card to the Tuberculosis Register kept at the sub-district (TU) level. Once the patient completes treatment or if s/he dies, defaults or is transferred, it should be ensured that all the information has been entered in the original card which is retained at the Peripheral Health Institution. (Treatment Card at Annex 3E, page 105).

- **Patient's TB 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 identity card. The front part of the ID card has patient information, name and address of the TU/ district and treatment details of patient including disease classification, type of patient, sputum results, category and information on the date of starting treatment. The back portion of the ID card has the results of follow-up sputum examination, appointment dates for visits for drug administration and treatment outcome. This information will help to continue treatment in case the patient is transferred, or admitted to any other health facility anytime during the treatment period. (Patient TB identity card at Annex 3F, page 107)

- **Referral form for treatment** – kept at all DMCs. Medical officer of the Designated Microscopy Centers which refer patients for treatment to other peripheral health institutions needs to fills in the top half of the form which includes the patient characteristics. Once the patient arrives, the receiving unit fills in the bottom half of the form, and sends it back to the referring unit. Information regarding referral of patient should also be noted in the Referral for treatment Register or in the remarks column of the TB Laboratory register (Referral form at Annex 3B, page 102)

- **Transfer Form** kept at all the PHIs administering treatment for TB. This form is to be used when transferring registered patients on treatment from one reporting unit to another. If a patient is being 'Transferred Out', a Tuberculosis Transfer Form and a copy of the Tuberculosis Treatment Card will be sent from the "transferring unit", i.e., referring health facility / TU to the "receiving unit", i.e., health facility/ TU where the patient will receive further treatment. This form has four parts and should be filled up in triplicate. The first part of the form contains information about the patient, her/his disease, treatment details and address of the transferring unit. This information should be used to complete a new Tuberculosis Treatment Card for the patient, who would be reregistered as a "transfer in" case in the receiving unit. When the patient has reported to the receiving unit, the bottom (fourth) part of the form is completed by the receiving unit and returned to the transferring unit. The third and second parts are to communicate patients' sputum results at the end of intensive phase and treatment outcome respectively to the transferring unit (Transfer form at Annex 3C, page 103).

- **Mycobacteriology culture /sensitivity test form** Request for culture/sensitivity tests would be sent to the reference laboratory by the District TB Officer along with the patient or patient's sputum samples in case of failure to respond to directly observed Category II treatment regimen. (Culture sensitivity form at Annex 3D, page 104).

Registers

- **Tuberculosis Laboratory Register** is kept at all designated TB microscopy centres. The Tuberculosis Laboratory Register is used to record the results of sputum smear examinations. The LT assigns a Laboratory Serial Number for each patient who has been referred to the Laboratory for sputum microscopy. The following information about the patient are recorded: Date of sputum smear examination; Full name; Sex, Age, Name of the health facility that requested the examination (e.g. primary health centre, medical college, private practitioner, NGO, etc.); Complete address; Reason for examination (diagnosis and follow-up); and the Results of sputum smear examinations. The last two columns of the register are for the LTs signature and any remarks the LT or supervisor wishes to make. The remarks column is also used by the STS, enters TB No. and category of treatment from the TB Register. The remarks column can also mention in brief the action taken for patients belonging to other TU/districts, e.g., "Referred for treatment to…" The laboratory technician should summarize the information on sputum smear examinations done during that month. This information should be summarized in the format at the end of each month, printed in the Laboratory Register itself. The STLS should write their monthly supervisory abstract after the last entry of the month. Patients from the following month should be started from the next new page. (Laboratory register at Annex 3H and Laboratory Monthly Abstract at Annex 3-I, page 109-110)

- **Tuberculosis Register** is kept at the Tuberculosis Unit which is at sub-district level and contains information on all TB patients registered in the area. The Tuberculosis Register is used to record the following information about the patient: Tuberculosis Number (TB No.); Date of registration; Name (in full), address, age/sex; Name of PHI; Date of starting treatment; Regimen/Category; Disease classification; Type of patient; Details of sputum examinations; Treatment outcome with date; Remarks; and Summary at the bottom of the page The tuberculosis register is maintained by the STS (Senior Treatment Supervisor) at the TU (Tuberculosis Unit) level. All TB patients, who are put on DOTS and non-DOTS, must be registered in the Tuberculosis Register so that all the patients in the unit are monitored. The STS should register the patients as early as possible, and in no case more than a month after starting treatment. The TB register should be updated by the STS during the supervisory visits to the PHI. The initial and subsequent information required for registration and updating of the Tuberculosis Register is obtained from the Tuberculosis Treatment Card. Information from the TB register is used to compile the quarterly reports. (Tuberculosis Register at Annex 3K, page 112).

- **PHI level Supervisory Register** This is maintained at each PHI. All supervisors (STO, CDHO, District TB Officer, MOTC, STS, STLS, etc) should summarize their observations in the Supervision register. The 'Summary of observations and Recommendations of visit' is filled in triplicate. A copy of the summary is detached for future record of the supervisor, a copy is sent to the next higher level officer, and the third copy is left in the register, which should be reviewed during all subsequent supervisory visits to ascertain whether corrective actions were taken by the concerned MO-PHI. (RNTCP Supervisory Register at Annex 3G, 108)

- **Referral for Treatment Register** should be maintained in all big hospitals and Medical colleges where large numbers of cases are expected to be diagnosed and referred for treatment to other reporting unit. The referring unit should receive feedbacks on patients referred to other TUs in the same district within 14 days and for patients referred outside the district/state within one month.(Referral for Treatment Register at Annex 3J, page 111).

- **Stock Register** is maintained at state/ district/ TU drug store. It is used for recording the information on stock of drugs and consumables received and issued by the health unit. The register also mentions the batch numbers and date of expiry of drugs and consumables. The reconstituted PWBs should be recorded in the DTC stock register as receipts. The format of the register can be referred to in the 'Standard Operating Procedures Manual for State Drug Stores'.

- **Reconstitution Register** is maintained at all the DTCs for recording the receipt of drugs of patients who have defaulted, died, failed treatment or transferred out. Such drug boxes are reconstituted and the details thereof are also recorded in the register. The format of the register can be referred to in the 'Standard Operating Procedures Manual for State Drug Stores'.

Reports

The quarterly reporting system used in RNTCP enables analysis of cohorts of patients. A cohort in this context is a group of patients who were registered for treatment in a specified area over a specified period of time. Under RNTCP, specified areas are TB Unit, district, state and country. The specified periods of time are four quarters of a year and one calendar year itself. A quarter is a three month period with the first quarter starting on 1st January of the year and one year is divided into four quarters (1st, 2nd, 3rd and 4th). This information helps national, state and district levels to assess the performance and monitor the implementation of the programme. Every patient initiated on RNTCP treatment is registered in the TB Register. The cohort based quarterly reports are initiated from the TU level. Using the information in the Tuberculosis Register, the Senior Tuberculosis Supervisor (STS), under the supervision of the Medical Officer-Tuberculosis Control (MO-TC), prepares Quarterly TU-level Reports. The MO-TC submits the report to the District Tuberculosis Officer (DTO), who, in turn, compiles the reports received from all Tuberculosis Units in the district and sends the

District-level Reports to the State Tuberculosis Officer (STO) and the Central TB Division electronically. Computers with internet facilities have been provided at all District TB Centers in the country for electronic transmission of reports.

At the state, district and TU -levels, following reports are used:

Quarterly Report on New and Re-treatment case of tuberculosis includes the number of tuberculosis cases diagnosed and registered under DOTS regimens CAT I, II and III during a quarter. Every patient started on treatment and registered (except those typed as 'transfer in') must be included. The case-finding data provides details of the new sputum-positive (age and sex distribution), new sputum-negative, extra pulmonary and re-treatment cases registered during the quarter. It also includes information on patients belonging to the pediatric age group. (Annex 3M, page 116)

Quarterly Report on Sputum Conversion of new and re-treatment cases registered 4-6 months earlier This report gives the proportion of smear-positive cases of the cohort registered in the previous quarter who became smear-negative or are still positive at 2 and 3 months of treatment. Although sputum conversion rates are determined for all different types of smear positive patients (new smear positive, relapse, failure and treatment after default) the most important evaluation is that of new sputum smear positive patients. The sputum conversion rate is not only an indicator of the efficacy of the treatment regimen, but also of the effectiveness of programme implementation. (Annex 3 N, page 117).

Quarterly Report on results of Treatment of tuberculosis cases registered 13-15 months earlier This report shows the various treatment outcomes (cured, treatment completed, died, failure, defaulted and transferred out) of all cases registered during the corresponding quarter. (Annex 3-O, page 118)

Quarterly Report on Programme Management and logistics (TU/ District/ State) indicates the status of involvement of PHIs, staff position and training, supervisory activities, referral activities, microscopy, treatment initiation, quality of DOTS implementation, Laboratory quality control network (EQA), TB-HIV cross referrals, Medications, Consumables and equipment in place. The district level report has additional information on involvement of Medical colleges and other sectors, IEC and financial management in the District. In addition to the information stated above the State level report also collects information on District internal evaluations performed during the quarter, details of training held at STDC / state level; state level drug stock and the availability of drug susceptibility testing facility in the state. (Annex 3P, 3Q, 3R; pages 119-129).

At the PHI-level, the following report is generated:

Monthly PHI report on programme management, logistics and microscopy filled at all PHIs by the MO on the last working day of the month and sent to the CMO/CDHO

with a copy to the concerned TU, on or before 5th of the next month. This report contains information on drugs and consumables, staff position, referral activities, microscopy activities, treatment initiation and status of microscope. This report is to be complied after physical verification of the stock. It is the responsibility of the MO-TC and STS to ensure that all PHIs submit their monthly reports on time. The DTO should collect copies of this report from the office of CMO/CDHO for close monitoring of microscopy activities and logistics in the district on a monthly basis. The copies at the TU level shall be used for monitoring as well as preparation of quarterly reports. (Annex 3L, page 114)

SUPERVISION, MONITORING AND EVALUATION 9

A 'Supervision and Monitoring Strategy' with specific indicators to monitor and evaluate the programme at different levels with the objective to further improve the performance of RNTCP, is in place. The detailed strategy can be referred to in the 'Strategy document on Supervision and Monitoring'.

Effective supervision at all levels (Central, State, District, Sub-District, Designated Microscopy Centres and DOT Centres) is crucial to the successful implementation of the programme. RNTCP lays out clear responsibilities to the respective staff at each level in relation to supervisory activities.

Role of Central TB Division

- The role of the Central TB Division (CTD) includes supervision of the State level implementation and of the State TB Training and Demonstration Centre (STDC), monitoring and evaluation of overall performance of RNTCP throughout the country and regular reporting on RNTCP performance. Regular supervisory visits are also made to the States implementing RNTCP and to districts of "concern". The CTD provides overall oversight of RNTCP and its activities, and provides technical and policy guidance to the programme.

- At the State level, the STO, with the support of the Deputy STO and MO of State TB Cell (STC), is responsible for the planning, supervision, monitoring and evaluation of all TB control activities in the respective State. The STC / STDC staff together is expected to make supervisory visits to all the implementing districts every quarter. The state level programme review meetings should be held quarterly and chaired by the Secretary Health. The major points that require attention at the review meeting should be prepared by the STO prior to the meeting and provided to the Secretary in advance of the review meeting. STO is responsible for the submission of the consolidated state level RNTCP quarterly reports, which are sent to the CTD as per programme guidelines. The STO is also responsible for sending feedback to all districts on their quarterly reports within 30 days of the end of the quarter.

- At the district level, the District TB Officer (DTO), with the support of Medical Officer (MO) of the District TB Centre (DTC), is responsible for ensuring the quality of diagnosis, treatment, logistics and reporting in their respective district. DTOs should be full time for RNTCP activities. The DTO, along with the MO, are expected to undertake supervisory visits (3-5 days in a week i.e. 20 days in a month) to all the Tuberculosis Units (TUs) and any Medical Colleges in the district every month, and all the Designated Microscopy Centres, Community Health Centres (CHCs), Primary Health Centres (PHCs) and other hospitals in the district every quarter. One sub centre from each PHC, and a proportion of the tribal sub-centres, and participating NGOs and private practitioners, (PPs) should also be visited every quarter. They

should also visit atleast 3 randomly selected NSP cases and their DOT providers on every field visit day.

- The DTO will complete a tour diary containing all relevant findings of his/her supervisory visits. The DTO, and DTC MO if in place, will also write all relevant findings in the 'Summary of observations' sheet in the RNTCP supervisory register (Annexure 3 G, page 108) held at the relevant PHI/DMC. One copy of the summary of observations will be held by the DTO for his /her record and the second copy will be sent to the respective CMO.

- The DTOs will also review the monthly activity reports of all MO-TCs, STLSs and STSs within the respective district during the monthly district level meeting of said staff. The monthly PHI reports should be available at these meetings. Representatives of the other health institutions should also be called for this review. The date of the review should be fixed in advance. Minutes of these meetings should be kept by the DTO.

- The DTO is responsible for the consolidated district level RNTCP quarterly reports, which are sent to the State TB Cell (STC) and the Central TB Division (CTD) as per programme guidelines.

- The Chief Medical Officer (CMO) is also expected to review the programme on a regular basis. Guidance on programme review will be provided to the CMOs, and also to District Collectors.

- At the TU level, the Medical Officer-TB Control (MO-TC), Senior Treatment Supervisor (STS) and Senior TB Laboratory Supervisor (STLS), are responsible for undertaking supervisory visits to all the Peripheral Health Facilities, NGOs and PPs. The MO-TC is responsible for supervising the work of TU and of the STS and STLS, in addition to his/her other responsibilities. The MO-TC should reserve 7 days in a month for field visits and visit all DMCs every month, and visit most of the participating private as well as public PHIs every quarter.

- The STS is responsible for the quality of case detection and treatment activities being provided by all the health facilities, both in the public and private sector, NGOs, including PPs, Medical Colleges and community volunteers under the respective TU. He/she is expected to visit all CHCs and PHCs every month and sub-centres, NGOs/PPs and community workers every quarter.

- The STLS is responsible for the quality of sputum smear microscopy services provided by the Designated Microscopy Centres (DMCs) under the respective TU. He/she is expected to visit all the DMCs under the respective TU at least once a month. The STLS is also expected to do blinded rechecking of slides at the DTC as per the roster put up by the District TB Officer.

- The Supervisory Team at the TU (MO-TC, STS and STLS) are primarily responsible for the supervisory activities in their area of coverage. Though they may go individually for supervisory activity, some visits should be made as a team for better coordination. The DTO will also supervise the field units as per programme guidelines. During supervisory visits, one observes and reinforces stipulated practices in the various components of the RNTCP as well as identifies and corrects inadequate performance and recording discrepancies, if any, before these become a major problem. The focus of supervisory visits is on education, coordination, motivation, facilitation and guidance with the overall objective of implementing corrective action.

- A supervisory checklist and list of key indicators (refer 'Strategy document on supervision and monitoring') are to be used to identify the administrative and technical problems systematically. The indicators relevant to different levels of programme management are grouped to indicate

    - political and administrative commitment
    - human resource
    - diagnostic practices
    - drugs
    - DOT and follow-up services
    - recording and reporting
    - TB/HIV coordination
    - supervision
    - IEC, and
    - financial management.

Prioritization of health units to be supervised:

The important guiding criteria for prioritizing health units which are to be supervised are:

- Low proportion of patients receiving directly observed treatment as per guidelines
- High proportion of patients who were wrongly categorized
- Sputum conversion rate for new sputum smear positive patients at 3 months is less than 85%
- Cure rate for new sputum smear positive patients is less than 80%
- High proportion of sputum negative and extra-pulmonary cases

- Low case detection of new sputum smear positive cases
- High Default, Death or failure rate

By and large, the health units should be sent prior information of the supervisory visit. However, some surprise visits to the health units should also be undertaken.

Monitoring

The programme is monitored on a quarterly basis from reports which include the report on case finding, sputum conversion, treatment outcomes and programme management. The programme has also evolved an in-built monitoring system.

The quarterly reports are analyzed using the list of indicators at all levels, from the PHI, TU level, district, state to the centre. Detailed feedback on the performance of the districts is sent to the districts by the state at the end of every quarter in order to support the districts to improve performance. CTD gives additional feedback and helps in building the capacity of the state to monitor and evaluate the programme in their respective states.

Besides the routine monitoring of the quarterly performance reports, the programme undertakes specific measures to monitor the programme implementation in the districts. These initiatives include:

"Internal Evaluation" of the Programme:

Intensive supervision and monitoring at all levels is critical to the success of RNTCP. The state level "Internal Evaluation" is a tool for comprehensive review of the district programme, with the purpose of giving specific recommendations to improve the programme performance. "Internal Evaluations" of two districts per state per quarter are expected to be carried out in large states. During "Internal Evaluation" there is an objective assessment of programme services and activities. The objectives are:

- To validate the cure rates of the district for the last reported quarter
- To assess the programme performance as well as financial as well as logistics management
- To give recommendations for improving the quality of recording and reporting; and
- To give recommendations for improving the performance (with a timeframe)

"Central level Evaluation" of the districts

In addition to the state level driven internal evaluations, a centrally driven evaluation with the active participation of the respective states to carefully review the systems and programme implementation of poorly performing districts is undertaken. The purpose of the enhanced monitoring process is not only to improve the performances of the districts in question, but also to identify generic problems and find solutions which might be equally relevant to or applicable in other districts as well. This evaluation will also cover districts where excellent performance is being reported. This is in part to check the validity and correctness of the data and reporting, but also to find out best practices which could then also be implemented in other districts. These evaluations are not meant to be an exercise in criticism or praise, but as a strategic tool leading to the systematic and systemic improvement in the implementation and performance of RNTCP.

National Review of the Programme

Apart from the routine state level monthly review of RNTCP, a national review of the performance of the states is undertaken twice in a year. The national review helps to identify state level problems and suggest remedial measures or actions; deliberate on new initiatives and advocacy.

External Evaluation of the Programme

The programme also plans for periodic external assessment of the programme by International agencies and partners of the RNTCP, in order to enhance the quality of services provided under the programme.

Assessment of impact

The impact of the programme on the TB epidemiology in the community will determine whether TB will be controlled in India. Impact related to TB control activities however can only be seen after many years of activities. In addition, the outcomes seen can be the result not only of the programme activities, but also due to other factors such as improved socio-economic conditions, severity of the HIV epidemic, etc. The impact indicators should link directly with the Millenium Development Goal (MDG) targets and indicators (see box). Thus impact indicators, such as annual risk of TB infection and incidence rate, mortality rate due to TB, and levels of drug resistance etc are to be measured in the medium and long term timeframe.

Millennium Development Goals

Relevant to TB control are:

Goal 6 – to combat HIV/AIDS, malaria and other diseases

Target 8 – to have halted by 2015 and begun to reverse the incidence of malaria and other major diseases, including tuberculosis.

Indicators for Target 8 to be used to evaluate the implementation and impact of TB control:

Indicator 23: Between 1990 and 2015, to halve the prevalence and death rates associated with tuberculosis; and

Indicator 24: by 2005, to detect 70% of new smear positive TB cases arising annually, and to successfully treat 85% of these cases.

The RNTCP surveillance system collects routine information to measure treatment success and case detection. To evaluate the impact of RNTCP on the incidence of tuberculosis, Annual Rate of Tuberculosis Infection survey (ARTI) will be repeated every 3-5 years. The first such ARTI study was completed in 2003. State specific ARTI studies are also planned. Estimation of the prevalence and deaths due to tuberculosis in the country will be done directly through field surveys and indirectly by modeling exercises. Such estimations over a period of time will show the long term impact of the programme towards halting and reversing the incidence of TB by 2015.

TRAINING 10

RNTCP is implemented through the state health systems. The states contribute significantly to RNTCP in terms of human resources and man-hours. The Human Resource Development policy envisages having at all times adequate numbers of staff at different levels of the health system who have the skills, knowledge and attitude necessary to successfully implement and sustain TB control activities based on the DOTS strategy, including the implementation of new and revised strategies and tools. Development of standardized training material is the responsibility of Central TB Division. A wide range of standardized training material has been made available to the states by Central TB Division emphasizing the need for standardized training throughout the country. Continuous efforts are to be made to ensure good quality of training at all levels.

The states are expected to prepare projections of training requirement and make an annual training plan which would be sent to Central TB Division as part of the States' Annual Action Plan. The training plan takes into account the existing staffing in the state, existing training status and ongoing turnover of staff. The training plan endeavours to have in place maximum numbers of trained staff and plans to minimize delay in training of newly placed staff.

The training is undertaken at different levels. National and Central institutes like NTI Bangalore, TRC Chennai, LRS Institute Delhi, selected medical colleges as well other institutes of eminence undertake training for the State/Corporation level officers implementing RNTCP. Trainers from State TB Training and Demonstration Centres, teachers and researchers of the Medical Colleges and other institutes from all over the country are also trained at Central institutes.

It is planned to have three tiers of training which will address different needs of the staff providing RNTCP services:

1. Initial RNTCP training. This would include induction trainings for all new / replacement staff hitherto untrained in RNTCP. Standard modular training is imparted to all categories of staff responsible for programme implementation. It would also include the initial training of NGO personnel, private practitioners, medical college faculty & students and health staff of other sectors.
2. Re-training. These trainings would be mainly for individuals who have already received initial RNTCP training, but during supervision activities have been identified to have needs which require re-training on basic RNTCP activities. The re-training for the individual would be need based and hence staff may need re-training on the complete set of initial training modules, or only on sections related to specific activities.

3. Updates on new activities and initiatives. As RNTCP introduces new activities and initiatives, it is important that the field staff are updated accordingly. These updates could be given during regular programme review meetings such as the monthly district level meeting of the DTO, MO-TCs, STSs and STLSs, or the quarterly state level review meetings.

Standardized training modules for different categories of staff have been developed. The entire training process should be closely monitored by the STO/CMO/DTO/MO-TC, even if s/he is not directly responsible for each step. The state/district must develop a schedule/calendar for training, select course facilitators, conduct the training, supervise and evaluate the quality. The training should run at least 8 hours a day.

The details of duration of training, size of each batch and venues are as below.

Initial RNTCP training

Category	Duration (working days)	Batch size	Training Material	Venue
STO/STDC staff/District TB Officer/ TB-HIV co-ordinator	14	20	RNTCP MO Modules 1-9, STCS/ DTCS guidelines, Financial Management manual, Procurement + SDS Manual, Monitoring strategy	Central Institute
MO-TC/ Urban TB co-ordinator	12	20	RNTCP MO Modules 1-9	STDC
MO	5	20	RNTCP MO Modules 1-4	District
STS (2+6)	8	12	MPW Module, then STS Module	STDC
STLS (10+5)	15	6	LT Module, then STLS Module	STDC
LT	10	8	LT Module	District
State Drug Store Staff /Pharmacist in RNTCP	2	25	MPW Module/ Manual on Std. Operating Procedures for State Drug Store	District/TU
MPHS	3	25	MPW Module, sections of STS Module	District/TU
TB Health Visitor etc.	2	25	MPW Module	TU/PHI
MPW/HA etc.	2	25	MPW Module	TU/PHI
Anganwadi Worker/ Midwives/ Community Volunteers, etc.	2	25	DOT Provider Module	TU/PHI

Community based DOT providers	1	25	DOT Provider Module	TU/PHI
Private/NGO/ other sector Medical Practitioners (for PPM module)	6 hrs	20	Training Module for Medical Practitioners	DTC/IMA
TO / SA	6	12	STS Module	STDC/District
IEC Officer	6	Need based	IEC Module + MPW module	Central level
Data entry operator	2+2	12	MPW module, then Epicentre training	MPW module & Epicentre at state level
Accountants for district	1	Need based	Manual on Financial Management and Guidelines	State level
Accountant – state level	3	Need based	Financial Management manual, DTCS/ STCS guidelines	Central TB Division

Initial Training on EQA

Category	Duration (days)	Batch Size	Training Material	Venue
EQA (Master Trainers/ Microbiologist)	5	10	EQA Manual	Central Institute
EQA IRL LTs	5	6	EQA Manual	Central Institute
EQA STDC Dir/ STO	2	15	EQA Manual	Central Institute
EQA DTO/MOTC	2	25	Sections from EQA Manual	State Level
EQA STLS	2	6	Sections from EQA Manual	District Level
EQA LTs	1	25	Sections from EQA Manual	District Level

Initial training on TB/HIV

Category	Duration (days)	Batch Size	Training Material	Venue
TB-HIV Master Trainers	5	10	TB HIV Modules	Central
STO/ DTO/ MO-DT/ MOTC	2	10	Module for MOs on TB/HIV	State
MO	1	30	Module for MOs on TB/HIV	District
STS/STLS	2	10	Module for STS STLS on TB/HIV	District
DOT Provider	1	30	Module for Health Workers on TB/HIV	TU/PHI

Initial RNTCP training for Medical College staff

Category of staff to be trained	Type of training	Place of training	Trainers	Training material	Duration (in days)
Medical Staff					
STF Chairperson	Concise modular	National institute	Central institute staff	RNTCP –Key facts and concepts	1*
Faculty in charge of RNTCP	MO-TC modular	State-level	STC/STDC staff	1-9 modules	12
TOT's	MO-TC modular	National/ State-level	Central Institute/ STC/STDC staff	1-9 modules	12
HODs and Senior staff	Concise modular	State-level	STC/STDC staff	RNTCP –Key facts and concepts	1
Other faculty members (interested)	MO modules	Medical college	Faculty in charge of RNTCP	1-4 modules	5
PG students/ Residents/ Interns /UG's	Part of Curriculum + Sensitization	Medical College	Faculty in charge of RNTCP	Curriculum	2-3 hrs**
Paramedical staff					
Nurses	MPW training	Medical College	Faculty in charge of RNTCP	MPW module	2
Pharmacists	MPW training	Medical College	Faculty in charge of RNTCP	MPW module	2
Other paramedical staff	MPW training	Medical College	Faculty in charge of RNTCP	MPW module	2

* *5 days or 12 days modular training for those interested*

** *Consists of theory classes. Practical training will be imparted during posting to the Chest or Medicine Departments and the DOTS Cell.*

Retraining schedules

During field visits, supervisors should identify staff requiring retraining and the specific areas for the same. Duration of the training will depend on the contents of the training. The maximum duration of training for different categories of staff is listed in the table below:

Category	Maximum duration (days)	Venue
STO/STDC	5	Central Institute
DTO/ MO-TC	3	STDC
STS	2	STDC
STLS	3	STDC
LT	2	District
MO/TO/ SA/ IEC Officer	2	District
Pharmacist/ Staff Drug Management (State/ District/ TU)	1	District/TU
MPHS	1	District/TU
TB Health Visitor etc.	1	TU/PHI
MPW/HA etc.	1	TU/PHI
Anganwadi Worker/ Midwives/ Community Volunteers, etc	1	TU/PHI
Community based DOT providers	1	TU/PHI
Accountant	1	State/District
EQA (Master Trs./ Microbiologist)	2	Central Institute
EQA-IRL LT	2	Central Institute
EQA (STDC Dir/ STO)	1	Central Institute
EQA (DTO/MOTC)	1	STDC
EQA (STLS)	1	District
TB-HIV(DTO/ MOTC)	1	STDC
TB-HIV (MO)	1	District
TB-HIV (STS/STLS)	1	District

SPECIAL INITIATIVES 11

Public Private Mix (PPM)

India has the largest private sector in the world that manages a considerable proportion of tuberculosis cases. The few available studies of the health-seeking behavior of TB symptomatic individuals and patients have shown that more than 50% of patients first approach the private health sector.

Tuberculosis is encountered at all levels and by all types of health services ranging from primary health care services to the highly specialized hospitals in the different health care sectors. Traditionally, control of tuberculosis was considered a responsibility of the public health sector. As a consequence, tuberculosis control programmes were designed to be implemented through the available network of public health services. Over the years, the private sector has grown considerably in India. The private health sector in India varies considerably in its size, composition, and level of organization, types of services delivered and socio-economic groups served.

Public Private Mix (PPM) includes Public-public as well as Public-private collaborations. While involving the private sector and other sectors, it is important to have a well-functioning RNTCP in the public sector first. The involvement of other sectors is important to improve the case detection rates under DOTS and successfully treat additional numbers of TB patients. All RNTCP sites including other sectors will be under regular supervision and monitoring by the programme using the same yardsticks for quality assurance.

Other health providers involved in PPM

- Government health facilities outside state health departments
- Medical Colleges
- Private Providers
- Non-Government Organizations
- Corporate Sector

GOVERNMENT HEALTH FACILITIES OUTSIDE STATE HEALTH DEPARTMENTS

All health establishments under ESI, Railways, CGHS, Defence, Petroleum & Natural Gas, Chemical & Fertilizer, Coal, Steel, Mines, Power, Ports and Prisons come under this group. Most of these departments have been involved in the RNTCP at the central level. State/ districts have to ensure that these facilities at the local level are also involved. Directives from the various ministries / departments that control these

government health facilities have been made available to the District TB Officers so that they can facilitate the process.

Private Providers

Private Providers are very accessible to patients and can play a key role in TB control. They can be Private Practitioners (PPs) or Private Hospitals/ Nursing homes practicing modern medicine or other systems of medicine. The first contact of a large proportion of TB patients is a private practitioner. It has been acknowledged that involving private providers helps to improve both case detection and access to standard services under RNTCP. It is vital to have a regular and continuous interaction with the private health care providers to sustain their involvement. To achieve good treatment outcomes, Private Providers must follow standard RNTCP guidelines. A laboratory owned by a private provider could be considered to be designated as a microscopy centre only after it has fulfilled all criteria laid down under RNTCP.

The details of schemes are available in the document “Involvement of Private Practitioners in the RNTCP” published by Central TB Division.

Corporate Sector

Corporate sector includes registered for-profit companies, whether under government or private ownership. They are involved in managing TB in the workplace, either by referring suspects to the RNTCP or, where appropriate, implementing their own workplace programmes, especially as DOT centres or Designated Microscopy Centre-cum DOT centres.

Corporate sector may refer patients to the public sector Designated Microscopy Centre (DMC) / DOT centre, recognized private sector DMC/ DOT centre, or may run a DMC or DOT centre on its own following the policies and guidelines of RNTCP. RNTCP provides drugs, laboratory consumables, printed material and training to the key staff. A laboratory owned by a corporate sector entity could be designated as a microscopy centre only after it has fulfilled all criteria laid down under RNTCP.

Non-Governmental Organizations (NGOs)

For expanding the reach of RNTCP, the government of India has prepared policies, guidelines and schemes to involve the NGOs. Commodity assistance and Grant-in-aid are provided as per the scheme of involvement.

The details of schemes are available in the document “Involvement of Non-Governmental Organisations in the RNTCP” published by Central TB Division.

Medical Colleges

Involvement of medical colleges in the RNTCP is a high priority. Continuing success of RNTCP requires involvement of all large providers of health care including medical

colleges. Under RNTCP Medical Colleges play important roles in service delivery, advocacy, training and operational research.

A National Task Force (NTF) and five zonal task forces (ZTF) have been formed for their effective involvement in RNTCP. Within each zone, nominated medical colleges have been given the responsibility to function as nodal centres. All states which have medical colleges have formed State Task Forces (STF). In each medical college, there should be a Core Committee to arrange for training and oversee the functioning of RNTCP in their respective institutions.

The NTF comprises of representatives from 7 nodal medical colleges, CTD, TRC, NTI, LRS and WHO. It has a Chairman who is selected on rotational basis from amongst the 7 nodal medical colleges. DDG(TB) is the member-secretary of the NTF. The main task of NTF is to provide leadership and advocacy, coordination, undertake monitoring, lead operational research and support policy development on issues related to effective involvement of medical colleges in RNTCP.

The ZTF has a representative from the nodal centre as Chairman, member secretary is the STO of the State where nodal centre is located and the members include representatives of the State Task forces within the zone (1 medical college per State) and STOs of the States within the zone.

The STF has a representative from a medical college in the State as Chairman, member secretary is the STO of the State and the members include representatives of each of the Medical colleges of the State, on rotation basis if required.

A Medical College Core is formed in each Medical college including least 4 members, with representatives from department of medicine, chest medicine, microbiology and community medicine. Coordination of TB control activities is done by District TB Officer (DTO).

Functions of the NTF, ZTF, STF, Deans/Directors and medical college core committee are listed in Annex 2 (page 97).

Details of training for Medical College faculty and staff are given in the section on training (page 59).

Management of TB cases presenting to a hospital as Outdoor patients

RNTCP diagnostic algorithms are to be strictly adhered to by all attending physicians. Diagnosed TB patients should be referred to the local DOTS centre in the respective hospital / medical college. Patients coming from the district in which the hospital is situated should be started on DOTS therapy only after verification of their address. Wherever required RNTCP can provide medical colleges with additional human resource to implement and coordinate the activities with the TU/DTC. One Medical Officer, one STLS, one LT and one TB health visitor can be provided on contractual

basis through the District TB Control Society. Drugs, consumables, etc. will be provided by the District TB Officer.

If patient is required to be referred to another health facility for DOTS, the 'referral for treatment' mechanism is to be followed (refer to section on recording and reporting). The respective STS is responsible for tracking of these referral cases. Programme review meetings held in the district should be utilized to facilitate tracking and feedback of referred cases. The receiving treatment facility should honour diagnoses made at the medical college/hospital and must provide feedback to the referring unit.

Management of TB cases presenting to a hospital as Indoor patients

All indoor patients are to be treated with RNTCP regimens using prolongation pouches which will be supplied by DTO. The DOTS Centre of the respective Medical College must be informed of the patient's admission at the earliest, to enable transfer of the patient to their respective DOTS Centre on discharge. On discharge, patients may be given a maximum of three doses (1 week drug supply) to cover intervening period prior to their continuation of treatment at their respective DOTS Centre, hence ensuring no interruption in treatment.

All indoor patients treated under RNTCP, should be registered under the local TU where the medical College is located. The smear conversion and treatment outcome of all the transferred patients should be sent back to the TU of the medical college by the TU where the patient was transferred to.

Flow chart for management of outdoor patients and indoor patients in medical colleges and large hospitals is given in Annex 6A and Annex 6B (page 142-143).

Multi-Drug Resistant Tuberculosis and DOTS Plus

Multi-drug resistant TB (MDR-TB) is a specific form of drug resistant TB due to bacilli resistant to at least isoniazid and rifampicin, with or without resistance to other anti-TB drugs. The diagnosis of MDR-TB is a laboratory based diagnosis (from an RNTCP quality assured culture and drug susceptibility testing laboratory) and NOT a clinical diagnosis. Drug resistance arises due to improper use of anti-tuberculosis drugs during the treatment of tuberculosis patients. This improper use includes:

- Administration of inadequate treatment regimens by various health care providers
- Wrong treatment categorization due to failure to elicit the history of previous anti TB treatment by attending physician
- Poor treatment management, when the treatment is not directly observed
- Irregular and incomplete treatment due to lack of effective counseling of patients.

Regular chemotherapy under DOTS strategy can prevent the emergence of MDR-TB.

Extent of MDR TB in India

The prevalence of MDR-TB among new smear-positive cases is relatively low in the country. Studies carried out in six districts during 1999-2002 as per the WHO guidelines on drug resistance surveillance, showed that 0.5% to 3% of new cases and 12% of previously treated patients were found to harbor MDR TB bacilli.

Drug resistance surveillance

In order to monitor the level of drug resistance in the country, drug resistance surveillance (DRS) is being conducted among both new and previously treated cases in a phased manner in selected states. The national and state-level RNTCP culture and drug susceptibility testing laboratory network will undertake these DRS surveys. The RNTCP designated microscopy centres in each district are assigned the role of identification and enrolment of smear-positive cases for the DRS surveys. RNTCP accredited state level Intermediate Reference Laboratories perform the culture and drug susceptibility tests (DST), with the 3 National Reference Laboratories (LRS, NTI and TRC) providing technical support. TRC, which is also a WHO Supra-national Reference Laboratory, is responsible for overall quality assurance.

Prevention of MDR-TB

As the management of MDR-TB is very complex, its occurrence must be prevented by effective implementation of the DOTS strategy.

Proper categorization for treatment of patients by the attending medical officer, by eliciting any history of previous TB treatment, is very important. The diagnosed patients

should be explained why it is essential to know about previous anti-TB treatment, and subsequently the need for them to take their drugs under direct observation. DOT Providers should be supervised to ensure DOT provision is as per guidelines. DOTS has been documented to not only prevent the emergence of multi drug resistance but also to decrease its prevalence in the community.

Management of MDR-TB

Firstly it must be remembered that the most important cause of treatment failure is the inability to administer complete and regular treatment to a patient, and not due to drug resistant bacilli. However TB cases who continue to be smear-positive at the end of 4 months or later of an RNTCP Category II treatment may be suspected of having MDR-TB. Only these patients should have a sputum sample collected and sent for culture and DST to an RNTCP quality assured culture and DST laboratory. The STDCs/ IRLs are being strengthened to provide such facilities in each state. Diagnosed cases of MDR-TB should be referred to and treated only at a specialized centre. Treatment of MDR-TB requires prolonged chemotherapy (24 months), which is also very expensive and toxic. Moreover the chances of treatment success are moderate.

In 1998, WHO and several partners around the world conceived the DOTS-Plus strategy. DOTS-Plus works as a supplement to the standard DOTS strategy, and is a comprehensive management strategy to address both drug susceptible and MDR-TB, which includes sustained political commitment, diagnosis of MDR-TB through quality assured culture and DST, appropriate treatment strategies that utilize second line drugs under proper management conditions, uninterrupted supply of quality assured second line anti-TB drugs and a standardized DOTS Plus recording and reporting system. RNTCP plans to start treatment in 2006 of MDR-TB patients at selected DOTS Plus sites in the country. By 2010, there will be a network of RNTCP DOTS Plus sites throughout the country with the facilities to enroll on treatment at least 5000 MDR TB patients a year (refer to RNTCP DOTS Plus guidelines).

INFECTION CONTROL AND HOSPITAL WASTE MANAGEMENT 12

The Government of India under its Environment Protection Act (1986), passed the Biomedical Waste (Management and Handling) Rules in 1998 and a subsequent amendment followed in 2000. The rules form the legal framework for the collection, segregation, transportation, treatment and disposal of biomedical waste throughout the country. The State Pollution Control Boards (SPCBs) in the states and the Pollution Control Committees (PCCs) in the Union Territories, are monitoring the compliance to the rules in the respective states.

The RNTCP is integrated into the general health system of the states. Waste management is a component of overall facility management of the respective state health system institutions where RNTCP centres are located. Accordingly, **the waste generated by RNTCP should not be viewed in isolation, but is to be integrated in the broad framework of the peripheral institutions' waste management practices**. The peripheral health institutions would be responsible for disposal of the wastes and reporting to their respective PCBs.

Types of wastes generated by the RNTCP

- Human/biological waste (sputum);
- Sharp waste (needles, glass slides etc.);
- Used blister packs, drug packaging material;
- Plastic waste (waste generated from disposable syringes, cups and glasses
- Laboratory and general waste such as liquid waste, broomsticks, and paper waste
- Construction waste (waste generated from civil work activities).

Waste generated under RNTCP will be discarded with the overall waste of the health facility in which services under RNTCP are provided. The staff carrying out RNTCP activities like LTs and DOT providers in PHIs will adopt infection control techniques as detailed in these guidelines and will take action to integrate waste generated under RNTCP into the waste management activities of the concerned PHI. The activities by the PHIs will include organized waste collection, information dissemination, reporting and monitoring of disposal of the waste.

Disposal of sputum container with specimen and wooden sticks

Sputum containers procured under RNTCP should be made of non PVC plastic material (polypropylene wherever available).

Step 1: After the smears are examined, remove the lids from all the sputum cups.

Step 2: Put the sputum cups, left over specimen, lids and wooden sticks in the foot operated plastic bucket/bin with 5% phenol or phenolic compound diluted to 5%. The cups and lids should be fully immersed in the solution. Keep it overnight/ for at least 12 hours.

Step 3: Next day, after at least 12 hours of immersion, drain off the phenol solution into the drain.

Step 4: Take out the sputum cup/lid/wooden sticks and put into a reusable metal or autoclavable plastic container or red bag. The red bag should have a biohazard symbol and be of adequate strength in order to withstand the load of waste. It should be made of non-PVC plastic material.

Step 5: Put this container / bag into the autoclave with other autoclavable biomedical waste and autoclave at 121^0C under 15 psi pressure for 15 – 20 minutes. The autoclave shall comply with the standards stipulated in the rules. Under certain circumstances, if autoclaving is not possible, boil such waste in a pressure cooker of approximately 7litre capacity containing adequate amount of water to submerge the contents and boiled for at least 20 minutes using any heating source, electrical or non-electrical. However the District Hospital/CHC/PHC etc. shall ultimately be expected to make the necessary arrangements to impart autoclaving treatment on regular basis.

Step 6: After adequate cooling, the material can be safely transported to a common waste treatment facility for mutilation/shredding/disposal.

lf a common waste treatment facility (CWTF) is not available in the area, the sputum cups/lids/ wooden sticks after autoclaving, can be disposed in a deep burial pit

LTs and support staff handling biological waste should wear gloves (Universal Infection Control Precautions).

Refer to Bio-Medical Waste (Management and Handling) Rules and guidelines.

Disposal of used Syringes/needles/broken vials

Step 1: Immediately after administering the injection, cauterize the needle on site using a suitable needle destroyer / cutter, followed by cutting of the plastic hub of the syringe without detaching the needle from the syringe.

Step 2: Put the cauterized needles, broken vials and ampoules into a sturdy puncture proof white translucent plastic / cardboard container.

Step 3: Segregate and store cut plastic syringes in a reusable metal or autoclave-able plastic container / red bag. If a bag is used, its strength should be such that it can withstand the load of waste inside and be made of non-PVC plastic material.

Step 4: Label both the container with biohazard symbol as stipulated in the Schedule III of the Biomedical Waste (Management and Handling) Rules 1998.

Step 5: Put both the containers in the prescribed bag and transport in a dedicated vehicle to the Common Waste Treatment Facility for autoclaving, mutilation/shredding, and/or disposal.

Step 6: If a CWTF does not exist, put both sharp container (needles) and metal / plastic container / red bag (syringes) into an autoclave with other BMW, and autoclave at 121^0C under 15 psi pressure for 15- 20 minutes. Under certain circumstances if autoclaving is not possible, boil such waste in water for at least 20 minutes. However the District Hospital/CHC/PHC etc. should ultimately be expected to make the necessary arrangements to autoclave the waste on regular basis.

Step 7: Dispose off the autoclaved waste as follows:

- Dispose off the needles and broken vials into a sharps pit; and
- Send the syringes for shredding/mutilation or as a landfill in a deep burial pit.

Disposal of used slides

Step 1: Place the slides into a puncture proof container or red bag. The red bag should have a biohazard symbol and should be made of non-PVC plastic material. This bag/sharp container should then be put in to an autoclave or pressure cooker for autoclaving/boiling.

Step 4: Dispose of the slides into a pit for sharps

Under no circumstances should the slides be broken or recycled.

INFORMATION, EDUCATION AND COMMUNICATION 13

Information, Education, and Communication (IEC) is an important component of the RNTCP. IEC activities under the RNTCP aim to promote a better understanding of TB, especially its diagnosis, treatment and cure; improve the quality of care provided to TB patients; reduce stigma and improve utilization of RNTCP services.

IEC under RNTCP has the strategic frame work for communication that identifies the communication need (objectives), communication players/audience (target groups), and communication tools (channels, activities and materials).

Objectives of IEC under RNTCP:

1. *Awareness raising* for behaviour change to increase understanding about TB and the use of DOTS services among:
   - the public so that they make use of RNTCP services
   - health care providers so that they adopt DOTS strategy
2. *Advocacy* to create, facilitate, develop and forge political, administrative and community-level commitment to TB control in India.
3. *Patient - Provider communication and counseling* to help ensure patient compliance with the treatment regimen, to enhance the reputation of a patient-friendly service, and to encourage patients and their families to become advocates for the program.

Target Audience

The target audiences for IEC include

- Patients and community
- Health care providers- both private and public
- Opinion Leaders, that includes: Political leaders, State bureaucrats and administrators, PRIs, Mahila mandals, youth clubs, self help groups, Professional organizations, etc.

Communication channels, activities and materials

The core messages for the target groups are standardized at central level to ensure that the accuracy of messages is not compromised or diverted from the programme's objectives. The messages are tailor-made for each of the target audience. The centre provides general outline, and states can develop adaptation using local innovations to reach all possible groups through the appropriate channels, material and activities.

A mix of media options is used to enhance the reach and impact of health communication messages. The use of interpersonal channels, mass media, and non-electronic media and outdoor media is used to address the large gamut of target audience.

Interpersonal channels

The value of interpersonal communication has been recognized: satisfied cured patients are good advocates; interactive meetings are effective in addressing social issues and barriers.

Mass media

Mass media plays an important role in raising general awareness of TB, efficacy and free availability of DOTS, and advocate support to the program among influential groups and individuals by raising the profile of the program and increasing its visibility amongst opinion leaders. Mass media is important to get information disseminated far and wide.

Non- electronic and out door Media

Interpersonal approaches are complemented by the options for reaching people in groups or on a collective scale. These include local popular folk media, street plays, use of local bazaars, mike publicity, puppet shows, activities in schools, wall paintings, hoardings, exhibitions at melas etc.

Roles and responsibilities for IEC activities at the Centre, State and District

The Centre takes leadership; states & districts plan and implement IEC activities. Districts draw support from local organization, PRIs, NGOs, Self Help Groups (SHGs) and there is two way flow of information/ ideas from and to the centre and the state.

Role of Centre in IEC

The centre has an Advocacy and IEC unit that is assisted by IEC Advisory group, comprising of honorary members from the centers of excellence in the field of communication, research, media planning and teaching. The centre provides:

- Overall leadership for the IEC component
- Procure services of IEC agency and coordinate activities
- Manage the mass media component at national level
- Provide oversight of the national level IEC strategy, assessing capacity for IEC at state level, and providing support where necessary.

Role of the State in IEC

The overall responsibility of planning and implementing IEC activities rest with the State Tuberculosis Officer. The IEC Officer is the nodal person at the state level to assist STO for undertaking following activities:

- Planning of IEC activities for the state including the district level activities
- Support to districts for planning & implementing IEC activities
- Monitoring and supervision of IEC activities
- Mobilizing support/ resources for implementing IEC activities with the involvement of other state/district departments
- Developing material in local languages
- Organizing events for advocacy
- Capacity building of districts for implementing activities for awareness generation and social mobilization

The Communication Facilitator can be an individual, NGO or an agency to help and assist districts in planning and implementing IEC activities at the sub district level. One communicator facilitator is responsible for 5-6 districts. The responsibility for identifying and appointing communication facilitator is with the state. All district must be covered by the communication facilitator.

Role of District in IEC

The district is a link between the state and the primary health institutions in terms of training and dissemination of IEC activities. District is to develop IEC action plan (according to the needs, targets audiences and available communication channels) with the help of IEC Officer of the state and is assisted by communication facilitator for implementation of IEC activities. The district is responsible to:

- Develop plan for IEC activities with sufficient flexibility to allow for local initiatives and variations.
- Use local appropriate medium for dissemination of information.
- Seek involvement of local organizations, leaders, *panchayats,* and NGOs for IEC.
- Organize certain minimum number of activities, such as community meetings, mike publicity, display of posters at each PHI, interaction meetings, wall paintings, puppet shows/ street plays/nautakis/ nukkad nataks, etc.

Monitoring of IEC in RNTCP

Monitoring and supervision of IEC activities is an important aspect. States are responsible for overseeing district and sub district level IEC activities. Monitoring indicators for IEC activities have been included in the monitoring strategy for reporting on the activities conducted at the district level, as part of PMR report. Supervisory IEC checklist is used for overseeing that activities have been undertaken as planned.

ANNEX 1A

Functions of CTD

1. CTD provides strategic leadership, overall supervision and direction to the programme.
2. Priority activities of CTD is the planning and budgeting for TB control in India and of ensuring uninterrupted adequate funding for TB control activities.
3. Co-ordination of all the activities related to 'formulation of technical, operational, and financial policies at country level and dissemination of the policies formulated at the country level to all the states and districts and ensuring compliance
4. Undertake activities for national consensus building for TB control amongst academia, non-governmental and private sectors and civil society. Promote widespread acceptance of DOTS strategy in the country amongst medical community in all sectors.
5. CTD formulates training plans and materials for all categories of staff for use at state and district level on a periodic basis. Training material is updated at regular intervals. It also monitors the quality of training in the states by visits during the training.
6. Plan and conduct need based training at national level for various categories of staff.
7. Capacity building of the state and districts for effective implementation of the programme. Ensuring smooth implementation of the activities under programme in the districts through the dissemination of strict quality assurance protocols.
8. Monitoring and Evaluation of TB control activities in the country including newer initiatives like EAQ, DRS, TB/HIV co-ordination, PPM activities. CTD collates, analyzes and summarizes quarterly and annual cohort reports from the states and districts.
9. Planning and co-ordination of periodic external reviews of RNTCP with partner agencies.
10. Monitoring the financial management by TB Control/ equivalent Societies. It carries out all functions related to financial management like planning, budgeting, allocations to states, expenditure tracking, feedback to states, financial review of state and districts and reporting to concerned authorities and donors.
11. CTD shoulders the major responsibility of the procurement and distribution, of anti TB drugs, consultant services, goods and materials and supplies procured at the central level. Procurement and distribution of binocular microscopes, culture & drug sensitivity equipment etc are also done at the CTD level. It also co-ordinates the conducting of quality assurance testing of the drugs procured.

12. Conduct national level IEC and advocacy for promoting DOTS. Core messages for IEC are standardized at the national level. Advocacy material is prepared and disseminated to the states with the support of IEC agency. Plan IEC strategies, and supervise and monitor IEC activities of the states against the IEC action plans.
13. Strengthening of human resource, laboratory and operational research activities by involvement of Central Institutes and continuous co-ordination with these institutes for above activities.
14. Coordinate with multilateral and bilateral international organizations like CIDA, DFID, GDF, GFATM, USAID, World Bank, WHO, etc.
15. Coordinate with other ministries, other sectors including NGOs, associations of private health providers and corporate sectors etc. for their involvement in the programme
16. Promotion of operational research under programme and conducting nation wide surveys to monitor the epidemiological impact of the programme with the help of national research institutes.

All the above mentioned activities are facilitated and coordinated by the five units established at the Central TB Division which are as follows:

I. Supervision, monitoring and epidemiological surveillance unit;

II. Human resource development unit;

III. Procurement, supply and logistic unit;

IV. Finance unit; and

V. Advocacy and IEC unit.

These five units work in close co-ordination with each other, and are responsible for routine as well as any special tasks assigned to them and work under direct supervision of DDG(TB).

ANNEX 1B

Functions of the State TB Cell

1. Assess the status of the tuberculosis control services in the State. Determine the resource requirements of the State pertaining to different components of the programme on the basis of inputs from the districts and STDC.
2. Formulate, in conjunction with STDC, an annual action plan for implementation of the RNTCP in the districts.
3. Conduct and facilitate advocacy at the State, District and Local levels, both within and outside the health sector
4. Operationalize a planning and budgeting process that flows bottom-up, i.e. from DTCS or its equivalent to 'STDC-STCS or its equivalent' to CTD and a fund release process that flows top-down, i.e. from CTD to 'STCS or its equivalent-STDC' to DTCS or its equivalent.
5. Monitoring the financial management by District TB Control/ equivalent Societies. It carries out all functions related to financial management like planning, budgeting, allocations to states, expenditure tracking, feedback to districts, and financial review of districts and reporting to concerned authorities.
6. Strengthen supervision and monitoring by the STDC and DTCs in terms of technical performance and expenditure vis-à-vis activities planned and accomplished. Conduct regular supervisory visits to the districts, undertake internal evaluations of the districts and organize quarterly programme review in the state with District TB Officers as per the Supervision and Monitoring Strategy of RNTCP.
7. Play an active role in drug requisitioning, procurement of some items, storage and distribution, ensuring uninterrupted drug supply and virtually no expiry of drugs throughout the state, especially in those states were a State Drug Store has been established.
8. Facilitate quality control in the purchase of laboratory consumables by the districts.
9. Facilitate special plans for tribal and difficult areas (if any) in the State.
10. Promote participation of NGOs and private sector organizations at the State level and facilitate the same at the District level. Identify regional level NGOs and private sector organizations according to their capacity and range of services provided and promote their involvement in RNTCP.
11. Appoint State level contractual staff (MO, IEC Officer, Accountant, etc.), and identify/ engage communication facilitators at the sub-district level for IEC activities.

12. Ensure that the technical parameters of the RNTCP like case detection rate, cure rate, default rate, death rate, etc. are within the acceptable range, and when not within range, identify causes for this and take the necessary corrective action(s).
13. Collate and summarize quarterly reports at the state level and send the reports to CTD on a quarterly basis.
14. Oversee the functioning of the DTCS or its equivalent.
15. Oversee the quality control network for sputum microscopy. Ensure civil works of DMCs and IRL, AMC for BMs and procurement of lab consumables for IRL.
16. Oversee all activities of IRL and will ensure submission of action taken reports on CTD/NRL recommendations for Laboratory EQA network.
17. Responsible for overall RNTCP DOTS Plus activities in the state (as and when recommended by CTD) and ensure that DOTS Plus guidelines are followed.
18. Responsible for coordinating and facilitating OR activities in the state.
19. Ensure smooth coordination between RNTCP and VCTC especially in states implementing the TB-HIV coordination plan
20. Oversee the implementation of any other initiative/activity undertaken by RNTCP

ANNEX 1C

Functions of the State TB Training and Demonstration centre (STDC)

1. Training:
   - To assist State TB Officer in all areas of human resource development, including planning and monitoring of initial training, retraining and update training.
   - To plan and impart quality training to all the District level key personnel and supervisory staff (MOTC, STS and STLS).
   - To train relevant personnel in EQA, DRS and other new initiatives.
   - Raise a group of master trainers within the State
   - Build capacity for imparting quality training at district level.
   - Evaluation of training activities in the State.
   - Ensure use of standard RNTCP training material, including translation of training material into local languages, if required
2. Supervision, monitoring and evaluation
   - To undertake supervisory visits to the districts in coordination with the STO.
   - Coordinate and support the STO in monitoring of the programme and providing feedback on the programme activities to districts.
   - To help the STO to carry out periodic internal evaluation of district programme
3. Quality Assurance (QA) of sputum microscopy:
   - The STDC will act as an intermediate reference laboratory (IRL) and carry out all activities that are laid out for IRL in the RNTCP protocol for quality assurance in sputum smear microscopy. This would include panel testing and on-site evaluation of district level and participation in the panel testing for the IRL conducted by the national reference laboratory, and routine submission of required reports to STC and CTD as per programme guidelines.
4. Culture and sensitivity:
   - To provide quality assured Culture and DST facilities for M. tuberculosis
   - To undertake Drug Resistance Surveillance in the states as and when instructed by CTD.

5. Operational Research (OR):
   - Undertake OR and provide technical support to research activities in the state
6. Advocacy and IEC
   - Assist the STO in planning and coordinating the advocacy and IEC activities in the state.

Undertake all programme related activities as directed from the state and CTD from time to time.

ANNEX 1D

Responsibilities of the State IEC Officer

IEC Officer is the nodal person at the state level for planning and implementation of IEC activities in the state and districts.

1. Assists state and districts in planning and implementation of IEC activities.
2. Develop state IEC action plans and assist districts in preparing their IEC action plans.
3. Ensure conformity with the Central TB Division's IEC strategy and guidelines at all levels so as to achieve the broader programme goals. Liaise with CTD for ensuring consistency of state activities with the IEC strategy laid down under the programme by CTD.
4. Initiate and sustain advocacy activities in the state for promotion of political and administrative commitment for the programme with opinion leaders in the state.
5. Organize IEC activities at the state level. Maintain a monthly schedule of planned IEC activities in all districts and at state level and monitor them regularly.
6. Identify agencies/ departments/ NGOs for organizing social mobilization activities
7. Help in the development of IEC material at the state / district level.
8. Identify agency/NGO/communication facilitators in the state/ districts whose service can be utilized for organization of public events, social mobilization and media activities.
9. Regular visits to districts to monitor field level IEC activities.
10. Help districts in organization of social mobilization activities.
11. Work closely with the communication facilitators at the district level.
12. Compile quarterly reports on the IEC activities of the districts and prepare the same at the state level.

Responsibilities of State Accountant

The State Accountant provides support in all finance and accounts matters pertaining to the State and District Societies, including release of funds to District Tuberculosis Control Societies or its equivalent societies, settlement of advances and monitoring of expenditure. Responsibilities include to:

1. Prepare the annual budget for the State and review the budgets of the District Societies or its equivalent societies.

2. Prepare and maintain the books of accounts of State TB Society or its equivalent societies as per STCS guidelines.
3. Ensure that adequate internal controls are in place in STCS and DTCS or its equivalent societies to support the payments and receipts.
4. Ensure (by way of training and support to the District Accountants) that common reporting formats as provided in financial guidelines are used by Districts in order that consolidation of accounts is facilitated at state level.
5. Support the audit of the accounts of the state society and district societies in accordance with the financial guidelines.
6. Monitor expenditure and receipt of SOEs from the Districts
7. Review the accounts and records of the District Societies on a periodic basis.
8. Ensure timely consolidation of accounts/financial statements of the state (including those of District TB Control Societies or its equivalent societies). Prepare consolidated SOE of the State to be sent to the Central TB Division on a quarterly basis.
9. Coordinate with the District Societies to address the audit objection / internal control weaknesses, issues of disallowances if any.

ANNEX 1E

Responsibilities of the CMO/ CDHO

1. Ensure that high priority is given to the TB Control Programme in the overall health activities so that the objectives of the RNTCP are achieved.
2. Provide all necessary resources within his command to the DTO for effective implementation of the Programme.
3. Issue all necessary administrative instructions and facilitate all activities for successful implementation of DOTS at the peripheral level.
4. Ensure that all MOs and paramedical workers (MPHS/MPW/AWW etc) are involved in RNTCP.
5. Ensure that DTCS meetings are held as per guidelines
6. Coordinate with and keep the administrative head of the district (District Magistrate/District Collector) informed on the progress of the RNTCP from time-to-time and ensure his intervention in getting inter-sectoral coordination.
7. Review the programme on a monthly basis with the DTO, MO-TCs, MOs of PHIs and STS/STLS.

Responsibilities of the DTO

1. Responsible for smooth implementation of the RNTCP and for achieving the Programme objectives in his district.
2. Planning and execution of the District Annual Action Plan.
3. Ensure the identification of designated microscopy centres, DOT providers and staff responsible for DOTS.
4. Arranging, maintaining and distributing supplies (drugs, laboratory reagents, sputum containers, forms, etc.) and equipment.
5. Organize training of staff of the TUs and all medical and paramedical staff of the peripheral health institutions.
6. Supervise and support the TUs (sub-district level), with the help of the Medical Officer and other DTC staff and ensure all TUs, CHCs, Block PHCs in the area are visited at least once every quarter.
7. Compile and analyse quarterly programme performance reports of the District, and send them to the State and National levels within the dates prescribed.
8. Conduct review meetings with the MOTC, STS and STLS on at least a monthly basis to evaluate the performance of the programme in the PHIs and take corrective actions.

9. Establish linkages with Medical Colleges, private practitioners, non-governmental organizations and community leaders.
10. Ensure smooth coordination between RNTCP and VCTC especially in states implementing the TB-HIV coordination plan
11. Organize IEC activities within his district
12. Keep the CMO/CDHO and the DM (Chairman DTCS) informed on the progress of RNTCP activities especially in respect of achievement of the laid down performance indicators.
13. Function as member secretary of the District TB Society or its equivalent and convene its meetings every quarter for smooth functioning of the programme in the District.
14. Ensure maintenance of appropriate financial records and submit quarterly and annual financial reports.
15. Undertake all programme related activities as directed from the state and CTD from time to time.

Responsibilities of the Medical Officer of the DTC

1. To assist the DTO in all the above functions.
2. In addition, to act as MO-TC for the TB Unit in the area of the DTC as assigned by DTO.

Responsibilities of the Treatment Organizer (wherever available)

1. Assist the DTO in treatment and supervisory activities.
2. Any other assignment related to the programme and entrusted by the DTO from time to time.

Responsibilities of the Statistical Assistant

1. Statistical Assistant (SA) is responsible for collecting; collating, compiling and maintaining reports received from the TUs and PHIs in the district and ensuring their timely onward transmission to the concerned authorities. S/He ensures that all records and reports are received on time, and are complete and consistent.
2. Ensures that the STS prepare the Quarterly Reports as per the guidelines laid down.
3. Help in documentation of the quarterly and annual report on TB, reflecting the progress, based on the established performance indicators.

4. Assist DTO in calculating the sample size for RBRC of EQA and compiling data for EQA.

5. Ensure that the DOT Directory is regularly updated and circulated to all concerned.

6. Undertake all programme related activities as directed by the DTO.

Responsibilities of the Data Entry Operator

1. Assist the SA in collecting, collating, compiling and maintaining reports received from the TUs and PHIs in the district and ensuring their timely onward transmission to the concerned authorities. The Data entry under RNTCP is done on “Epicentre” software and the DEO is responsible for correct entry of Data in Epicentre and sending the epicentre data files electronically to the State and Centre within the Scheduled time frame.
2. Ensure that all electronic communication (emails) to the district is regularly communicated to the District TB Officer and details of communications to and from the districts is maintained in a systematic manner to facilitate future reference.
3. Maintain a backup of all data pertaining to the district on a regular basis.
4. Ensure proper maintenance and upkeep of the computer and its accessories including virus defence.
5. Assist the DTO in preparation of presentations and reports on RNTCP as and when required.
6. Undertake all programme related activities as directed by the DTO.

ANNEX 1F

Key functions of the Tuberculosis Unit team

1. Maintain the Tuberculosis Register.
2. Organize and ensure effective diagnosis and direct observation of treatment in the TB unit.
3. Conduct supervisory visits to health centres and patients home as per guidelines, and ensure all RNTCP guidelines are adhered to.
4. Prepare quarterly reports on case finding, sputum conversion, results of treatment, and programme management and submit to DTO as per scheduled time-fame.
5. Ensure adequate supply of drugs, reagents and logistics regularly.
6. Involvement of other sectors in RNTCP.
7. Ensure effective IEC activities.

Responsibilities of Medical Officer-Tuberculosis Control (MO-TC)

1. Responsible for the smooth implementation of the RNTCP and achieving its objectives through the sub-district supervisory team (STLS and STS).
2. Supervise directly the functioning of STS and STLS. Ensure regular visits (seven days a month) to the field and when required help STS in retrieval of defaulters. Cross check the results of field visits recorded by STS/STLS in their diaries, reports and registers. The overall supervision of the TU will be done by the DTO.
3. Organize sputum smear examination at all DMCs of the sub-district,
4. Carry out correct treatment categorization of diagnosed patients and also support other MOs of the sub-district to do the same.
5. Ensure that MOs of neighbouring peripheral centres follow the RNTCP Guidelines for diagnosis, treatment, recording and reporting.
6. Act as a referral point for patients who present with:
   - diagnostic problems
   - drug reactions
   - refusal to take drugs
   - failure of treatment and require further investigation
   - not converting to sputum-negative status at the end of the intensive phase to identify the reasons for the same

7. Refer problematic cases to the DTO.
8. Ensure that DOT is taking place as per guidelines at all DOT centres.
9. Evaluate outcome at the end of treatment, e.g., cured, treatment completed, etc. Also conduct death and default audit and to report the findings to the DTO.
10. Update records and prepare quarterly reports on case finding, sputum conversion, results of treatment outcome and programme management of the corresponding TU and timely submission of these RNTCP reports to the respective DTO.
11. Approve, in advance, field visit programme of the STS and STLS for the coming month and communicate the same to the concerned MO in-charge of the CHC/ PHC. Review the performance of STS/ STLS along with their tour diaries, registers and reports.
12. Ensuring a regular supply of drugs and other logistics and ensuring their uninterrupted availability in all peripheral health institutions in the sub-district. Oversee requisition, receipt and monitoring of supplies.
13. Co-ordination with NGO, PP and other sectors in the TU area.
14. Any programme related assignment given by DTO from time-to-time.

Responsibilities of the Senior Treatment Supervisor (STS)

1. Ensure the quality of the DOTS services provided in order to achieve the programme objectives in the assigned areas.
2. Organize direct observation of treatment in the sub-district and ensure registration of all cases diagnosed and initiated on treatment in the sub-district;
3. Maintain the Tuberculosis Register, updating the required information in respect of all cases diagnosed in the sub-district in a timely manner;
4. Prepare Quarterly Reports on case-detection, sputum conversion, treatment outcome, and programme management and send them to the DTO after review and approval by MO-TC. The STS should ensure timely submission of these RNTCP reports.
5. Maintain a map of the area detailing all health facilities in the area, both government organizations and NGOs which specifically carry out TB activities, including the staff responsible for these TB activities (name, position and location);
6. Supervise each PHC, CHC and hospitals in the area at least once in a month, on a systematic basis and visit all treatment observation centres once in quarter.
7. Visit all new sputum positive patients at their homes within one month of treatment initiation.
8. Ensure that patients are correctly classified; appropriate treatment prescribed, provided and taken; laboratory tests carried out and treatment outcome indicated

appropriately at the completion of treatment. This can be done by checking Tuberculosis Treatment Cards, comparing the Tuberculosis Register and the Laboratory Register, by visiting the field and comparing findings with diaries of field workers (particularly in relation to retrieval of defaulters); by discussing with staff; and by interviewing patients at random. Any discrepancies found during checking should be brought to the notice of MO-TC/DTO.

9. Ensure that all patients presenting with productive cough of 3 weeks or more duration undergo 3 sputum smear examinations for AFB;
10. Ensure that all contacts of sputum positive patients with cough of any duration undergo sputum examination. Also ensure that children below six years in contact with sputum positive patients are screened for TB by the MO and if found to be free from the disease receive chemoprophylaxis.
11. Provide continuous training to the staff of health facilities under his/ her jurisdiction to carry out TB control-related activities
12. Establish liaison with private practitioners, NGOs and other sector dispensaries / hospitals who provide TB services to promote compliance with national norms, facilitate referral, and ensure registration and notification;
13. If the STS is visiting without the STLS, collect information on all parameters of laboratory performance, cross-check whether all sputum smear-positive cases have been placed under treatment. Also, take necessary steps to trace initial defaulters and bring them back under treatment. Inform the MO in-charge and the STLS about any deficiencies observed in laboratory functioning;
14. Undertake all such activities which are required to achieve the stipulated performance indicators, with special emphasis on poorly performing area and difficult section of society.
15. Make a monthly tour programme in advance in such a fashion that all the field units are covered at least once a month and get it approved from the MO-TC;
16. Maintain a tour diary recording the details of field visits and feedback given on the observations made. Also record observations in supervisory register at all PHIs visited.
17. Assist MOTC/ DTO in undertaking such activities with a view to improve overall performance.
18. Participate in review meetings convened at the district level for advocacy among other health functionaries.
19. Ensure that the Tuberculosis Treatment Cards reach the TB Unit from the treatment centres as soon as the treatment outcome is recorded and within a maximum of one month time.
20. Ensure that the treatment outcome is recorded in the TB Register within one month of the completion of the treatment in case of cured and treatment completed cases.

Similarly the outcomes of patients declared defaulted or died should be recorded within one month of the event

21. Conduct death and default audit and report findings to the MOTC and the DTO.
22. Maintain drug stock register at TU level and monitor movement of drug to PHI according to guidelines, including prolongation pouches for indoor patients
23. Ensure no stock outs at PHI. Monitor drug expiry dates and inform MOTC/DTO about short expiry drugs under their charge.
24. Ensure opened drug boxes of patients who die or default from treatment are returned to the respective District TB Centre for reconstitution.
25. Organize community based IEC activities like patient – provider group interaction meetings and community meetings.
26. Co-ordinate with VCTC Centres by providing feedback on referred persons regarding the TB status and their treatment.
27. Undertake all programme related activities as directed by the DTO/MO-TC.

Responsibilities of the Senior TB Laboratory Supervisor (STLS)

1. Responsible for maintaining the quality of sputum microscopy including all activities under the QA guidelines, and for the smooth functioning of laboratory services.
2. To organise smear examination at the designated microscopy centres of the sub-district.
3. To assess the training and retraining needs of Lab Technicians and to provide on the job training. Motivate, coordinate, facilitate and guide all microscopist in the area.
4. To maintain a list of all designated microscopy centres in the sub-district which carry out TB activities, including distribution (map of the area) and staff responsible (name, position and address) in collaboration with the STS.
5. To supervise all designated microscopy centres at least once a month, and perform quality control of slides as per the Laboratory Manual and QA guidelines. They will provide feedback in the proper format as per EQA and support the MO in carrying out corrective measures.
6. Check slides for RBRC at the DTC as per the roster put up by the District TB Officer.
7. To check the record-keeping (Laboratory Register) and compare the workload for case-finding with the general OPD attendance of symptomatic patients in the health facilities.

8. To inform the MO-TC/ MO in case of leave of Laboratory Technician of a DMC, and facilitate organization of alternative arrangements so that there is regular and permanent availability of smear examination or sputum transport mechanism at that microscopy centre.
9. To prepare and distribute reagents, and ensure regular and sufficient supply of reagents and sputum containers in each health facility.
10. To ensure proper storage and transport of sputum specimens, safety of laboratory staff, proper waste disposal and maintenance of microscopes.
11. To prepare and forward reports on the microscopy centre to the DTO, in collaboration with the STS, regarding implementation, quality control, supervision and management of laboratory supplies.
12. Whenever the STLS is not accompanied by the STS, he will check that sputum-positive cases have been put on treatment and if not, he will inform the Medical Officer in-charge and the STS so that they may take necessary action.
13. To make a monthly tour programme in advance in such a fashion that all the field units are covered at least once a month and get it approved from the MO-TC.
14. Maintain a diary recording the details of their field visits.
15. Undertake all programme related activities as directed by the DTO/MO-TC.

ANNEX 1G

Responsibilities of Medical Officer

1. Responsible for case-finding, categorization and treatment of TB patients to achieve the objectives of the RNTCP and the laid down performance indicators.
2. History-taking and examination of patients. If TB is suspected, ensure 3 diagnostic sputum smear examinations. If patient is found to be sputum positive, MO shall ensure treatment initiation for all such patients found to be sputum positive, including the retrieval of initial defaulters, with the help of MPHS/ STS/STLS.
3. Diagnosis of TB patients, classification and prescription of adequate and correct treatment regimen. Careful history-taking is required, particularly to determine if patients have been treated previously for tuberculosis.
4. Discuss with new patients the most convenient location for Directly Observed Treatment (DOT) and most appropriate DOT Provider, to ensure regularity and completion of treatment, and educate them about the importance of completing therapy.
5. Ensure that contacts of sputum-positive cases undergo sputum examination and record the result of the same in the Treatment Card.
6. Ensure that children below six years in contact with sputum positive patients are screened for TB and if found to be free from the disease receive chemoprophylaxis.
7. Monitoring of progress, management of complications and discharge from treatment, according to guidelines.
8. Ensure correct registration of patient data in the Treatment Card, and that the patient undergoes the necessary bacteriological examinations at the stipulated period and continues regular medication until cure or treatment completion.
9. Evaluate patients with drug reactions, treatment failure and cases not converting to sputum-negative status in the initial intensive phase of treatment. Personal attention should be paid to all patients who refuse to take drugs in the prescribed manner to ensure an operationally viable procedure convenient to the patients and the staff.
10. Ensuring that sufficient stock of drugs and other logistics is available and regular supply is maintained. Ensure that PWB reaches the DOT provider using MPWs or other health functionaries. Ensure that the partially used PWBs are returned to the STS in a timely manner.
11. Supervising the paramedical health supervisor.
12. Identifying and assigning responsibility for DOT, and discussing problems with the MPW during weekly meetings.

13. Ensuring that all the peripheral health functionaries understand and carry out their job responsibilities.
14. Ensure that original Treatment Cards at the PHI are updated at least every fortnight.
15. Ensure that the monthly PHI report is completed and sent to the CMO and the TB unit by the 5th of next month.
16. Undertake all programme related activities as directed by the DTO/MO-TC.

Responsibilities of the Laboratory Technician / Microscopist or Trained Laboratory Assistant

1. Instruct and demonstrate to the patients the proper methodology of bringing out sputum.
2. Prepare smears from the thickest portion of sputum, stain, read and record results.
3. Maintain the Laboratory Register and report the results in the Laboratory Form for Sputum Examination to the concerned Medical Officer within a day.
4. Coordinate with other staff to ensure that patients with productive cough for three weeks or more undergo three initial sputum examinations for diagnosis and two sputum examinations for follow-up.
5. Undertake all activities as per the revised EQA guidelines - Keep slides serially in a slide box until the STLS reviews them for QA; collect slides identified by STLS for RBRC, arrange them serially in a slide box, complete annexure B (results of corresponding slides selected for RBRC); place the annex B in an sealed envelope; label the slide box and handover the envelope and slide box to the STLS.
6. Maintain laboratory equipment – keep the microscope in good working condition.
7. Maintain records of the laboratory consumables and reagents; ensure proper storage and order supplies well in advance to avoid shortages.
8. Ensure that the laboratory premises are neat and clean.
9. Dispose of contaminated material as per RNTCP guidelines.
10. Assist the MO-PHI in completing the monthly PHI report.
11. Undertake all programme related activities as directed by the DTO/MO-TC.

Responsibilities of the Multipurpose Health Worker / TB Health Visitor

1. Initial verification of address of the tuberculosis patients. During this period, the contact person whose name is also mentioned in the Treatment Card should also be contacted so as to ensure from him, his concern about the patient.

2. Motivation of the patient with respect to treatment requirements and expected duration of the treatment.
3. Ensure that every patient diagnosed as a case of tuberculosis is started on treatment within 7 days of diagnosis and treated for the full duration.
4. Ensure that contacts of sputum-positive cases undergo sputum examination and record the result of the same in the Treatment Card.
5. Ensure that children below six years in contact with sputum positive patients are referred to the MO for advice.
6. Fix the time and place for DOT, keeping in view the patient's convenience and operational feasibility, so that the DOT is ensured.
7. Ensure that all doses in the intensive phase and the first dose of each weekly blister during the continuation phase are taken under direct observation. Also ensure collection of empty blister packs which should be preserved till the end of treatment.
8. Ensure timely examination of sputum at defined intervals, until the patient completes the course of treatment.
9. Maintain the Treatment Card and update the original card at the PHI on a fortnightly basis.
10. Ensure that every Treatment Card you have received is given a TB Number. Put up this card to the Senior Treatment Supervisor (STS) during his visit for transfer of the required information to the TB Register.
11. Immediate retrieval of patients who do not report as scheduled during treatment. During the intensive phase it should be done with in 24 hrs and during the continuation phase within 7 days of the patient missing the dose. If the MPW is unable to retrieve the patient, this should be intimated to the MO of the PHI and to the STS.
12. Refer all TB suspects for sputum examination to the nearest microscopy centre/sputum collection centre.
13. Provide health education to the patient and their families.
14. If a community volunteer is the DOT provider, the MPW has to ensure that the CDP is trained on how to give DOT and how to mark the treatment card and also ensure that the Original card at the PHI is updated on at least a fortnightly basis. The MPW also needs to supervise the community DOT Provider to ensure that the patient gets DOT as per guidelines.
15. Ensure that partially used PWBs (of patients who have died / defaulted / failed treatment / transferred out) are returned to the PHI within a month of such event.
16. TBHVs working in the medical college should ensure coordination between various departments and RNTCP facility for Indoor DOTS.

17. Undertake all programme related activities as directed by the DTO/MO-TC.

Responsibilities of Multipurpose Health Supervisors / Lady Health Visitor / Health Assistant

These categories of staff are responsible for the immediate supervision of the MPWs/DOT providers. Their job description, therefore, includes supervisory activities in addition to their role in service delivery.

1. Ensure that all patients especially those who are smear positive are put on DOTS.
2. Discuss with new patients to find out the most convenient location for DOT and appropriate DOT Provider, and continuously educate them on the importance of taking complete treatment.
3. Ensure initial visit to the home of the patient by MPW prior to starting treatment and follow-up visits for retrieval of defaulters.
4. Ensure DOT as per programme guidelines. Ensure collection of empty blister packs by the DOT provider. The MPHS during their supervisory visits should check PWB of patients on treatment to verify if the number of full and empty strips in the PWB matches the markings in the tuberculosis treatment card.
5. Ensure proper maintenance of Treatment Cards by the MPW / CDP and updating of original cards at the PHI fortnightly by the MPW.
6. Ensure that follow-up smear examinations are carried out as per guidelines.
7. Retrieval of initial defaulters.
8. Ensure that symptomatic contacts of sputum positive patients are suitably examined. Also ensure that chemoprophylaxis is given to the child contacts (below 6 years) of sputum positive patients.
9. Co-ordinate with the STS and Senior TB Lab Supervisor (STLS) to update the follow-up data of all the patients and maintenance of an adequate stock of lab material and drugs.
10. Provide patient data to the STS. Ensure that monthly PHI reports are sent in a timely manner by the PHI and that they are accurate.
11. Ensure appropriate display of health education materials.
12. Arrange and conduct group health education activities.
13. Identify and guide community DOT providers as per need.
14. Ensure that treatment cards of patients who have completed treatment are handed over to the STS within one month.
15. Undertake all programme related activities as directed by the DTO/MO-TC.

Responsibilities of the Pharmacist

1. The Pharmacist shall be responsible for all operations at the store including the upkeep of store records.
2. Take stock of PWBs and other drugs received from the State/District/TU and ensure proper storage following FEFO.
3. Maintain drug stock register, issue and monitor movement of drugs to PHI according to guidelines. Pharmacist at the PHI should ensure that PWBs are made available for transfer to the DOT centres in the PHI area, and that proper documentation is maintained about the transfer of such PWBs and that PWBs are not lost in transit.
4. Pharmacist at the PHI should ensure that there is no stock outs at their PHIs. Monitor drug expiry dates and inform MO/MOTC/DTO about short expiry drugs under their charge.
5. Ensure that drug records in the monthly PHI reports are accurate and up to date and sent in a timely manner by the PHI.
6. Ensure that MPWs return partially used PWBs from the non PHIs in their area (subcentre/ anganwadi/ community DOT Provider) to the PHIs in a timely manner and that these are returned to the STS, with details of the number of strips being returned, within one month.
7. Pharmacist at the District drug store shall be responsible to undertake reconstitution of patient wise boxes under the supervision of DTO and maintain appropriate record of the same.
8. Pharmacist is also responsible for ensuring the transfer of drugs to other TUs/PHIs in case of dire emergencies under the overall supervision of DTO/MOTC.
9. Pharmacist of the PHIs may be assigned the responsibility of acting as a DOT provider for the patients who come to their institution for DOT Ensure DOT at the PHI as per programme guidelines.

ANNEX 1H

Functions of National Reference Laboratories:

RNTCP expects the Central Institutes in their role as the National Reference Laboratories (NRLs) to guide some major RNTCP activities, and broadly they are:

1. External Quality Assurance of RNTCP Lab network: The allotted IRLs will be visited by the central institutes as part of the on-site evaluation under the RNTCP protocol. Standard checklists and formats would be used. The following activities have been envisaged for national institutes under the revised Sputum Microscopy Quality Assurance protocol:
   a. On site visit once a year to the assigned IRLs and more frequently, if needed, for supervision and panel testing of IRL staff.
   b. Training the lab technicians and microbiologist of IRLs on the revised EQA protocol
   c. Sensitization to STDC/ IRL Directors on the revised RNTCP EQA procedures.
   d. Reporting to Central TB Division on standard formats for EQA
2. Training: Responsibility of 'Training of the trainers' of the State and district level will be undertaken by the central institutes. They would conduct the following training programmes every year
   a. Training of Trainers including paramedical staff
   b. Training for IRL (STDC) staff (Epidemiologist, Microbiologist, TB Specialist, Statistician)
   c. Training for state level programme managers and DTOs
3. Drug Resistance Surveillance:
   a. Technical assistance in establishment of culture and drug sensitivity laboratory at the IRLs.
   b. Proficiency testing in DST of IRLs allotted.
   c. Technical guidance for conducting DRS to the respective IRLs allotted.
4. DOTS Plus
   a. Will take leadership role to monitor and review DOTS Plus activities in the country.
5. Research: The central institutes will carry our basic TB research and support RNTCP in its operational research studies on TB within the country.

Functions of Intermediate Reference Laboratory:

1. Training plan for EQA, operationalize initial training and maintain ongoing training
2. Ensure staffing at IRL is adequate.
3. Ensure quality of lab consumables throughout the state.
4. Implementation of EQA-
    a. Onsite evaluation visits to districts by IRL staff and to peripheral centres by sub-district staff at least on an annual basis.
    b. Panel testing – manufacturing and validating of panel testing slides by IRLs
    c. Checking of records of random blinded rechecking done by the district
5. Reporting and monitoring – Details of EQA activities would be made available in state level RNTCP news letters, performance reports.

Responsibilities of the Microbiologist:

1. Operationalize the Sputum Microscopy EQA protocol in the respective state. Carry out all activities related to this – On-site evaluation visits, panel testing, verification of district level blinded rechecking process and monitoring of EQA data, etc
2. Conduct trainings of IRL staff and health staff of the state to undertake sputum microscopy EQA, culture sensitivity testing and DRS (as determined by CTD) at state level.
3. Strengthen IRL to undertake mycobacterial culture and drug sensitivity testing and development of proficiency in drug sensitivity testing
4. Assist in developing capacity for manufacturing of slides for panel testing at IRL.
5. Actively assist states and Central Institutes in collection, analysis and interpretation of data, prepare reports related to sputum microscopy EQA, culture sensitivity testing and DRS as may be required at the IRL/NRL from time to time.
6. Participate in Operational research relevant to RNTCP. Such participation would be with prior approval of Central TB Division.

ANNEX 2

Functions of National Task Force (NTF)

1. Ensure establishment of Zonal Task Force (ZTF)
2. Provide leadership and advocacy for RNTCP
3. Formulate policy regarding medical colleges involvement in RNTCP for presentation to CTD for approval.
4. Coordinate between NTF and CTD, NTF and ZTF
5. Monitor activities of the ZTF and State Task Force (STF) through yearly review meetings
6. Facilitate in availability of funds for NTF, ZTF and STF activities

Functions of Zonal Task Force (ZTF)

1. Ensure that State Task Force (STF) are formed in all States of the respective zone
2. Compile and update the list of Medical Colleges with their RNTCP implementation status in the zone.
3. Organize ZTF meetings to review progress and draw up annual action plans
4. Ensure RNTCP training of ZTF members
5. Organize zonal level CMEs/Seminars/workshops and other academic activities for promotion of RNTCP in medical colleges and the private sector at least once a year
6. Facilitate in operational research by medical colleges
7. Field visits / attend meetings of STF, workshops etc. All States to be visited at least once every quarter. Field visits to the medical colleges to supervise and monitor implementation of RNTCP should be conducted jointly by members of ZTF and STF in coordination with the STO.
8. Disseminate information about RNTCP to medical colleges.

Functions of State Task Force (STF)

1. Ensure establishment of DMC cum DOT centres in all Medical Colleges located in the districts of the respective state.
2. Disseminate information about RNTCP to medical colleges.
3. Help organize training for core committee members of individual medical colleges.

4. Visit every Medical College at least twice a year to supervise and monitor implementation of RNTCP in coordination with the STO and DTO.

5. Organize State level CMEs/Seminars/workshops and other academic activities for promotion of RNTCP in Medical Colleges and the private sector at least twice a year.

6. Hold STF meetings to review RNTCP progress / performance of medical colleges in the State.

7. Define priorities for operational research based on the national and zonal workshop. Review research proposals and facilitate in conduction of research by medical colleges.

Functions Medical College core committee

1. Establish DMC cum DOT centre in all medical college hospitals, even if the DTC is within the same premises of the medical college.
2. Organize sensitization / workshops / trainings for faculty members / PGs / UGs / Interns / paramedical staff, etc.

3. Ensure that teaching on TB/RNTCP form part of curriculum for PG students/ Residents / Interns / UG students. Teaching should include practical training through visits to DOTS centres as well as classes/lectures taken by departments of Medicine, TB & Chest Medicine, Microbiology, PSM etc.

4. Coordination between various departments so that patients get the services in respect of their TB problem under one roof.

5. Coordinate with the district TB programme for participation in the quality assurance network of sputum microscopy, referral for treatment network, management of complicated cases of TB, and submission of monthly PHI report.

6. Undertake operational research for RNTCP on the priority areas defined by the STF for the State. Encourage research on TB by faculty members as well as by students for their thesis, etc.

7. Undertake advocacy for the programme by publishing articles on TB, newsletters, giving radio / TV talks, etc.

8. Hold monthly meeting of the core committee to review performance of the DMC cum DOT centre in the hospital.

9. Submit a monthly PHI report to the DTO.

10. Submit a compiled quarterly report of the MC cum DOT centre to the STF.

11. Participate in RNTCP related activities carried out by the state/district whenever requested.

Roles of STO/DTO in strengthening involvement of medical college hospitals in the RNTCP

1. Identify all major hospitals to be involved in the RNTCP as a TU/DMC/DOT referral centre as appropriate. Prioritise those with heavy OPD attendance.
2. Coordinate with the Core Committee of the medical college to conduct sensitization workshops/training on RNTCP for faculty members where the same has not been done.

3. Coordinate with the Core Committee of the medical college to organise RNTCP training of Medical officers, Laboratory Technician and DOT providers and other staff as required.

4. Provide binocular microscopes if available wherever required and upgrade the laboratory for the RNTCP designated microscopy centres. Laboratory consumables, forms and registers required should be provided by the District TB Centre.

5. Provide 100% requirement of RNTCP drugs

6. Ensure supervision of the laboratory and treatment services and coordinate in providing feedback of the diagnosed TB patients referred to other PHIs within district/state.

7. Provide technical inputs, guidance and supervision as per programme.

8. Where required, hire additional contractual staff to implement and coordinate the activities of RNTCP in Medical Colleges/Hospitals as per provisions under the programme.

Roles of the Deans/Directors of the Medical College hospitals in RNTCP

1. Provide space for an RNTCP Designated Microscopy Centre and a DOT centre in the hospital.
2. Identify one senior faculty member, preferably from the Dept. of TB & Chest or from Medicine as a nodal person for RNTCP activities.

3. Designate 1 Laboratory Technician for sputum microscopy and 1 health worker as DOT provider (treatment observer). It should be ensured that the designated staff has sufficient time for RNTCP work.

4. Issue directions to the major OPDs of the college/hospital to refer all patients with cough of 3 weeks or more to the DMC of the hospital.

5. Ensure availability of faculty members for sensitization regarding the RNTCP and for training of key staff like the MO in charge of the MC, LT, DOT providers.

6. Issue instructions to all the doctors to follow RNTCP diagnostic algorithm for all patients and standardized treatment policies as per the RNTCP. Proper referral of patients who reside outside the district in which Medical College is situated should be undertaken with the help of the staff in the hospital DMC.

7. Stop procurement of anti-TB drugs except for those patients who are critically ill and require in-door and specialized treatment. RNTCP drugs should be used for majority of TB patients

8. Agree to supervision by RNTCP staff and submit reports as required under the RNTCP

ANNEX 3A

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Laboratory Form for Sputum Examination

Name of Referring Health Facility: _____ Date: _____

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

Complete address: _____

_____

Type of suspect / disease: ❑ Pulmonary

❑ Extra-pulmonary Site: _____

Reason for examination:

❑ Diagnosis

❑ Repeat Examination for Diagnosis

❑ Follow-up of anti-TB treatment Patient's TB No _____

(Name and signature of referring person/ official)

If sputum sample are being transported:

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

Specimen Collector's name and signature _____

RESULTS (To be completed in the laboratory of DMC)

Name of DMC: _____

Lab. Serial No.: _____

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

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

** *Write actual count of AFB seen in 100 oil immersion fields*

Date: _____..... Examined by (signature): _____

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

ANNEX 3B

Form A **Serial Number**

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Referral for treatment form

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

Name and address of referring health facility _____

_____

Name of health facility to which patient is referred _____

_____

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

Complete Address _____

_____

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

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

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

Sputum Status

Date **Month** **Year**

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

Remarks

Signature _____

Date referred _____ **Designation** _____

----------✂----------✂----------

Form A Serial Number_____

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

Name of patient _____ TB nos (if available)

Age _____ Sex M ☐ F ☐ Date of referral _____

Name of receiving health facility _____ Name of TB Unit and District _____

The above-named reported at this facility on _____ and has been put on treatment on _____

Signature _____ Designation _____ Date _____

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

ANNEX 3C

Revised National Tuberculosis Control Programme

Transfer Form

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

A copy of treatment card may be included along with transfer form given to patient
Name and Address of the transferring Unit (District/TB Unit): _____
Name of Unit (District/TB Unit) to which patient is transferred (if known): _____
Name of the Patient: _____ **Sex: M ☐ F ☐ Age:** ____
TB No: _____ **Date of starting treatment** _____

Disease Classification	**Type of Patient**	**Category of Treatment**	**Most Recent Sputum Status**
❑ Pulmonary	❑ New	❑ Category I	**Date:**
❑ Extra-Pulmonary	❑ Relapse	❑ Category II	**DMC:**
Site_____	❑ TAD	❑ Category III	**Lab NO:**
	❑ Failure		❑ Positive
	❑ Transfer in		❑ Negative
	❑ Other(Specify)__		_____

Number of doses administered before transfer: IP _____ CP_____
Remarks:_____
_____Signature_____
Date transferred _____ Designation:_____

For use by the receiving District/TB Unit **Date of outcome**_____

Name of patent_____

Old TB No (given at transferring TB Unit): _____ New TB No (given at receiving unit)_____
Treatment outcome ❑ Cured ❑ Treatment Completed ❑ Died
❑ Failure ❑ Defaulted ❑ Transferred Out

Date _____ Signature _____

(at the end of treatment send this form to the transferring District/TB Unit where the patient was initially registered.)
(a copy of treatment card after completion of treatment may be sent to the PHI of transferring the patient)

For use by the receiving District/TB Unit in case the patient was received during IP

Name of patient:_____
Old TB No (given at transferring TB unit): _____ New TB No (given at receiving unit):_____
Sputum Results at the end of IP: ❑ Positive ❑ Negative
Date _____ Signature _____
(at the end of Intensive phase this form has to be sent to the transferring District/TB Unit where the patient was initially registered.)

For use by the receiving District/TB unit

Name of patient _____
Old TB No (given at Transferring TB unit)_____ New TB No (given at receiving unit)_____
Age: _____ Sex: M ❑ F ❑ Date of Transfer_____
Name of TB Unit:_____ District _____
The above –named reported at the TB unit on: _____
Signature _____ Designation _____ Date_____ _____
(Send this part back to the transferring District/TB Unit as soon as the patient has reported and has been registered in the receiving TB Unit.)

ANNEX 3D

Revised National Tuberculosis Control Programme

Mycobacteriology Culture/Sensitivity Test Form

(1) Name of referring Unit: _____ Name of Laboratory:_____

Send results to (address): _____

_____

Months of treatment taken:_____

Name of patient::_____ Patient's TB No.: _____

(PLEASE TICK)

(2) ❑ Category I (new case: pulmonary smear-positive, seriously ill smear-negative, or seriously ill extra-pulmonary)

❑ Category II (retreatment: relapse, failure, treatment after default)

❑ Category III(new case: pulmonary smear-negative, not seriously ill; or extra-pulmonary, not seriously ill)

❑ Other regimen (specify):_____

TREATMENT GIVEN	Form date	To date
(H) Isoniazid	_____	_____
(R) Rifampicin	_____	_____
(Z) Pyrazinamide	_____	_____
(E) Ethambutol	_____	_____
(S) Streptomycin	_____	_____
Other	_____	_____

Date:_____ Medical Officer's name: _____

Prior sensitivity results and dates if known:_____

(3) Source of specimen if not sputum (specify):_____

Date of collection

				2	0		
d	d	m	m				

(4) **FOR LAB USE ONLY** Lab Serial No.:_____

Smear ❑ Positive (Grade: ❑ 3+ ❑ 2+ ❑ 1+ ❑ Scanty)
❑ Negative

Culture ❑ Positive ❑ Negative ❑ Contaminated ❑ Other

(5) **SENSITIVITY TESTS**

Drug	Sensitive	Resistant	Comments
(H) Isoniazid			
(R) Rifampicin			
(Z) Pyrazinamide			
(E) Ethambutol			
(S) Streptomycin			

Date:_____ Signature:_____

Revised National Tuberculosis Control Programme

ANNEX 3E

Treatment Card

State _____ City / District with code_____ Name of TB Unit with Code_____

Name _____ Patient TB No / Year:_____

Sex M ☐ F ☐ Age _____ Occupation _____ PHI: _____

Complete Address_____ Name and designation of DOT provider_____

_____

Name and Address of Contact Person _____ DOT center_____

_____

Initial home visit by _____ Date_____ Signature of MO with date_____

Disease Classification	Type of patient	
☐ Pulmonary	☐ New	☐ Relapse
☐ Extra Pulmonary	☐ Transfer in	☐ Failure
site_____	☐ Treatment after default	☐ Other(Specify)_____

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

H/o previous Anti-TB treatment with duration _____

I. INTENSIVE PHASE - Prescribed regimen and dosages:

Tick (✓) the appropriate Category below

Category I ☐

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

3 times / week

H	R	Z	E

Category II ☐

Retreatment, (relapses, failure, treatment after default, others)

3 times / week

H	R	Z	E	S

Category III ☐

New Case
(Pulmonary Smear Negative, not seriously ill: or extra pulmonary, not seriously ill)

3 times / week

H	R	Z

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

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

II Continuation Phase

Prescribed regimen and Dosages

Category I ☐ 3 times / week

H	R

Category II ☐ 3 times / week

H	R	E

Category III ☐ 3 times / week

H	R

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

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

Treatment out come with date _____

Signature of MO with date _____

Details of X ray / EP tests

Contacts (Children < 6 yrs)

No	Chemoprophylaxis

Remarks _____

Retrieval actions for missed doses

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

ANNEX 3F

Tuberculosis Identity Card

Front

Revised National Tuberculosis Control Programme IDENTITY CARD

Name of Patient: _____

Complete address:_____

_____

TU / district name _____

_____**Ph**_____

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

PHI:_____

Disease Classification
☐ Pulmonary
☐ Extra-pulmonary
Site:_____

Treatment Started on

Date Month Year

Type of Patient
- New
- Relapse
- Treatment after default
- Failure
- Transfer In
- Other-Specify _____

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

Back

Follow up sputum examination

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

Appointment dates

IP	CP
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Treatment outcome with date:

Signature and stamp of MO with date:

_____

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

ANNEX 3 G

RNTCP SUPERVISION REGISTER

SUMMARY OF OBSERVATIONS AND RECOMMENDATIONS OF VISIT

Name of health facility visited:	Date of visit:
Name and designation of the person completing this form:	
Number of visits made to this health facility in the current year (including the current visit):	

Key Observations and Recommendations	Responsible	What actions were taken [1]
Politico-administrative commitment and resource management: (including staffing, training, review meetings, etc)		
Diagnosis: (including binocular microscope, civil works, TB suspects undergoing sputum microscopy, sputum positivity rate, initiation of treatment, missing “diagnosed” patients, case detection, quality assurance, whether DMC functional, visits by STLS, referral system for diagnosed cases, etc)		
Drugs and lab consumables: (including drug stock levels in “months” as on last date of previous month, whether there was any stock-out of drugs or lab consumables for more than 7 days since last visit, etc)		
DOT and follow-up: (including adequacy of number of DOT-centers, health system delays in initiation of treatment, timeliness of sputum follow-ups, DOT-as-per-guidelines, outcome, patient transfer-out system, etc)		
Records and Reports: (including timeliness, completeness and correctness of records and reports: DMC-register, treatment cards, identity cards, TB register, transfer/referral forms, monthly PHI reports, quarterly TU reports, etc)		
IEC Activities: (whether adequate currently, future plans, etc)		
Special Groups: (pediatrics, slums, scheduled caste/tribe, etc)		
Findings of home visit of patients (categorization, DOT happening as per guidelines in IP & CP , follow up sputum microscopy correctly done & recorded)		

[1] *To be reviewed and mentioned during the subsequent supervisory visit*

ANNEX 3 H

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 Facility	Reason for Examination*		Results			Signature	Remarks
							Diagnosis	Follow-up	a	b	c		

If sputum is examined for diagnosis, put a tick (✓) mark in the space under “Diagnosis”

If sputum is examined for repeat diagnosis, put RE 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”

ANNEX 3 I

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME
Tuberculosis Laboratory Monthly Abstract
(Record Numbers)

Month Year 200.	TB Suspects Examined For Diagnosis	TB Suspects Found Positive	TB suspects Undergoing Repeat Sputum Examination	TB suspects Found Positive on Repeat Examination	Follow-up Patients examined	Patients Positive on Follow up	Total Slides Examined	Total Positive slides	Total Negative slides	Signature of LT and STLS
Jan										
Feb										
Mar										
Apr										
May										
Jun										
Jul										
Aug										
Sep										
Oct										
Nov										
Dec										
Total										

Signature of the M.O.

ANNEX 3J

FORMAT OF REFERRAL FOR TREATMENT REGISTER

S. No	Date of referral	Name	Age	Sex	Complete Address[1]	Lab Serial No	Date of sputum exam[2]	Sputum results[2]	Diagnosis			Referred to PHI/TU/ District (Name)	Date of feedback from receiving health facility/Date of starting treatment[3]
									P/EP	Type of patient (N/R/F/ TAD/O)	Cat (I/II/III)		

[1] Complete address of the patient where he/she will be residing during the course of treatment and where he/she can be contacted.

[2] if a extra-pulmonary TB patient, it should be written whether the patient was diagnosed on clinical examination alone or by additional technique which should be specified.

[3] The date when the feedback is received by the referring health facility from the receiving health facility that the patient has been received by that unit, should be written here. Also the date that the patient started on treatment should be written here. In addition, if available the patient's TB number should be written in here.

Note: For patients referred within a district, if no feedback has been received by the referring health facility from receiving health facility within 14 days of the referral date, the STS responsible for the referring health facility should be informed. They should then subsequently take up the matter with the STS of the receiving health facility during the regular meetings of the STS of the respective district.

ANNEX 3K

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Tuberculosis Register

TB No.	Date of Registration	Name (in full)	Sex M/F	Age	Complete address	Name of PHI	Date of starting treatment	Treatment category (I, II, III, ND1, ND2)	Disease class (P/EP)	Type of Patient*	Pretreatment Sputum Examination			
											Date	DMC Name	Lab No	Smear

SUMMARY								
Regimen	New Smear-positive		Relapse		New Smear-negative		New Extra pulmonary	
	M	F	M	F	M	F	M	F
DOTS								
Non-DOTS								

✸Type of Patient (do not use abbreviation)

- New
- Relapse
- Transferred in
- Failure
- Treatment after Default
- Others

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Tuberculosis Register

Follow-up Sputum examinations												Treatment Outcome *		Remarks
End of I.P / Extended IP				2 months in CP				End of treatment				Outcome	Date	
Date	DMC Name	Lab No	Smear	Date	DMC Name	Lab No	Smear	Date	DMC Name	Lab No	Smear			

SUMMARY (DOTS cases only)						
Type of Patient	Cured	Treatment Completed	Died	Failure	Defaulted	Transferred out
New Smear Positive						
New Smear Negative						
New Extra-pulmonary						
Relapse						
Failure						
Treatment After Default						
Others treated with Cat - II						

✱Treatment outcomes (do not use abbreviation)

- **Cured**
- **Treatment completed**
- **Died**
- **Defaulted**
- **Failure**
- **Transferred out**

ANNEX 3L

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Monthly Report on Programme Management, Logistics and Microscopy

Peripheral Health Institution Level

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

Name of Peripheral Health Institution: _____

TU: _____ **District:** _____

Month: _____ **Year:** _____

Medications

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

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

Staff Position and Training

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

** STLS to be reported by medical colleges only*

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

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

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

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

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

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

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

Item	Unit of Measure-ment	Stock on first day of Month	Stock received during Month	Consumption during Month	Stock on last day of Month	Quantity requested
Sputum containers*	Nos.					
Slides	Nos.					
Carbol Fuchsin	Litres					
Methylene Blue	Litres					
Sulphuric Acid	Litres					
Phenol/hypochlorite	Litres					
Immersion Oil	mL					
Methylated Spirit	Litres					

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

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

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

Name of officer reporting (in Capital Letters) : .

Signature :_____ .

Date : _____

ANNEX 3M

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME
Quarterly Report on New and Retreatment Cases of Tuberculosis

Patients registered during ____ quarter of 200__.		Name of area _____. No.#_____

Name of Reporter:_____.

Signature : _____

Date of completion of this form

Block 1 : All new and relapse patients registered in the quarter

Pulmonary tuberculosis							New extra-pulmonary tuberculosis (4)		Total (5)		
Smear-positive					New smear-negative (3)						
New cases (1)			Relapses (2)								
M	F	Total	M	F	M	F	M	F	M	F	Total

Block 2 : Smear – positive new cases only : from Column (1) above

Age – group (years)														Total		
0 –14		15 –24		25 – 34		35 – 44		45 – 54		55 – 64		65 and above				
M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	Total

Block 3 : Treatment regimen given

Type of patient	Category I				Category II				Category III				Total
	Smear-positive		Smear-negative/ extra-pulmonary		Smear-positive		Smear-negative/ extra-pulmonary		Smear-negative		Extra-pulmonary		
	0-14	Above 14	0-14	Above 14	0-14	Above 14	0-14	Above 14	0-14	Above 14	0-14	Above 14	
New													
Relapses													
Failures													
Treatment after default													
Others													
Total													

Notes: Quarterly: 1st quarter January, February, March
2nd quarter April, May, June
3rd quarter July, August, September
4th quarter October, November, December

ANNEX 3N

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Quarterly Report of Sputum Conversion of New and Retreatment cases Registered 4-6 Months Earlier

Patients Registered during
_____quarter of 200 _____.

Name of area: _____
No. _____

Name of reporter: _____
Signature:_____

Date of completion of this form:

Complete this proforma for sputum smear-positive patients. The total no should be the same as in the Quarterly Report on New and Retreatment Cases of Tuberculosis.

Total no. of New Sputum – Positive Patients	Sputum at the end of IP (2 months)			Sputum at the end of extended IP (3 months)		
	Negative	Positive	N.A.	Negative	Positive	N.A.

Total no. of Sputum – Positive Relapse Patients	Sputum at the end of IP (3 months)		
	Negative	Positive	N.A.

Total no. of **Sputum – Positive Failure Patients**	Sputum at the end of IP (3 months)		
	Negative	Positive	N.A.

Total no. of Sputum – Positive Treatment After Default Patients	Sputum at the end of IP (3 months)		
	Negative	Positive	N.A.

N.A.: Not available. Sputum Examination was not done.

ANNEX 3O

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME
Quarterly Report on the Results of Treatment of
Tuberculosis Patients Registered 13-15 Months Earlier

Name of area:_____. No: _____. Date of completion of this form _____	Patients registered during _____ quarter of_____ .	Name of Reporter*: _____. Signature :

Patient reported during quarter **		Type of Patient	Cured (1)		Treatment completed (2)		Died (3)		Failure (4)		Defaulted (5)		Transferred to another district (6)		Total number evaluated (sum of columns 1 to 6)	
Male	*Female*	*NEW CASES*	*Male*	*Female*	*Male*	*Female*	*Male*	*Female*	*Male*	*Female*	*Male*	*Female*	*Male*	*Female*	*Male*	*Female*
Total			*Total*		*Total*		*Total*		*Total*		*Total*		*Total*		*Total*	
		Smear-positive														
		Smear-negative														
		Extra-pulmonary														
		Total New cases														
Male	*Female*	*RETREATMENT CASES*	*Male*	*Female*	*Male*	*Female*	*Male*	*Female*	*Male*	*Female*	*Male*	*Female*	*Male*	*Female*	*Male*	*Female*
Total			*Total*		*Total*		*Total*		*Total*		*Total*		*Total*		*Total*	
		Smear-positive relapses														
		Smear-positive failures														
		Smear-positive treatment after default														
		Others treated with Category II														
		Total Category II														

* The Reporter is the Medical Officer responsible not the person completing this form. This form includes patients on category I, category II and category III treatment both smear-positive and smear-negative. These totals should match those of the Quarterly Report on New & Retreatment cases for the quarter.

** Of these, _____ (number) were excluded from evaluation of chemotherapy for the following reasons.

ANNEX 3P

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Quarterly Report on Programme Management and Logistics
Tuberculosis Unit Level (including Tuberculosis Unit at DTC)

Name of the TB Unit: _____. **State: _____.**

Name of the District: _____. **Quarter: _____.**

Total population of the TB Unit (in numbers): _____. **year: __._____**

Stake- holders	Public Sector (including Medical Colleges, Govt. health department, other Govt. department and PSUs)	Private Sector (Private Medical college, Private practitioners, Private Clinics/Nursing Homes, and Corporate sector)	NGOs	Total (in the TU)
Number of DMC				

A. Number of PHIs expected to submit monthly PMRs	
B. Number of PHIs that submitted monthly PMRs for all 3 months in the quarter	

The following reports are enclosed (Tick [✓] to indicate that the report is enclosed)

- ❑ Quarterly Report on Case - Finding
- ❑ Quarterly Report on Sputum – Conversion
- ❑ Quarterly Report on Results of Treatment

If any report is not enclosed, give reason _____

Supervisory activities

Type of Unit	Number of (1) in the TB Unit	Number of (2) participating in the RNTCP	Number of these (3) visited * during quarter by		
(1)	(2)	(3)	(4)		
			MO-TC	STS	STLS
D Microscopy Centres					
PHIs other than DMC					
Medical College					
TB Hospital					
Other Govt. hospitals					
Treatment Observation Centres/DOT providers					
Non-governmental organization health facilities					
Private sector hospital/ Nursing home					
Patients					
VCTC					

Referral Activities

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

Microscopy Activities

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

Treatment Initiation

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

Quality of DOTS implementation

1. Number (%) of PHIs referring 2-3% of New Adult out patients for sputum examination	
2. Number (%) of NSP cases started on RNTCP DOTS treatment within 7 days of diagnosis (Information from TB Register)	
3. Number (%) of NSP cases registered within one month of starting RNTCP DOTS treatment (Information from TB Register)	
4. Number (%) of NSP cases on RNTCP DOTS treatment who received DOT during IP as per guidelines [Information from patient interviews conducted by MO-TC during the quarter]	
5. Number (%) of cured NSP cases* having end of treatment follow-up sputum examination done within one week of last dose (Information from TB Register)	

** These cases should be from the same quarterly cohort which have been included in the report on Results of Treatment*

Laboratory Quality Control Network (Unblinded On-site supervision)

Initial Reading	Total number of slides	Number of slides cross-checked by STLS	Supervisor reading		Total number of discordant slides
			Number of positives	Number of negatives	
Positive slides					
Negative slides					

Staff Position and Training

(Tick [√] if in place or not during quarter and trained or not)

Medical Officer_-TB Control (MO-TC) ❑Yes ❑No Trained in RNTCP ❑Yes ❑No

Full-time Senior Treatment Supervisor (STS) ❑Yes ❑No Trained in RNTCP ❑Yes ❑No

F/T Senior Tuberculosis Laboratory Supervisor (STLS) ❑Yes ❑No Trained in RNTCP ❑Yes ❑No

Category of staff	Sanctioned	In Place	In place and trained in RNTCP	Trained in RNTCP in the quarter	Total trained in RNTCP since implemen-tation	Re-trained in RNTCP in the quarter
Medical Officer (at BPHC / PHC / CHC / other)						
All Laboratory Technicians/Microscopists in the TB Unit (including designated MCs)						
Laboratory Technician/Microscopist of designated MCs						
Pharmacist						
MPH Supervisor						
Multipurpose Health Worker or equivalent						

Medications

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during the quarter	Patients initiated on treatment	Stock on last day of Quarter (a+b) – (c)	Quantity Requested [(c/3) x 4] – (d)
		(a)	(b)	(c)	(d)	(e)
Category I	Boxes					
Category II	Boxes					
Category III	Boxes					

Item	Unit of Measur ement	Stock on first day of Quarter	Stock received during the quarter	Consum-ption during Quarter	Stock on last day of Quarter (a+b) – (c)	Quantity Requested
		(a)	(b)	(c)	(d)	(e)
Prolongation pouches	Pouch					
INH 300 mg	Tablets					
INH 100 mg	Tablets					
Streptomycin 0.75 g	Vials					
Rifampicin 150 mg	Capsule s					
Pyrazinamide 500 mg	Tablets					
Ethambutol 800 mg	Tablets					

Is there any drug at the risk of expiry*? Yes No
If yes attach details

* Cat I 12 months Cat II 14 months Cat III 11 months
Is there any expired drugs ? Yes No
If yes attach details

Consumables

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during Quarter	Consumption during Quarter	Stock on last day of Quarter	Quantity requested
Sputum containers	Nos.					
Slides	Nos.					
Carbol Fuchsin	Grams					
Methylene Blue	Grams					
Sulphuric Acid 25%	Litres					
Phenol	Grams					
Immersion Oil	mL					
Methylated Spirit	Litres					

Equipment in place

Item	Number in place	In working condition	Not in working condition and since when
Monocular microscopes			
Binocular microscopes			
Two-wheeler			

Vehicle for MO-TC: ❑ Jeep in working condition ❑ Hired vehicle ❑ Personal vehicle ❑ None

Name of Medical Officer Tuberculosis Control reporting (in Capital Letters) : ——————

Signature: _____.

Date: _____.

ANNEX 3Q

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Quarterly Report on Programme Management and Logistics

District Level

Name of the District: _____ State : _____ .
Total population of the District (in numbers): _____ Quarter: _____.
Population of the District covered by the RNTCP (in numbers): _____ Year:_____.

Stakeholders	Public Sector (including Medical Colleges, Govt. health department, other Govt. department and PSUs)	Private Sector (Private Medical college, Private Practitioner, Private Clinics/Nursing Homes and Corporate sector)	NGOs	Total (in the district)
Number of TU				
Number of DMC				

The following reports are enclosed (Check [√] to indicate that report is enclosed)

- ❑ Quarterly Report on Case Finding (number of TB Units reporting* : _____)
- ❑ Quarterly Report on Sputum Conversion (number of TB Units reporting* : _____)
- ❑ Quarterly Report on Treatment Outcomes (number of TB Units reporting* : _____)
- ❑ Quarterly Report on Programme Management and Logistics (number of TB units reporting*: ____)

*If any TB Unit did not report, list name(s) and report(s) _____

A. Number of PHIs expected to submit monthly PMRs	
B. Number of PHIs that submitted monthly PMRs for all 3 months in the quarter	

Supervisory activities by the Staff of the DTC (DTO and second MO of DTC)

Type of Unit	Number of (1) in the District	Number of (2) participating in the RNTCP	Number of these (3) visited * during quarter by	
(1)	(2)	(3)	(4)	
			DTO	MO(s)-DTC
Tuberculosis Units				
Designated MCs				
PHIs other than DMCs				
TB Hospital/ Medical College				
Other Govt. hospitals				
Treatment Observation Centres/DOT providers				
Non-governmental organization health facilities				
Private sector hospital/ Nursing home				
Patients				
VCTC				

** Write only the number of health facilities visited and not the number of times that they were visited*

Referral Activities

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

Microscopy Activities

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

Treatment Initiation

h.	Of the smear-positive patients diagnosed (g), number put on DOTS within the district	
i.	Of the number of smear-positive patients diagnosed (g), number put on RNTCP Non-DOTS (ND1) within the district	
j.	Of the smear-positive patients diagnosed (g), the number referred for treatment outside the district	
k.	Initial defaulters k = g – (h+i+j)	

Quality of DOTS implementation

1.	Number (%) of NSP cases started on RNTCP DOTS treatment within 7 days of diagnosis (Information from TB Unit PMR report)	
2.	Number (%) of NSP cases registered within one month of starting RNTCP DOTS treatment (Information from TB Unit PMR report)	
3.	Number (%) of interviewed NSP cases on RNTCP DOTS treatment who received DOT during IP as per guidelines (Information from patient interviews conducted by the DTO and MO-DTC during the quarter)	
4.	Number (%) of cured NSP cases* having end of treatment follow-up sputum examination done within one week of last dose (Information from TB Unit PMR)	

** These cases should be from the same quarterly cohort which have been included in the report on Results of Treatment*

TB-HIV (to be reported by districts/states implementing TB-HIV Action Plan)

Referral of suspected tuberculosis cases from VCTC to RNTCP diagnostic units

		HIV positive	HIV Negative
a)	Number of persons suspected to have TB and referred to RNTCP Unit		
b)	Out of the above persons (a), number diagnosed as having:		
	(i) Sputum Positive TB		
	(ii) Sputum Negative TB		
	(iii) Extra-Pulmonary TB		
Total diagnosed TB patients			
c)	Out of above total (b) diagnosed TB patients, number receiving DOTS		

Random blinded re-checking of routine slides at DTC.

Number (%) of DMCs with High False Results (HFN and/or HFP results) in the year (January to December):

Staff Position and Training

(Tick {✓} if in place or not during quarter and trained or not)

District Tuberculosis Officer in place	❑ FT* ❑ PT*	❑ No	Trained in RNTCP	❑ Yes	❑ No		
Statistical Assistant in place	❑ Yes	❑ No	Trained in RNTCP	❑ Yes	❑ No		
Treatment Organizer in place	❑ Yes	❑ No	Trained in RNTCP	❑ Yes	❑ No		
Laboratory Technician in place	❑ Yes	❑ No	Trained in RNTCP	❑ Yes	❑ No		
Data Entry Operator	❑ Yes	❑ No	Trained in EpiCentre	❑ Yes	❑ No		
Driver	❑ Yes	❑ No					

* FT Full-time PT Part-time

Indicate numbers at all Tuberculosis Units and DTC combined

Category of staff	Sanctioned	In Place		In place and trained in RNTCP	Trained in RNTCP in past quarter	Total trained in RNTCP since implemen-tation	Re-trained in RNTCP in past quarter
		State Government Staff/staff from other programmes	Contractual staff under RNTCP				
Second Medical Officer of the DTC							
Designated Medical Officer (MO-TC) of the TB Unit							
Medical Officer (at BPHC / PHC / CHC/other)							
Senior Treatment Supervisor (STS)							
Senior Tuberculosis Laboratory Supervisor (STLS)							
All Laboratory Technicians/ Microscopists in the district (including designated MCs)							
Treatment Organizer							
Pharmacist							
MPH Supervisor							
Multipurpose Health Worker or equivalent							
TB Health Visitor							

Medications

Item	Unit of Mea-sure-ment	Stock on first day of Quarter	Stock received during the quarter	Stock trans-ferred in	Reconsti-tution of boxes during Quarter	Stock Trans-ferred Out *	Patients started on treatment	Stock on last day of Quarter (a+b+c+d) – (e+f)	Quan-tity Requ ested [(f/3) X 7]-g
		(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
Category I	Boxes								
Category II	Boxes								
Category III	Boxes								

Item	Unit of Measure-ment	Stock on first day of Qtr	Stock recei-ved during the Qtr	Stock transfer red in	Recon-stitu-tion of boxes during Qtr	Stock Trans ferred Out *	Consum ption during Qtr	Stock on last day of Qtr (a+b+c +d) – (e+f)	Quan-tity Requ ested
		(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
Pouches of blister strips for prolongation of intensive phase	Pouches each with 12 blister strips								
INH 300 mg	Tablets								
INH 100 mg	Tablets								
Streptomycin 0.75 g	Vials								
Rifampicin 150mg	Capsules								
Pyrazinamide 500 mg	Tablets								
Ethambutol 800 mg	Tablets								

* Enclose copy of drug transfer out form

Is there any drug at the risk of expiry**? Yes No

If yes attach details

** Cat I 12 months Cat II 14 months Cat III 11 months

Is there any expired drugs ? Yes No

If yes attach details

Consumables

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during Quarter	Consumption during Quarter	Stock on last day of Quarter
Sputum containers	Nos.				
Slides	Nos.				
Basic Fuchsin	Gms				
Methylene Blue	Gms				
Sulphuric Acid Conc	Litres				
Phenol	Grams				
Immersion Oil	mL				
Methylated Spirit	Litres				

Equipment in place

Item	Number in place	In working condition	Not in working condition and since when
Monocular microscopes			
Binocular microscopes			
X-ray machine of DTC			
Photocopier			
Computer			
Internet connection			
Overhead projector			
Fax machine			
Two-wheeler			

Vehicle for DTO: Jeep in working condition . Hired vehicle . None

Participation of Medical Colleges and TB Hospitals

(a) Nature of ownership

Health facility	Government		Private		Total	
	With RNTCP facility	Without RNTCP facility	With RNTCP facility	Without RNTCP facility	With RNTCP facility	Without RNTCP facility
Medical Colleges						
TB Hospitals						

Staff provided on contractual basis to Medical Colleges

Category of Staff	Total number in the district
MO	
STLS	
LT	
TBHV	

Number of NGOs participating in RNTCP (signed as well as unsigned schemes) during the quarter*: _____ (No.)

	Scheme I	Scheme II	Scheme III	Scheme IV	Scheme V
Signed					
Unsigned					
Total					

** In the event of an NGO participating in more than one scheme, the NGO may be shown against the higher scheme adopted (enter one facility against one scheme only).*

Number of Private Hospitals/ Practitioners participating in RNTCP (signed as well as unsigned schemes) during the quarter:_____(No.)**

	Scheme I	Scheme II	Scheme III A	Scheme III B	Scheme IV A	Scheme IV B
Signed						
Unsigned						
Total						

*** In the event of a private sector facility participating in more than one scheme, the private sector facility may be shown against the higher scheme adopted (enter one facility against one scheme only).*

Attach list of NGOs and private sector institutions, which have started participating in any of the above schemes in the most recent quarter including name, address, and scheme.

IEC

Number of patient-provider group interaction meetings held during the quarter reported on:

Number of community meetings held during the quarter reported on:

Financial management

a. Budget proposed by the district as per the Annual Action Plan

b. % of budgeted funds received from State during the financial year (from SOE and Annual Action Plan)

c. Total available funds [unspent balance brought forward from previous financial year + budget received]

d. % of available funds (c), expended during the financial year (from SOE and Annual Action Plan)

Name of District (Municipal) Tuberculosis Officer reporting (in Capital Letters) _____

Signature: _____.

Date: _____.

ANNEX 3R

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Quarterly Report on Programme Management and Logistics

State Level

Name of the State: _____ Quarter: _____
E-mail address of STO: _____. Year: _____
Number of RNTCP districts/reporting units in the State: _____
Number of RNTCP districts/reporting units with DTC: _____
The following reports are enclosed (Tick [√] to indicate that report is enclosed)

- ❑ Quarterly Report on Case Finding (number of Units reporting*: _____)
- ❑ Quarterly Report on Sputum Conversion (number of Units reporting*: _____)
- ❑ Quarterly Report on Results of Treatment (number of Units reporting*: _____)
- ❑ Quarterly Report on Programme Management and Logistics (number of Units reporting*:___)
- ❑ Quarterly Report on Infrastructure and Activities of STDC:
- ❑ Quarterly Report on State Task Force on Medical Colleges

(Unit – This would generally be the district, however in certain cases the district may have 2 or more separate reporting units like Municipal Corporation and rural areas. Each reporting unit should be counted for reporting purpose)
*If any unit did not submit reports, list name(s), report(s), reason(s) and action taken _____

Supervision and monitoring by the State

Number of districts in the RNTCP visited during quarter (By STO, Dy STO, MO at STC and/or STDC officials)	Number of districts not visited, attach list of districts not visited with reason/s

Review meeting of all DTOs of RNTCP Districts held this quarter? ❑ **Yes** ❑ **No**
If Yes: attach minutes. If No; reason/s _____
Was TU-wise analysis done and distributed to all districts? (if yes, attach) ❑ **Yes** ❑ **No**
Was individual district feedback provided to the districts? ❑ **Yes** ❑ **No**

Referral Activities

a.	Number of new adult outpatients attending different health facilities	
b.	Out of (a), number of chest symptomatics referred for sputum examination	

Microscopy Activities

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

Treatment Initiation

h.	Of the smear-positive patients diagnosed (g), number put on DOTS within the districts	
i.	Of the number of smear-positive patients diagnosed (g), number put on RNTCP Non-DOTS (ND1 and ND2) within the districts	
j.	Of the smear-positive patients diagnosed (g), the number referred for treatment (inter-district)	
k.	Initial defaulters k= g – (h+i+j)	

Quality of DOTS implementation

Number (%) of NSP cases started on RNTCP DOTS treatment within 7 days of diagnosis (Information from District Report)	
Number (%) of NSP cases registered within one month of starting RNTCP DOTS treatment (Information from District Report)	
Number (%) of interviewed NSP cases on RNTCP DOTS treatment who received DOT during IP as per guidelines (Information from patient interviews conducted by STO, State TB Cell and STDC staff during the quarter)	
Number (%) of cured NSP cases* having end of treatment follow-up sputum examination done within one week of last dose (Information from District Report)	

** These cases should be from the same quarterly cohort which have been included in the report on Results of Treatment*

Number of districts for which an internal evaluation was performed in the quarter:_____
Number of District Internal Evaluation reports sent to CTD in the quarter:_____

TB-HIV (to be reported by districts/states implementing TB-HIV Action Plan)
Referral of suspected tuberculosis cases from VCTC to RNTCP

	HIV positive	**HIV Negative**
a) Number of persons suspected to have TB and referred to RNTCP Unit		
b) Out of the above persons (a), number diagnosed as having:		
(i) Sputum Positive TB		
(ii) Sputum Negative TB		
(iii) Extra-Pulmonary TB		
Total diagnosed TB patients		
c) Out of above total (b) diagnosed TB patients, number receiving DOTS		

Random blinded re-checking of routine slides done in the district

Total number of DMCs in the State:

Number (%) of DMCs with High False Results (HFN and/or HFP results) in the year (January to December):

Staff Position and Training during quarter (Tick [✓] if in place or not during quarter and trained or not)

State Tuberculosis Officer in place ❑ FT* ❑ PT* ❑ No Trained in RNTCP ❑ Yes ❑ No
Deputy State Tuberculosis Officer in place ❑ FT* ❑ PT* ❑ No Trained in RNTCP ❑ Yes ❑ No
Medical Officer State HQs. in place (Regular/Contractual)* ❑ Yes ❑ No Trained in RNTCP ❑ Yes ❑ No
IEC Officer in place (Regular/Contractual)* ❑ Yes ❑ No Trained in RNTCP ❑ Yes ❑ No
Accountant, State TB Cell in place (Regular/Contractual)* ❑ Yes ❑ No Trained in RNTCP ❑ Yes ❑ No

Other staff of State TB Cell

Secretarial Assistant (Regular/Contractual)* ❑ Yes ❑ No
DEO (Regular/Contractual)* ❑ Yes ❑ No Trained in Epi-Centre ❑ Yes ❑ No
Driver (Regular/Contractual)* ❑ Yes ❑ No
*Tick (✓) whatever is applicable for each category of staff above

Staff position for the whole state (all districts combined)

Category of staff	Sanctio-ned	In place		In place and trained in RNTCP	Trained in RNTCP in the quarter reported on	Total trained in RNTCP since impleme ntation	Re-trained in RNTCP in past quarter
		State Govt Staff	Contrac-tual under RNTCP				
District Tuberculosis Officer							
Medical Officer – STDC							
Medical Officer of the DTC							
Designated Medical Officer TB Control (MO-TC) of the TB Unit							
Medical Officer (at BPHC PHC/CHC/other)							
Senior Treatment Supervisor (STS)							
Senior Tuberculosis Laboratory Supervisor (STLS)							
Laboratory Technician/ Microscopist of all microscopy centres (including designated MCs)							
Laboratory Technician/ Microscopist of designated microscopy centres							
TB Health Visitor							
Pharmacist							
MPH Supervisor							
Treatment Organizer							
Multipurpose Health Worker or equivalent							

Details of training activities held at STDC/State level during this quarter

Category of trainees (specify if re-training)	No. of trainees batch-wise	From (Date)	To (Date)	Duration (Days)
	(a)			
	(b)			
	(c)			
	(d)			
Total training days				

Equipment in place

Item	Number in place			In working condition		
	State HQ	STDC	All RNTCP Districts	State HQ	STDC	All RNTCP Districts
Binocular microscopes						
X-ray machine of DTC						
Photocopier						
Computer						
Internet connection						
LCD projector						
Overhead projector						
Jeep						
10 seater bus						
Two-wheeler						
Fax machine						
Incubator						
Class I laminar flow cabinet						
Inspissator						
Centrifuge						

Drug susceptibility testing facility available ❑ Yes ❑ No Location:

State Drug Store Status

Functional State Drug Store for anti-TB drugs in place? ❑ Yes ❑ No
If yes: whether monthly drug-stock report attached? ❑ Yes ❑ No

Medications

Item	Unit of Mea-sure-ment	Stock on first day of Quarter	Stock received during the quarter	Stock trans-ferred in	Reconstit u-tion of boxes during Quarter	Stock Trans-ferred Out *	Patients started on treatment	Stock on last day of Quarter (a+b+c+d) – (e+f)	Quantity Requested [(f/3) x 10]-g
		(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
Category I	Boxes								
Category II	Boxes								
Category III	Boxes								

Item	Unit of Measur-ement	Stock on first day of Qtr	Stock received during the Qtr	Stock trans-ferred in	Recon-stitution of boxes during Qtr	Stock Trans-ferred Out *	Consu mption during Qtr	Stock on last day of Quarter (a+b+c +d) – e+f)	Qty Reque sted
		(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f)**	**(g)**	**(h)**
Pouches of blister strips for prolongation of intensive phase	Pouches each with 12 blister strips								
INH 300 mg	Tablets								
INH 100 mg	Tablets								
Streptomycin 0.75 g	Vials								
Rifampicin 150 mg	Capsules								
Pyrazinamide 500 mg	Tablets								
Ethambutol 800 mg	Tablets								

** Enclose copy of drug transfer out form*

% (and names) of districts having drug stocks for less than one month at the end of quarter (from "Medications" section of District PM Report):

Participation of Medical Colleges and TB Hospitals

(a) Nature of ownership

Health facility	Government		Private		Total	
	With RNTCP facility	Without RNTCP facility	With RNTCP facility	Without RNTCP facility	With RNTCP facility	Without RNTCP facility
Medical Colleges						
TB Hospitals						

(b) Staff provided on contractual basis to Medical Colleges

Category of Staff	Total number in the state
MO	
STLS	
LT	
TBHV	

NGOs participating in RNTCP (signed as well as unsigned schemes) during the quarter*: _____(No.)

	Scheme I	Scheme II	Scheme III	Scheme IV	Scheme V
Signed					
Unsigned					
Total					

** In the event of an NGO participating in more than one scheme, the NGO may be shown against the higher scheme adopted (enter one facility against one scheme only).*

Private Hospitals / Practitioners participating in RNTCP (signed as well as unsigned schemes) during the quarter: _____(No.)**

	Scheme I	Scheme II	Scheme III A	Scheme III B	Scheme IV A	Scheme IV B
Signed						
Unsigned						
Total						

*** In the event of a private sector facility participating in more than one scheme, the private sector facility may be shown against the higher scheme adopted (enter one facility against one scheme only).*

IEC

Number of patient-provider group interaction meetings held during the quarter reported on:
Number of community meetings held during the quarter reported on:

Financial management

a. Budget proposed by the State as per the Annual Action Plan _____
b. % of budgeted funds received from CTD during the financial year (from SOE and Annual Action Plan) [As a % of (a)] _____
c. Total available funds [unspent balance brought forward from previous financial year + budget received] _____
d. % of available funds (c), expended during the financial year (from SOE and Annual Action Plan)

Name of officer reporting (in Capital Letters with designation): _____

_____

Signature: _____

Date: _____

General Information on Anti -Tubercular Drugs used in RNTCP

Drug	Dosage (Thrice weekly Intermittent regimen)	Formulations	Mode of action	General Information
Isoniazid (H)	10-15mg/Kg	Tablet : • 75mg • 100mg • 150mg • 300mg	Bactericidal	• Isoniazid, the hydrazide of isonicotinic acid, is highly bactericidal against replicating tubercle bacilli. • It is rapidly absorbed and diffuses readily into all fluids and tissues. The plasma half-life, which is genetically determined, varies from less than 1 hour in fast acetylators to more than 3 hours in slow acetylators. • It is largely excreted in the urine within 24 hours, mostly as inactive metabolites.
Rifampicin (R)	10mg/Kg	Tablet • 75mg Capsule • 150mg • 450mg	Bactericidal	• A semisynthetic derivative of rifamycin, a complex macrocyclic antibiotic that inhibits ribonucleic acid synthesis in a broad range of microbial pathogens. It has bactericidal action and a potent sterilizing effect against tubercle bacilli in both cellular and extracellular locations. • Rifampicin is lipid-soluble. Following oral administration, it is rapidly absorbed and distributed throughout the cellular tissues and body fluids; if the meninges are inflamed, significant amounts enter the cerebrospinal fluid. A single dose of 600 mg produces a peak serum concentration of about 10 µg/ml in 2-4 hours, which subsequently decays with a half-life of 2-3 hours. • It is extensively recycled in the enterohepatic circulation, and metabolites formed by deacetylation in the liver are eventually excreted in the faeces. • Since resistance readily develops, rifampicin must always be administered in combination with other effective antimycobacterial agents. To prevent emergence of drug resistance unobserved rifampicin should no be given.
Pyrazinamide (Z)	35mg/Kg	Tablet • 250mg • 500mg • 750mg	Bactericidal	• A synthetic analogue of nicotinamide that is only weakly bactericidal against M. tuberculosis but has potent sterilizing activity, particularly in the relatively acidic intracellular environment of macrophages and in areas of acute inflammation. It is highly effective during the first 2 months of treatment while acute inflammatory changes persist and its use has enabled treatment regimens to be shortened and the risk of relapse to be reduced. • It is readily absorbed from the gastrointestinal tract and is rapidly distributed throughout all tissues and fluids. Peak plasma concentrations are attained in 2 hours and the plasma half-life is about 10 hours. • It is metabolized mainly in the liver and is excreted largely in the urine.

Drug	Dosage (Thrice weekly Intermittent regimen)	Formulations	Mode of action	General Information
Ethambutol (E)	30mg/Kg	Tablet • 200mg • 400mg • 600mg • 800mg	Bacteriostatic	• A synthetic congener of 1,2-ethanediamine that is active against M. tuberculosis, M. bovis and some nonspecific mycobacteria. It is used in combination with other antituberculosis drugs to prevent or delay the emergence of resistant strains. • It is readily absorbed from the gastrointestinal tract. Plasma concentrations peak in 2-4 hours and decay with a half-life of 3-4 hours. • Ethambutol is excreted in the urine both unchanged and as inactive hepatic metabolites. About 20% is excreted in the faeces as unchanged drug.
Streptomycin (S)	15mg/Kg	Powder for injection in a vial	Bactericidal	• An aminoglycoside antibiotic derived from Streptomyces griseus that is used in the treatment of TB and sensitive Gram-negative infections. • Streptomycin is not absorbed from the gastrointestinal tract but, after intramuscular administration, it diffuses readily into the extracellular component of most body tissues and attains bactericidal concentrations, particularly in tuberculous cavities. Little normally enters the cerebrospinal fluid, although penetration increases when the meninges are inflamed. • The plasma half-life, which is normally 2-3 hours, is considerably extended in the newborn, the elderly, and patients with severe renal impairment. • It is excreted unchanged in the urine.

Drug interactions and adverse reactions to anti-tubercular drugs used in RNTCP

Drug	Precautions	Drug Interactions	Contraindications	Adverse Reactions
Isoniazid (H)	• Monitoring of serum hepatic transaminases, where possible, in patients with pre-existing chronic liver disease. • Patients at risk of peripheral neuropathy, as a result of malnutrition, chronic alcohol dependence or diabetes, should additionally receive pyridoxine, 10 mg daily. Where the standard of health in the community is low, this should be offered routinely. • Since isoniazid interacts with anticonvulsants used for epilepsy, it may be necessary to reduce the dosage of these drugs during treatment with isoniazid.	Isoniazid • Raises plasma concentrations of phenytoin, carbamazepine, diazepam and warfarin by inhibiting their metabolism in the liver. • The absorption of isoniazid is impaired by aluminium hydroxide.	• Known hypersensitivity. • Active hepatic disease.	• Hepatitis • Peripheral neuropathy; • Pellagra-like syndrome; • skin rash; • drowsiness; • fatigue
Rifampicin ®	• Serious immunological reactions resulting in renal impairment, haemolysis or thrombocytopenia are on record in patients who resume taking rifampicin after a prolonged lapse of treatment. In this rare situation, it should be immediately and definitely withdrawn. • Careful monitoring of liver function is required in the elderly and in patients who are alcohol-dependent or have hepatic disease. • Patients should be warned that treatment may produce reddish coloration of urine, tears, saliva and sputum, and that contact lenses may be irreversibly stained.	• Rifampicin induces hepatic enzymes, and may increase the dosage requirements of drugs metabolized in the liver. These include corticosteroids, steroid contraceptives, oral hypoglycaemic agents, oral anticoagulants, phenytoin, cimetidine, cyclosporin and digitalis glycosides. • Since rifampicin reduces the effectiveness of oral contraceptives • Current antiretroviral drugs (NNRTIs and PIs) interact with rifampicin. This may result in ineffectiveness of antiretroviral drugs, ineffective treatment of TB or an increased risk of drug toxicity. • Biliary excretion of radiocontrast media and sulfobromophthalein	• Known hypersensitivity to rifamycins. • Hepatic dysfunction.	• Hepatitis • Flu-like syndrome; • Cutaneous syndrome -skin rash; • gastritis

Drug	Precautions	Drug Interactions	Contraindications	Adverse Reactions
		sodium may be reduced • Microbiological assays for folic acid and vitamin B 12 disturbed.		
Pyrazinamide (Z)	• Patients with diabetes should be carefully monitored since blood glucose concentrations may become labile. • Gout may be exacerbated.		• Known hypersensitivity. • Severe hepatic impairment.	• Hepatitis; • Arthralgia; • Gout; • Rashes;
Ethambutol (E)	• Patients should be advised to discontinue treatment immediately and to report to a clinician if their sight or perception of colour deteriorates. • Whenever possible, renal function should be assessed before treatment.		• Known hypersensitivity • Pre-existing optic neuritis from any cause. • Creatinine clearance of less than 50 ml/minute.	• Impairment of vision • Hyperuricemia • Nausea • Rashes
Streptomycin (S)	• Hypersensitivity reactions are rare. If they do occur (usually during the first weeks of treatment), streptomycin should be withdrawn immediately. Once fever and skin rash have resolved, desensitization may be attempted. • Streptomycin should be avoided in children, when possible, because the injections are painful and irreversible auditory nerve damage may occur. • Both the elderly and patients with renal impairment are also vulnerable to dose-related toxic effects resulting from accumulation. Where facilities are available to monitor renal function closely, it may be possible to give streptomycin in reduced doses to patients with renal impairment.	• Other ototoxic or nephrotoxic drugs should not be administered to patients receiving streptomycin. These include other aminoglycoside antibiotics, amphotericin B, cefalosporins, etacrynic acid, cyclosporin, cisplatin, furosemide and vancomycin. • Streptomycin may potentiate the effect of neuromuscular blocking agents administered during anaesthesia.	• Known hypersensitivity • Auditory nerve impairment. • Myasthenia gravis.	• Vestibular toxicity; • Renal toxicity; • hypersensitivity reactions • Exfoliative dermatitis • Eosinophilia

ANNEX 4C:

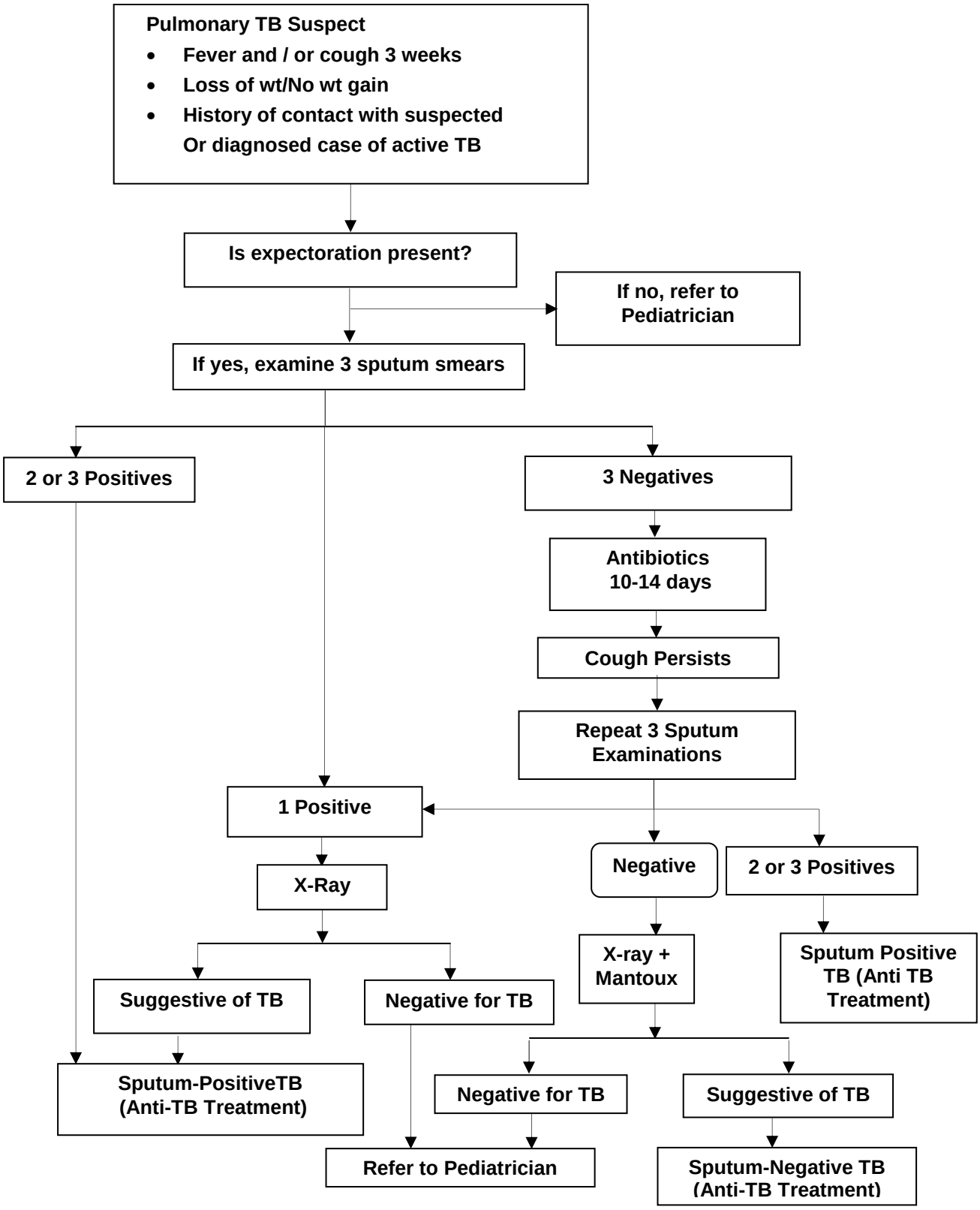
Symptom -based approach to evaluation of possible side effects of anti-TB drugs used in RNTCP

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

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

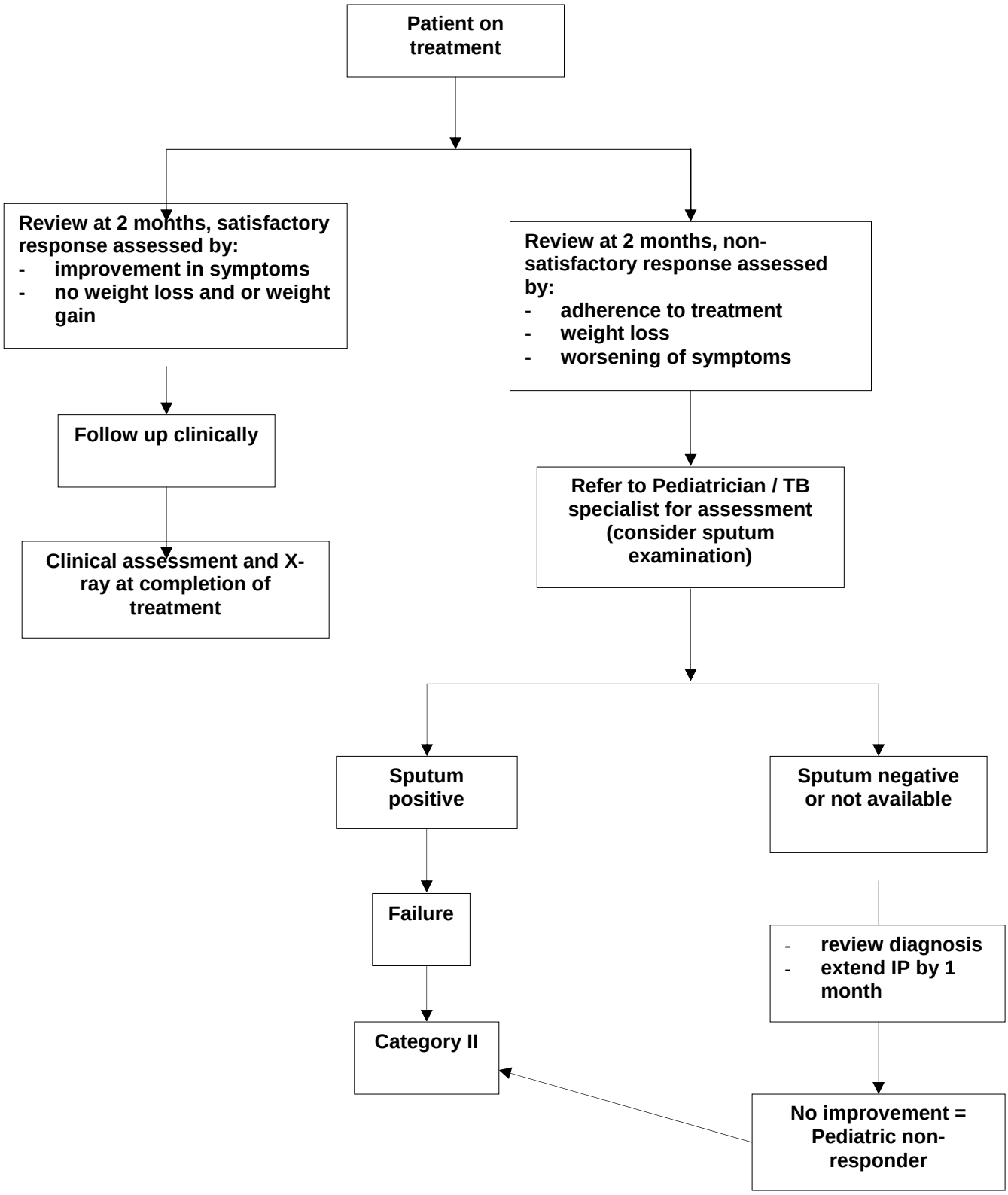
ANNEX 5A

Algorithm 1: Diagnostic Algorithm For Pediatric Pulmonary TB



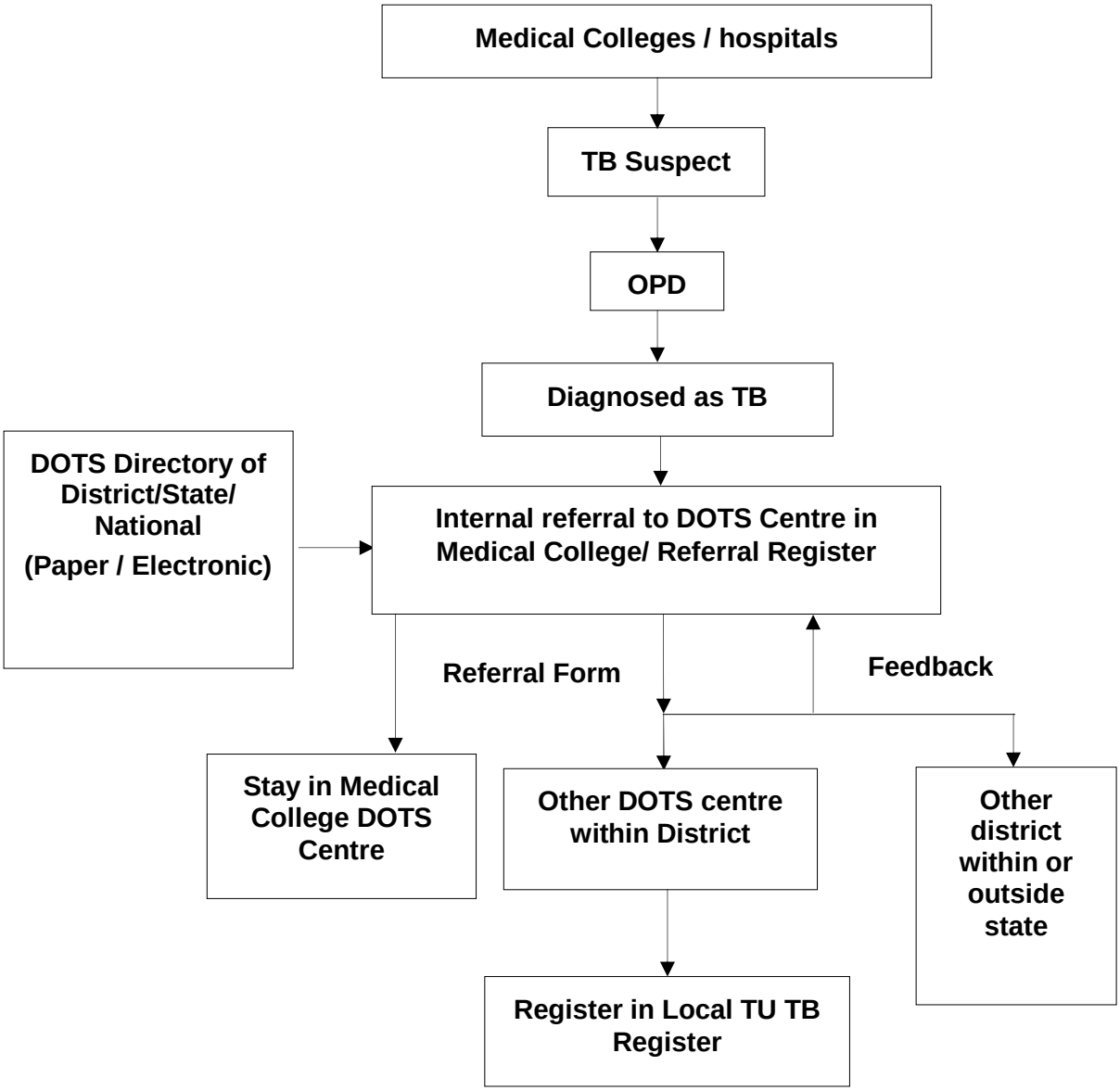
ANNEX 5B

Algorithm 2: for clinical monitoring



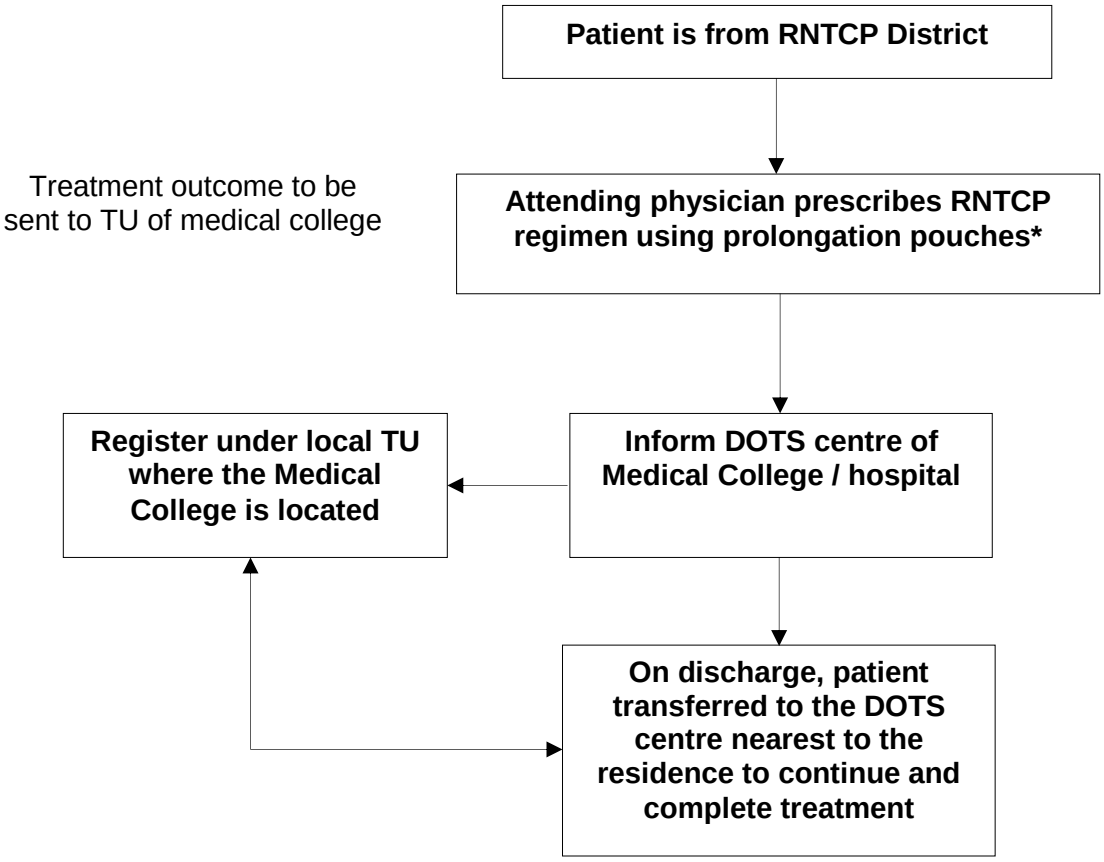
ANNEX 6A

Flowchart for Management of Outdoor patients in Medical Colleges / Large Hospitals



ANNEX 6B

Flowchart for management of Indoor patient in Medical College / Large Hospitals



*** If attending physician judges that RNTCP regimen is not appropriate for the individual patient, a non-RNTCP regimen will be prescribed**

DEFINITIONS: THE REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Case definitions	Types of cases	Treatment outcomes
Pulmonary Tuberculosis, Smear-Positive TB in a patient with at least 2 initial sputum smear examinations (direct smear microscopy) positive for AFB. Or: TB in a patient with one sputum smear 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 smear specimen positive for AFB and culture positive for M.tuberculosis. **Pulmonary tuberculosis, Smear-negative** TB in a patient with symptoms suggestive of TB with at least 3 sputum smear examinations negative for AFB, and radiographic abnormalities consistent with active pulmonary TB as determined by the treating MO followed by a decision to treat the patient with a full course of anti-tuberculosis therapy. Or: Diagnosis based on positive culture but negative AFB sputum smear examinations. **Extra Pulmonary tuberculosis** TB of any organ other than the lungs, such as the pleura (TB pleurisy), lymph nodes, intestines, genitourinary tract, skin, joints and bones, meninges of the brain, etc. Diagnosis should be based on culture-positive specimen from the extra-pulmonary site, histological, radiological, or strong clinical evidence consistent with active extra pulmonary TB followed by decision of the treating MO to treat with a full course of anti-TB therapy. Pleurisy is classified as extra pulmonary TB. A patient diagnosed with both sputum smear positive pulmonary and extra pulmonary TB should be classified as pulmonary TB.	**New** A TB patient who has never had treatment for tuberculosis or has taken anti-tuberculosis drugs for less than one month. **Relapse** A TB patient who was declared cured or treatment completed by a physician, but who reports back to the health service and is now found to be sputum smear positive. **Transferred in** A TB patient who has been received for treatment into a Tuberculosis Unit, after starting treatment in another unit where s/he has been registered. **Treatment after default** A TB patient who received anti-tuberculosis treatment for one month or more from any source and returns to treatment after having defaulted, i.e., not taken anti-TB drugs consecutively for two months or more, and is found to be sputum smear positive. **Failure** Any TB patient who is smear positive at 5 months or more after starting treatment. Failure also includes a patient who was treated with Category III regimen but who becomes smear positive during treatment. **Chronic** A TB patient who remains smear positive after completing a re-treatment regimen. **Others** TB patients who do not fit into the above mentioned types. Reasons for putting a patient in this type must be specified.	**Cured** Initially sputum smear-positive patient who has completed treatment and had negative sputum smears, on two occasions, one of which was at the end of treatment **Treatment completed** Sputum smear-positive patient who has completed treatment, with negative smears at the end of the intensive 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. **Died** Patient who died during the course of treatment regardless of cause **Failure** Any TB patient who is smear positive at 5 months or more after starting treatment. Failure also includes a patient who was treated with Category III regimen but who becomes smear positive during treatment. **Defaulted** A patient who has not taken anti-TB drugs for 2 months or more consecutively after starting treatment. **Transferred out** A patient who has been transferred to another Tuberculosis Unit/District and his/her treatment result (outcome) is not known.