Ministry of Health
& Family Welfare
Government of India

Revised National TB Control Programme

Technical and Operational Guidelines for Tuberculosis Control in India

2016

Central TB Division, Directorate General of Health Services
Ministry of Health & Family Welfare, New Delhi, India
www.tbcindia.gov.in

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Preface

The first technical & operational guidelines for Revised National TB Control Programme (RNTCP) were developed during the initial years of implementation of the programme & were updated in 2005. The current document outlines the guidelines on TB care in line with RNTCP National Strategic Plan for Tuberculosis Control 2012-17.

These guidelines were conceived by programme managers working at the national, state and district levels. Experts from national institutes, national and intermediate reference laboratories, medical colleges and partners were involved in the process of preparing it.

Standards for TB Care in India, National Strategic Plan document, Recommendations of the Joint Monitoring Mission 2012 and policy decisions taken in the National Committee on Diagnosis and Management of Tuberculosis under RNTCP, National Technical Working Group on TB-HIV, National Technical Working Group on Pediatric TB,Expert committee on regulation of newer anti-TB drugs were used as a foundation for developing this document. Existing technical and operational guidelines, training module for medical officers, National PMDT guidelines, National Air borne infection control guidelines, Revised pediatric TB guidelines, National guidelines on partnerships, Guidelines for Quality Assurance of smearmicroscopy for diagnosing tuberculosis, National Framework for Joint HIV/TBCollaborative Activities and Guidelines for use of Bedaquiline in RNTCP through conditional access under programmatic management of drug resistant TB in India have also been referred.

The document covers strategies and guidelines for diagnosis and treatment of all forms of TB including pulmonary, extra-pulmonary, drug resistant TB, TB with comorbidities, pediatric TB, etc. Programme management aspects covering patient support systems, human resource management, partnerships for TB control, advocacy, communication and social mobilization, infection control measures, planning and finance are also incorporated.

These technical and operational guidelines are intended to be used by all the personnel engaged in control of TB in the country. This is a living document open to further improvements and will be updated as lessons are learned through its use in the field.

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Introduction

Tuberculosis

Tuberculosis (TB) is an infectious disease caused predominantly by *Mycobacterium tuberculosis*. Tuberculosis is most commonly transmitted by inhalation of infected droplet nucleiwhich are discharged in the air when a patient with untreated TBcoughs or sneezes. TB disease usually affects the lungs,but can involve any part of the body.Pulmonary TB which affects lungs is an infectious form of disease. Extra-pulmonary TB can affect thelymph nodes, pleura, bones and joints, the genito-urinary tract, the nervous system(meningitis, tuberculoma), abdominal TB (intestines, mesentry, solid organs), skin, etc. All those who get infected do not necessarily develop TB disease. The life time risk ofbreaking down to disease among those infected with TB is 10–15%, which gets increasedto 10% per year amongst those co-infected with HIV. Other determinants such as diabetesmellitus, smoking tobacco products, alcohol abuse and malnutrition also increase the risk ofprogression from infection to TB disease.

Burden of TB

India accounts for one fourth of the global TB burden i.e. 2.2 million out of 9.6 million new cases annually. In India, more than 40% of population is infected (prevalence of infection) with *Mycobacterium tuberculosis*. It is estimated that there are 2.5 million prevalent cases of all forms of TB disease. It is also estimated that about 2.2 lakhs people die due to TB annually (mortality). The table below shows the estimated figures for TB burden globally and for India provided by WHO for the year 2014

	Incidence	Prevalence	Mortality
Global	9.6 million (176/lakh/year)	13 million (227/lakh/year)	1.1 million (21/lakh/year)
India	2.2 million (167/lakh/year)	2.5 million (195/lakh/year)	2.2 lakhs (17/lakh/year)

Source: Global TB Report 2015

TB now ranks alongside HIV as a leading cause of deathworldwide. TB kills more adults in India than any other infectious disease.
In India, every day:

- more than 6000 develop TB disease
- more than 600 people die of TB (i.e. 2 death every 5 minutes)

India has highest burden of both TB and MDR TB and second highest of HIV associated TB based on estimates reported in Global TB Report 2015. An estimated 71,000 cases of MDR-TB emerge annually from the notified cases of pulmonary TB in India. Based on sub-national DR surveys carried out in three states of India, ~3% among new TB cases and 12%-17% among previously-treated TB cases have MDR-TB. India bears second highest number of estimated HIV associated TB in the world. An estimated 1.1 lac HIV associated TB occurred in 2014 and 31,000 estimated number of patients died among them.

TB control strategy

The National Tuberculosis Programme of India (NTP) was initiated in 1962 and was originally designed for domiciliary treatment, using self- administered standard drug regimens.The NTP hadcreated an extensive infrastructure for TB control with a network of more than 446 District TB Centres, 330 TB clinics and more than 47,600 TB beds. The NTP had also raised the awareness of TB and TB treatment facilities, and had succeeded in placing more than 1.3 million patients on treatment annually. Despite the NTP being in existence since 1962, no appreciable change in the epidemiological situation of TB in the country had been observed. The HIV-AIDS epidemic and the spread of multi-drug resistance TB were threatening to further worsen the situation.

In view of this, in 1992, GoI, with WHO and SIDA reviewed the TB situation and the performance of the NTP. The observations revealed that the NTP, though technically sound, suffered from managerial weaknesses, inadequate funding, an over-reliance on X-Ray for diagnosis, had frequent interrupted supplies of drugs, and low rates of treatment completion. The Government decided to give a new thrust to TB control activities by revitalising the NTP, with assistance from international agencies. In 1993, the Revised National TB Control Programme was piloted in a population of 2.4 million in five states. This was later expanded to cover 13 million people by 1995, and 20 million by 1996.

In 1997, the RNTCP was launched as a national programme with a plan to scale up in a phased manner. The RNTCP thus formulated, adopted the internationally recommended Directly Observed Treatment Short-course (DOTS) strategy, as the most systematic and cost-effective approach to revitalise the TB control programme in India. Political and administrative commitment to ensure the provision of organised and comprehensive TB control services; reliable and early diagnosis through smear microscopy of self-reporting chest symptomatics in the general health services; an uninterrupted supply of good quality anti-TB drugs through patient wise boxes (PWBs); effective and patient-friendly treatment with SCC given under direct observation; and accountability through proper recording and reporting, and effective supervision were emphasised.

The objectives of the RNTCP were to achieve at least 85 percent cure rate among the new smear-positive cases initiated on treatment, and thereafter a case detection rate of at least 70 percent of such cases. The RNTCP was built on the infrastructure and systems built through the NTP. Major additions to the RNTCP, over and above the structures established under the NTP, was the establishment of a sub-district supervisory unit, known as a TB Unit, with dedicated RNTCP supervisors posted, and decentralization of both diagnostic and treatment services, with treatment given under the support of DOT providers. The entire country was covered by the end of 2005. The programme has made rapid strides ever since its implementation.The programme has consistently been achieving global benchmarks of case detection and treatment success rates since 2007.

The widespread implementation of the DOTS strategy has proved to be an effective tool in controlling TB on a mass scale and practiced in over 200 countries. The prime task for the next

decade was to achieve the Millennium Development Goals (MDGs) and related STOP TB Partnership targets for TB control. The target under MDG for tuberculosis is to halt and begin reversal of incidence of tuberculosis, malaria and other major diseases by 2015. The indicators were to reduce the prevalence and death rates by 50% between 1990 and 2015.

Meeting these targets required a coherent control strategy. The WHO released STOP TB Strategy in 2006 with six principal components to realize the global TB-related MDGs by 2015. These were pursuing high quality DOTS expansion and enhancement;Addressing TB/HIV, MDR-TB and other challenges;Contributing to health system strengthening;Engaging all care providers;Empowering patients and communities; andEnabling and promoting research.

India adopted the components of STOP TB Strategy and strived to achieve targets under it. National AIDS Control Programme (NACP) and RNTCP have developed "National framework of joint TB/HIV Collaborative activities" in 2007 which were revised in February 2008 to redefine the scope of TB/HIV collaborative activities being implemented in the country. Programmatic management of drug resistant (DR) TB services began in 2007 andnational coverage has been achieved in March 2013. Scope of engagement of all care providers was expanded with revisions in schemes for involvement of private providers and NGOs in 2008 and Global Fund supported engagement of professional associations like Indian Medical Association (IMA) and Catholic Bishop Conference of India (CBCI). Task force mechanisms were established to engage medical colleges to support patient care, training, advocacy and research.

Emboldened by its achievements, the programme in 12th Five Year Plan (2012-17) has articulated National Strategic Plan with a vision of TB Free India. The goal of the NSP is to achieve universal access to quality TB diagnosis and treatment for all TB patients in the community. The objectives of the National Strategic Plan are

1. To achieve 90% notification rate for all cases
2. To achieve 90% success rate for all new and 85% for re-treatment cases
3. To significantly improve the successful outcomes of treatment of DR-TB Cases
4. To achieve decreased morbidity and mortality of HIV-associated TB
5. To improve outcomes of TB care in the private sector

To achieve these objectives RNTCP further strengthened and improved the quality of basic DOTS services, align the sub-district level management unit with health system under National Health Mission [NHM], deploy improved rapid diagnostics to the field level, increase efforts to engage all care providers, strengthen urban TB Control, expand diagnosis and treatment of DR-TB, improving communication, outreach, and social mobilization and promoting research for development and implementation of improved tools and strategies. The Gazette of India, Ministry of Health and Family Welfare has notified for prohibiting the import of serodiagnostictest kits for TB and the manufacture, sale, distribution and use of such kits for TB, on 7th June 2012. A Government Order issued by the GOI in May 2012 mandates all healthcare providers to notify every TB case diagnosed and/or treated, to local authorities. To support TB notification and strengthen TB surveillance in general, a case based web based TB notification system – NIKSHAY was established to provide platform for notification from both public and private sector, decrease lead time of data transmission and increase use of information for programme management for betterment of care of delivery of services at local level.

RNTCP and World Health Organization jointly prepared Standards for TB Care in India (STCI) in 2014, which lays down uniform standards for TB care for all stakeholders in the country.

Standards for TB Care in India (STCI)

The vision of RNTCP is that the people suffering from TB receive the highest standards of care and support from all healthcare providers of their choice. It is spelt out in the National Strategic Plan (2012-17) to extend the umbrella of quality TB care and control to include those provided by the private sector.

The private sector holds a factual predominance of health care service delivery in India. There is very little information about TB patients from the private sector available to the programme and little is known about their quality of treatment, including treatment outcomes. The need for quality and standards for TB care is made particularly acute where a large unorganized private sector accounts for almost half of the TB care delivered in India.

Thus, it was felt essential to develop and disseminate the standards forTB care that is particularly relevant in Indian context, acceptable to the medical fraternity in both the public and private sector in India. Also, the availability of new diagnostic tools and strategies for early TB diagnosis, emerging evidences on existing regimens and newer regimens, and the need for better patient support strategies including addressing social inclusiveness necessitated the development of Standards for TB Care in India.

The standards in STCI differ from existing guidelines in that the standards present what should be done whereas guidelines describe how the action is to be accomplished. These standards represent the first what is expected from the Indian healthcare system. It is expected that the standards laid down in STCI are clear and usable and will be accessible to all TB providers as an easy reference.

Twenty six standards developed after a National Workshop with support from various public health administrators, programme managers, representatives from various professional associations (IMA, API, College of Physicians Association of India, IAP, FOGCI, etc.), academicians and specialists from public and private sectors (pulmonologists, physicians, surgeons, paediatricians, gynaecologists, orthopaedic surgeons, microbiologists, public health specialist etc.), donors, technical and implementation partners &pharmaceutical companies and pharmacists. There are six standards for diagnosis (standard 1 to 6), five for treatment (standard 7 to 11), nine for public health (standard 12 to 20) & six for social inclusion (standard 21 to 26).

The country achieved targets for TB under MDG and Stop TB Partnership. Post-MDG, the Global strategy & targets for prevention of TB care & control were endorsed by all member states at 2014 World Health Assembly. Achieving this global target is feasible only with the drastic decline in the TB deaths, cases & elimination of the catastrophic expenditures leading to elimination of economic & social burden of TB. To reach these ambitious goals, End TB strategy spells out the three pillars & components as in the table as below. Government of India is signatory to end TB strategy and is fully committed to implement its components under the programme.

END TB STRATEGY				
VISION	**A WORLD FREE OF TB** - Zero deaths, disease and suffering due to TB			
GOAL	**END THE GLOBAL TB EPIDEMIC**			
INDICATORS	**Milestones**		**Targets**	
	2020	2035	SDG 2030	End TB 2035
Reduction in number of TB deaths compared with 2015 (%)	35%	75%	90%	95%
Reduction in TB incidence rate compared with 2015 (%)	20% (<85/100,000)	50% (<55/100,000)	80% (<20/100,000)	90% (<10/100,000)
TB-affected family facing catastrophic costs due to TB (%)	0	0	0	0

PRINCIPLES

1. *Government stewardship and accountability, with monitoring and evaluation*
2. *Strong coalition with civil society organizations and communities*
3. *Protection and promotion of human rights, ethics and equity*
4. *Adaptation of strategy and targets at country level, with global collaboration*

PILLARS AND COMPONENTS

1. INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION

A. Early diagnosis of tuberculosis including universal drug-susceptibility testing, and systematic screening of contacts and high-risk groups
B. Treatment of all people with tuberculosis including drug-resistant tuberculosis, and patient support
C. Collaborative tuberculosis/HIV activities, and management of co-morbidities
D. Preventive treatment of persons at high risk, and vaccination against tuberculosis

2. BOLD POLICIES AND SUPPORTIVE SYSTEMS

A. Political commitment with adequate resources for tuberculosis care and prevention
B. Engagement of communities, civil society organizations, and public and private care providers
C. Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control
D. Social protection, poverty alleviation and actions on other determinants of tuberculosis

3. INTENSIFIED RESEARCH AND INNOVATION

A. Discovery, development and rapid uptake of new tools, interventions and strategies
B. Research to optimize implementation and impact, and promote innovations

Health System structure & functions for delivery of TB care

Healthcare is one of India's largest service sectors. Under the Indian Constitution, health is a state subject. Each state has its own healthcare delivery system in which both public and private (for profit as well as non-profit) actors operate.

Delivery of TB care in the public sector-

The organisation at the national level consists of the Union Ministry of Health and Family welfare (MoHFW). In each State, the organisation is under the State Department of Health and Family Welfare that is headed by a State Minister and with a Secretariat under the charge of the Secretary/ Commissioner (Health and Family Welfare).

a) **In 2005, National Rural Health Mission (NRHM**) was launched to provide accessible, affordable, accountable, effective and reliable primary health care facilities, to the rural population, especially vulnerable groups. In addition, the National Urban Health Mission (NUHM) was also launched to further strengthen urban health structure and both NUHM and NRHM have been clubbed together under National Health Mission (NHM) from 2013. The vision of NHM is "Attainment of Universal Access to Equitable, Affordable and Quality health care services, accountable and responsive to people's needs, with effective inter-sectoral convergent action to address the wider social determinants of health".

b) **NHM** further aims to provide support to the existing national programmes of health and family welfare including RCH-**II**, malaria, blindness control, iodine deficiency, filariasis, kala- azar, tuberculosis, and leprosy and for integrated disease surveillance

c) RNTCP is one of the components under the National Health Mission which is a flagship scheme under Govt. of India. The MoHFW follows equity-based approach to allocate funds under RNTCP to various States. The overall allocation is made on the basis of population of the states, disease burden and socio economic status. The financial management procedures for RNTCP are well established and administered by the Finance Cell of the CTD. These procedures are documented in manuals and guidelines available on the program's website.

I. Institutional arrangements: Overall responsibility for financial management of the program is with the Central Tuberculosis Division (CTD), Directorate General of Health Services, Ministry of Health & Family Welfare (DGHS) a part of the National Health Mission of the MoHFW. At state level these are through state TB cell and at district level through district TB cell.

ii. Budget and release of funds: Program expenditures are budgeted in the Demand for Grants of the MoHFW under the Disease flexi-pool funding arrangement under two separate budget lines for Externally Aided Component (EAC) and General Component (GC).

iii. Fund flow: Fund flow for the program will remain within the existing financial management systems of MoHFW, which operates through the Centralized Pay and Accounts Office. Funds are being released to state in 2-3 instalments. All the states are required to submit the annual audit report to CTD by 30th September.

RNTCP organogram

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

National Level

Central TB Division (CTD) of Directorate General Health Services (DGHS) is the technical arm of the Ministry of Health and Family Welfare (MoHFW). CTD, under the guidance of DGHS, manages the National TB Control Programme for the entire country at the central level through a National Programme manager, Deputy Director General TB (DDG-TB). The financial and administrative control of the programme is managed by the Joint Secretary from the administrative arm of the MoHFW.

The CTD is supported by *six national institutes*: National Institute for Research in Tuberculosis (NIRT), Chennai, National Tuberculosis Institute (NTI), Bangalore, National Institute of Tuberculosis and Respiratory Diseases (NITRD), Delhi, National JALMA Institute, Agra, Regional Medical Research Centre, Bhubaneshwar and BMHRC, Bhopal, and National Task Force of Medical Colleges.Various committees of experts to guide the programme at different levels on technical & policy matters are there supporting Central TB Division.

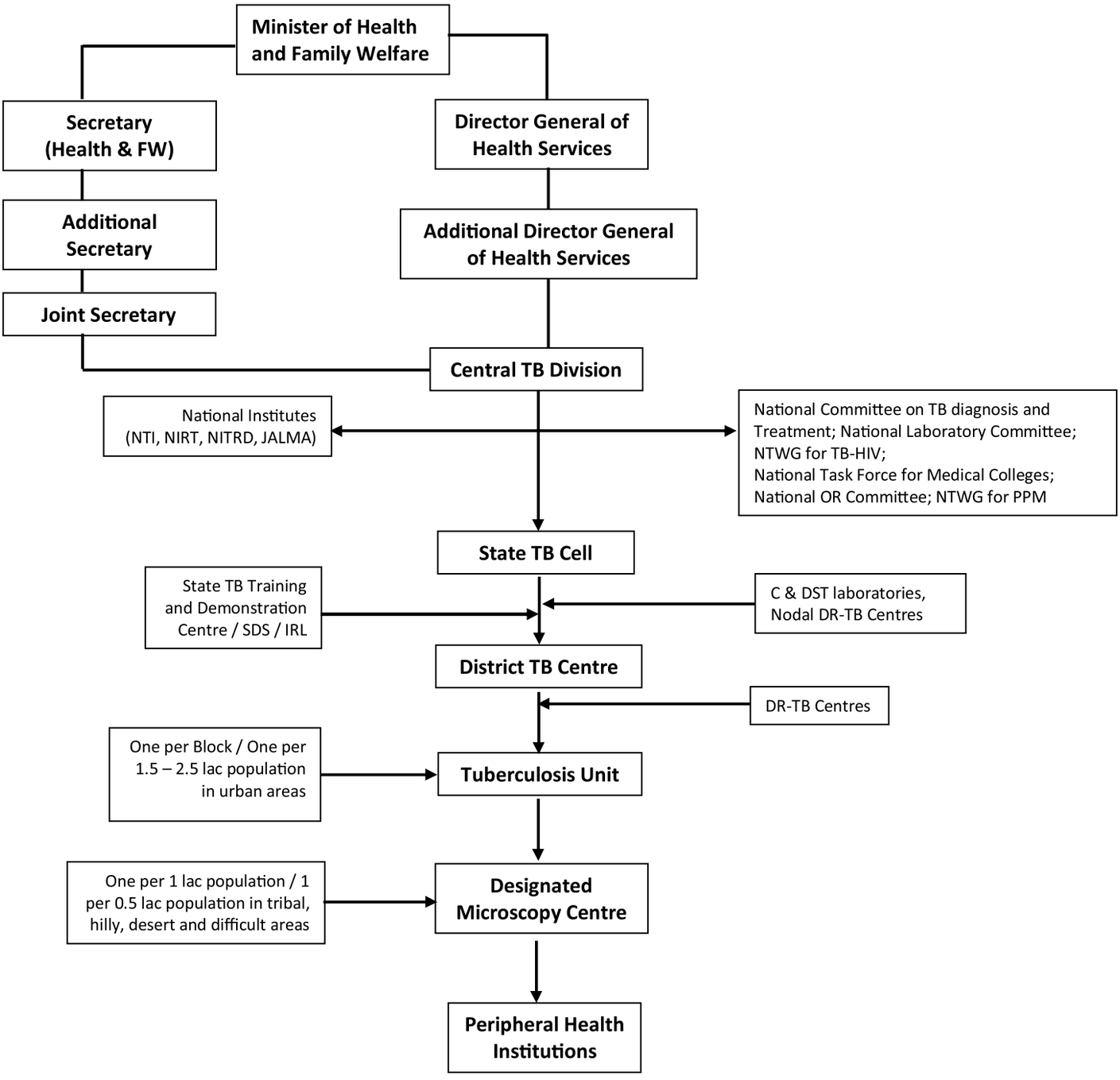
State Level

The States have total ownership and accountability for the TB control in their state. State Health Society or its equivalent under National Health Mission of the state manages the TB Control Programme. A full-time State Tuberculosis Officer (STO), trained at national level and based at the State TB Cell (STC), is responsible for planning, training, supervising and monitoring the programme in all the districts of their respective states. STO is administratively accountable to the State Government, technically follows the instructions of the CTD, and coordinates with CTD and the districts and is assisted by other technical & secretarial staff.

State TB cell is being supported by State TB Training and Demonstration Centre (STDC) in many states through its three units – a training unit, supervision and monitoring unit and an Intermediate Reference Laboratory (IRL) supporting an effective Quality Assurance system of the Sputum smear microscopy network and lab services for PMDT (molecular DR testing and C&DST) in the State.

Each state also has one (1 for each 50 million population at least) fully operational State Drug Store (SDS). It is responsible for effective management of medicines and other logistics and ensuring uninterrupted supply of good quality 1st& 2nd line anti-TBmedicines for adults and paediatric population.

Orgnogram


Minister of Health and Family Welfare
Secretary (Health & FW)
Director General of Health Services
Additional Secretary
Additional Director General of Health Services
Joint Secretary
Central TB Division
National Institutes (NTI, NIRT, NITRD, JALMA)
National Committee on TB diagnosis and Treatment; National Laboratory Committee; NTWG for TB-HIV; National Task Force for Medical Colleges; National OR Committee; NTWG for PPM
State TB Cell
State TB Training and Demonstration Centre / SDS / IRL
C & DST laboratories, Nodal DR-TB Centres
District TB Centre
DR-TB Centres
One per Block / One per 1.5 – 2.5 lac population in urban areas
Tuberculosis Unit
One per 1 lac population / 1 per 0.5 lac population in tribal, hilly, desert and difficult areas
Designated Microscopy Centre
Peripheral Health Institutions

District Level

The key level for the management of primary health care services is the district. The Chief District Health Officer (CDHO) / Chief District Medical Officer (CDMO) / Chief Medical Officer (CMO) / Civil Surgeon 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. A full-time District Tuberculosis Officer (DTO), trained at national level & based at the DTC, is responsible for planning, training, supervising and monitoring the programme in the district. DTO is assisted by other technical & secretarial staff. The primary role of the DTC is managerial.

Sub-District Level (Tuberculosis Unit Level)

Integrating the TB control programme with the health system increases effectiveness and efficiency of TB care and control. India's TB control programme has been mainstreamed efficiently with National Health Mission (NHM).

A major organizational change in RNTCP is the creation of a sub-district level (Tuberculosis Unit - TU). The TU is the nodal point for TB control activities in the sub-district. TUs are based mainly in NHM health blocks with the overall aim to align with NHM Block Programme Management Unit (BPMU) for optimum resource utilization and appropriate monitoring. In urban areas the TUs have been created based on a population of 1 per 2,00,000 (range 1.5 – 2.5 lakh). The Tuberculosis unit (TU) consists of a designated Medical Officer-Tuberculosis Control (MO-TC), as well as one full-time supervisory staff - Senior Treatment Supervisor (STS). One Senior TB Laboratory Supervisor (STLS) will continue to be in 5 lakh population and 1TBHV per one lakh urban population is there to support the urban TB control activities.

The Block Medical Officer also functions as a MO-TC who is trained in RNTCP at a state level institution. MO-TC has the overall responsibility of management of TB Control Programme at the TU and is expected to undertake supervisory visits for seven days in a month. The team of STS and STLS are under the administrative supervision of the MO-TC and the DTO. 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). Microscopy Centres are also located in Medical Colleges, Corporate hospitals, ESI, Railways, NGOs, private hospitals, etc.

Peripheral Health Institutions (PHIs)

For the purpose of RNTCP, a PHI is a health facility which is manned by at least a medical officer. At this level, there are dispensaries, PHCs, CHCs, referral hospitals, major hospitals, specialty clinics or hospitals (including other health facilities), TB hospitals, and Medical colleges within the respective district. All health facilities in the private and NGO sectors participating in RNTCP are also considered as PHIs by the programme. Some of these PHIs also function as DMCs. Peripheral health institutions undertake tuberculosis case-finding and treatment activities as a part of the general health services. 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.

TB Laboratory Services

The services of the laboratory are utilized for diagnosing TB & DR-TB cases and for monitoring of treatment of these patients. The Laboratory network under RNTCP is a **3-tier system** for provision of diagnostic services and maintaining its quality.

A. **The peripheral laboratories** are situated in the public sector like the dispensaries, PHCs, CHCs, referral hospitals, major hospitals, specialty clinics, other sector hospitals, TB hospitals, Medical colleges and in the private/NGO sectors. For establishment of microscopy centre in a lab, it must have adequate physical infrastructure, Binocular microscope and a trained LT. These laboratories are covered under quality assurance mechanisms

   I. Some of the labs not having facility for sputum microscopy, function as a sputum collection centres, and such facilities are also established in areas such as the tribal, hilly, desert and difficult to reach areas of the country for improving the access to diagnostic services.

   ii. In addition, largehospitals and medical colleges havefacilities of digital X-Ray, rapid molecular test (CBNAAT & LPA), FNAC, histo-pathology, and culture & DST for diagnostic services of TB.

B. **At the state level** a nodal laboratory is designated as Intermediate reference laboratory (IRL) which is usually situated in the State TB Training and Demonstration Centre (STDC) / medical college/ public health laboratory. The main functions of IRLs are monitoring of lab services across the state and maintenance of its quality through external quality assurance. There are 27 IRLs with facilities for culture & DST using Phenotypic (Solid – LJ & Liquid Culture – MGIT) and Genotypic technology (LPA & CBNAAT).

C. **At the central level** there are six designated National Reference Laboratories (NRLs) namely National Institute for Research in Tuberculosis (NIRT), Chennai, National Tuberculosis Institute, Bangalore, National Institute of Tuberculosis and Respiratory Diseases (NITRD), Delhi, National JALMA Institute, Agra, Regional Medical Research Centre, Bhubaneshwar and Bhopal Memoral Hospital & Research Centre (BMHRC), Bhopal. NIRT Chennai is also a Supra-Reference Lab (SRL) for World Health Organization (WHO) for the South East Asia Region. NTI is a WHO Collaborating Centre for Training, while NITRD is WHO centre of excellence in TB laboratory services.The NRLs are mainly responsible for External Quality Assurance of Lab network, drug resistance surveillance, training and research.

Delivery of TB care services in the private sector

The private sector referred to in this section is everything outside the ambit of the government run public health initiatives. The private sector in India varies widely in its size, nature of service delivery and the socio-economic groups served. It consists of a wide range of providers from individual medical practitioners of many different systems of medicine, including allopathic as well as Indian Systems of Medicine and Homeopathy, paramedics and even traditional healers who possess no formal training to private hospitals and nursing homes, NGO run hospitals, and corporate sector health care institutions.

The private sector holds a factual predominance of health care service delivery in India. As per National Sample Survey Organization report of 71st round of survey, more than 70% of patients seek care in private clinics or hospitals.

Delays in diagnosis, over-diagnosis of TB due to an over-dependence on X-rays, the use of multiple non-standard regimens for inappropriate durations, the lack of a mechanism to ensure the full course of treatment and to record treatment outcomes are some issues of concern in the private sector. Similar problems in varying degrees are encountered in other health sectors as well.

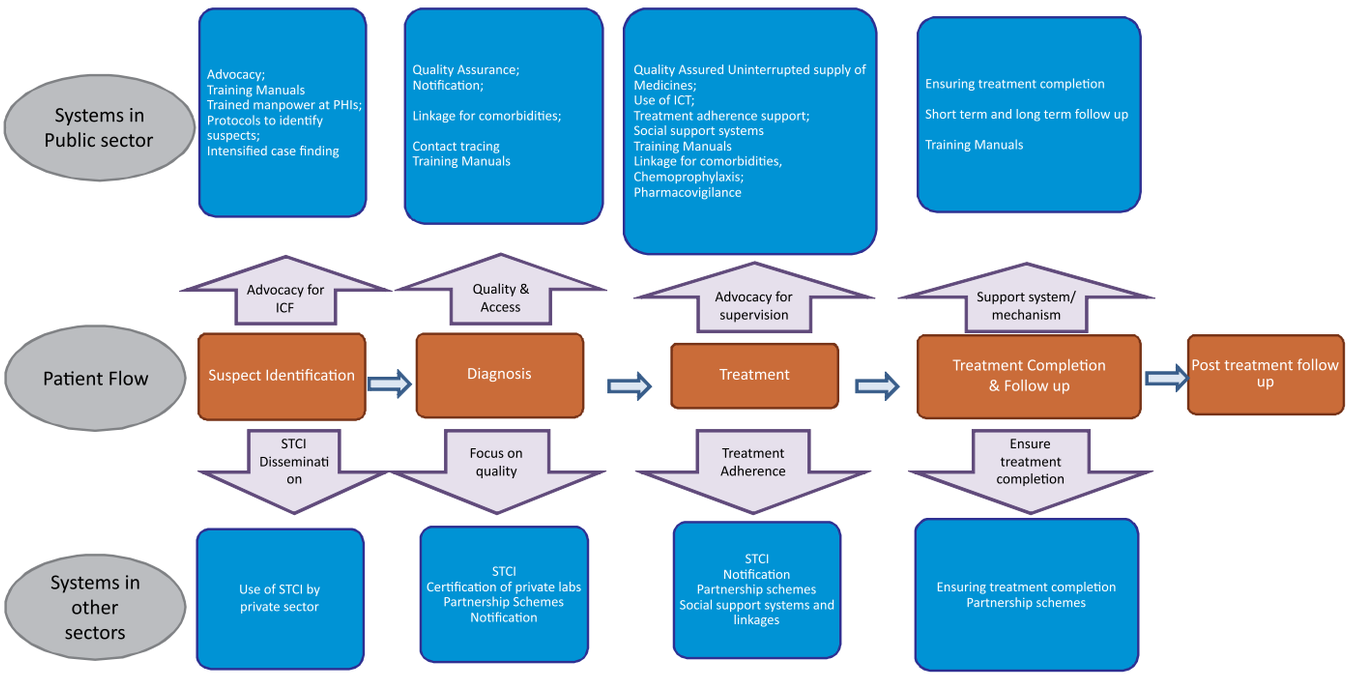
	Public Sector	**Private Sector**
Advantages	• Free diagnosis • Free treatment • Standardized regimen • Referral and transfer system • Supervision and monitoring • Accountability of treatment outcome	• Wide choices (> 5 lac practitioners) • Better access – Convenient timings – Shorter distances – Personal attention and care – Projected discounts • Faith and perceptions of better care
Disadvantages	• Staff's nonresponse to symptoms • Delays between tests and receiving results • Difficulty in transporting specimens • Financial expenditure on travel, food, daily necessities, extra medicines • Perceived low quality of services	• Cost of clinical examination fees • Cost of diagnostic tests • Cost of drugs • Irrational prescriptions • Infrequent use of quality sputum tests for diagnosis of TB • No adherence tracking mechanisms • Fear of losing patient if involved in RNTCP

The strategic vision of RNTCP is to lay down guidelines and norms for TB care in country. The underlying principle is for RNTCP to extend public services to privately managed patients. Standards for TB care in India, mandatory TB notification, NIKSHAY, ban on serodiagnostics and amendments in H1 schedule are among the tools to improve TB care services in private sector. Regulatory tools, however, are limited and partnership is preferred. Programme staff should understand that RNTCP needs private providers more than private providers need the RNTCP.

Other approaches include an expanded acceptance by RNTCP of internationally approved diagnostic and treatment protocols, reliance on market forces rather than normative exhortation, increased use of accreditation and contracting, further outreach to private laboratories, increased control of TB drugs, and innovative use of information and communication technologies for TB notification and treatment adherence monitoring. It is important to recognize that partnerships come in a wide variety of shapes and sizes, and operate at all levels, from local to global.

Model of care envisioned for delivery of services in continuum of care of TB patients from being a presumptive TB to the diagnosis, treatment and final treatment outcome in public and private sector is depicted below. It also shows what systems are in place for ensuring the various aspects of patient care in the public sector in the upper half and the other sectors in the lowerhalf. All these systems ensure quality of services being provided to the patients irrespective of the place where the patient seeks care.

Patients Centric Model of Care



Case finding and Diagnosis strategy

To achieve universal access to early accurate diagnosis of TB and enhancing case finding efficiency, identification of presumptive TB cases at the first point of care and linking them to the best available diagnostic tests is of paramount importance. Early case detection is vital to interrupt the transmission of TB disease as highlighted in the 12th five year plan for TB control in India.

Early identification of people with a high probability of having active TB (presumptive TB) is the most important activity of the case finding strategy. Screening and diagnosing patients with appropriate tests and strategies will largely determine the response to appropriate treatment.

Patients attending health institutions - government/private need to be systematically screened for symptoms of TB by the health care provider. Presumptive TB patients should be promptly identified and are to be referred to diagnostic facility for appropriate investigation using the RNTCP request form for examination of biological specimen.

Passive case finding alone can lead to missed cases or delayed diagnosis. Enhanced outreach activities to detect more TB cases are critical to universal access. Screening for TB has also to be undertaken at every point of contact with health care among key population including clinically and socially vulnerable group of people.

Definitions of presumptive TB

2.1 Presumptive Pulmonary TB refers to a person with any of the symptoms and signs suggestive of TB including cough >2 weeks, fever > 2 weeks, significant weight loss, haemoptysis, any abnormality in chest radiograph.

Note: In addition, contacts of microbiologically confirmed TB Patients, PLHIV, diabetics, malnourished, cancer patients, patients on immune-suppressants or steroid should be regularly screened for sign and symptoms of TB

2.2 Presumptive Extra Pulmonary TB refers to the presence of organ specific symptoms and signs like swelling of lymph node, pain and swelling in joints, neck stiffness, disorientation, etc and/or constitutional symptoms like significant weight loss, persistent fever for ≥2 weeks, night sweats.

2.3 Presumptive paediatricTB refers to children with persistent fever and/ or cough for more than 2 weeks, loss of weight*/ no weight gain and/ or history of contact with infectious TB cases**.

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

*** In a symptomatic child, contact with a person with any form of active TB with in last 2 years may be significant.*

2.4 Presumptive DR TB refers to those TB patients who have failed treatment with first line drugs, paediatric TB non responders, TB patients who are contacts of DR-TB (or Rif resistance), TB patients who are found positive on any follow-up sputum smear examination during treatment with first line drugs, previously treated TB cases, TB patients with HIV co-infection.

DIAGNOSTIC TOOLS

Tools for microbiological confirmation of TB

All efforts should be undertaken for microbiologically confirming the diagnosis in presumptive TB patients. Under RNTCP, the acceptable methods for microbiological diagnosis of TB are:

Sputum Smear Microscopy (for AFB):

- Zeihl-Neelson Staining
- Fluorescence staining

Culture:

- Solid (Lowenstein Jensen) media
- Automated Liquid culture systems e.g. BACTEC MGIT 960, BactiAlert or Versatrek etc.
- Drug Sensitivity Testing:
- Modified PST for MGIT 960 system (for both first and second line drugs)
- Economic variant of Proportion sensitivity testing (1%) using LJ medium (as a back up when indicated)

Rapid molecular diagnostic testing:

- Line Probe Assay for MTB complex and detection of RIF& INH resistance
- Nucleic Acid Amplification Test (NAAT) Xpert MTB/Rif testing using the GeneXpert system

Smear microscopy being the most commonly used method for microbiological diagnosis of TB for the last several decades, has had enormous value in TB diagnosis but with limited sensitivity, more so in children and PLHIV. Under RNTCP, two methods of microscopy are currently being used- ZN stain based microscopy using conventional microscope and Light Emitting Diode based Fluorescent Microscopy (LED FM).

Culture though highly sensitive and specific method for TB diagnosis, requires 2-8 weeks to yield results and hence alone does not help in early diagnosis. However culture will be used for follow up of patients on Drug Resistant TB treatment to detect early recurrence as part of using the indicator of relapse free cure.

Nucleic Acid Amplification Test (NAAT) provides accurate and rapid diagnosis of TB by detecting *Mycobacterium tuberculosis* (*M. tuberculosis*) and Rifampicin (Rif) resistance conferring mutations, in sputum specimen as well as specimen from extra-pulmonary sites. Presently, under RNTCP, its use is recommended for diagnosis of DR-TB in presumptive DR-TB patients and TB preferentially in key population such as children, PLHIV and Extra-pulmonary TB.

Other diagnostic tools

Radiography

Where available, CXR to be used as a screening tool to increase sensitivity of the diagnostic algorithm. Any abnormality in chest radiograph should further be evaluated for TB including microbiological confirmation. In the absence of microbiological confirmation, careful clinical assessment for TB diagnosis should be done. Diagnosis of TB based on X-ray will be termed as clinically diagnosed TB.

Tuberculin Skin Test (TST) & Interferon Gamma Release Assay (IGRA)

Standardized TST may be used as complementary test in children in combination with microbiological investigations, history of contact, radiology and symptoms. Interferon-Gamma Release Assays (IGRAs) are being used in place of skin test in low prevalence countries to detect TB infection. The exact advantage of IGRA in high burden countries like India is still not clear, hence these are not recommended for use for adults in diagnostic algorithm for tuberculosis in India.

Serological tests

The Government of India issued Gazette notification (vide 433E 7th June 2012) has banned the manufacture, importation, distribution and use of currently available commercial serological tests for diagnosing TB. These tests are not recommended for diagnosis of TB.

Process of Biological Specimen Collection & testing for microscopy

Medical Officers of health care facilities (governmental or non-governmental) should identify all presumptive TB from patients attending health facilities and refer them for examination using the RNTCP request form for examination of biological specimen. In Medical Colleges and other hospitals, indoor-patients suspected of TB should also be referred by the treating physician using the same RNTCP laboratory request forms.

Patients are given specimen containers with instructions to provide quality specimen which are then subjected for microscopy examination.

Two samples are collected within a day or two consecutive days. One sample is collected on the spot under supervision and other is collected early in the morning. The sputum containers should be labelled properly by writing the patient's laboratory serial number on the side of the sputum container and not on the lid. Sputum should be at least 2 ml in quantity and preferably mucopurulent. Results of sputum tests should be reported within a day. If needed, storage of sputum samples should be in cool place/ refrigerator. A smear is made, fixed and stained using the Ziehl-Neelsen staining / Fluorescence technique.

Transport of Biological specimens

Arrangements should be made locally for transporting the specimens to the DMC and for sending the results to the referring health centres. The specimens should be packed carefully in a box to avoid spillage. Before sending the sputum specimens to the DMC, the person should verify that:

1. The accompanying dispatch list contains the necessary information for all patients and clearly identifies the referring health facility collecting the sputum.
2. The total number of sputum specimens corresponds to the total number in the accompanying dispatch list.
3. The Specimen Identification Numbers on the sputum containers correspond to those on the accompanying list.
4. One RNTCP request form for examination of biological specimen is to be enclosed for each patient.
5. The health worker should then mark the date of dispatch on the dispatch list, put the list in an envelope and attach it to the box outside.
6. Sputum specimens should be examined by microscopy not later than 2 days after collection. Once examined, the microscopy results should be reported on the same day.
7. The containers along with the sample MUST be disinfected with 5% phenol solution and disposed as per guidelines after the sputum smears results are recorded in the laboratory Register.
8. Refer SOP for sputum collection & transportation **(Annexure 3)**

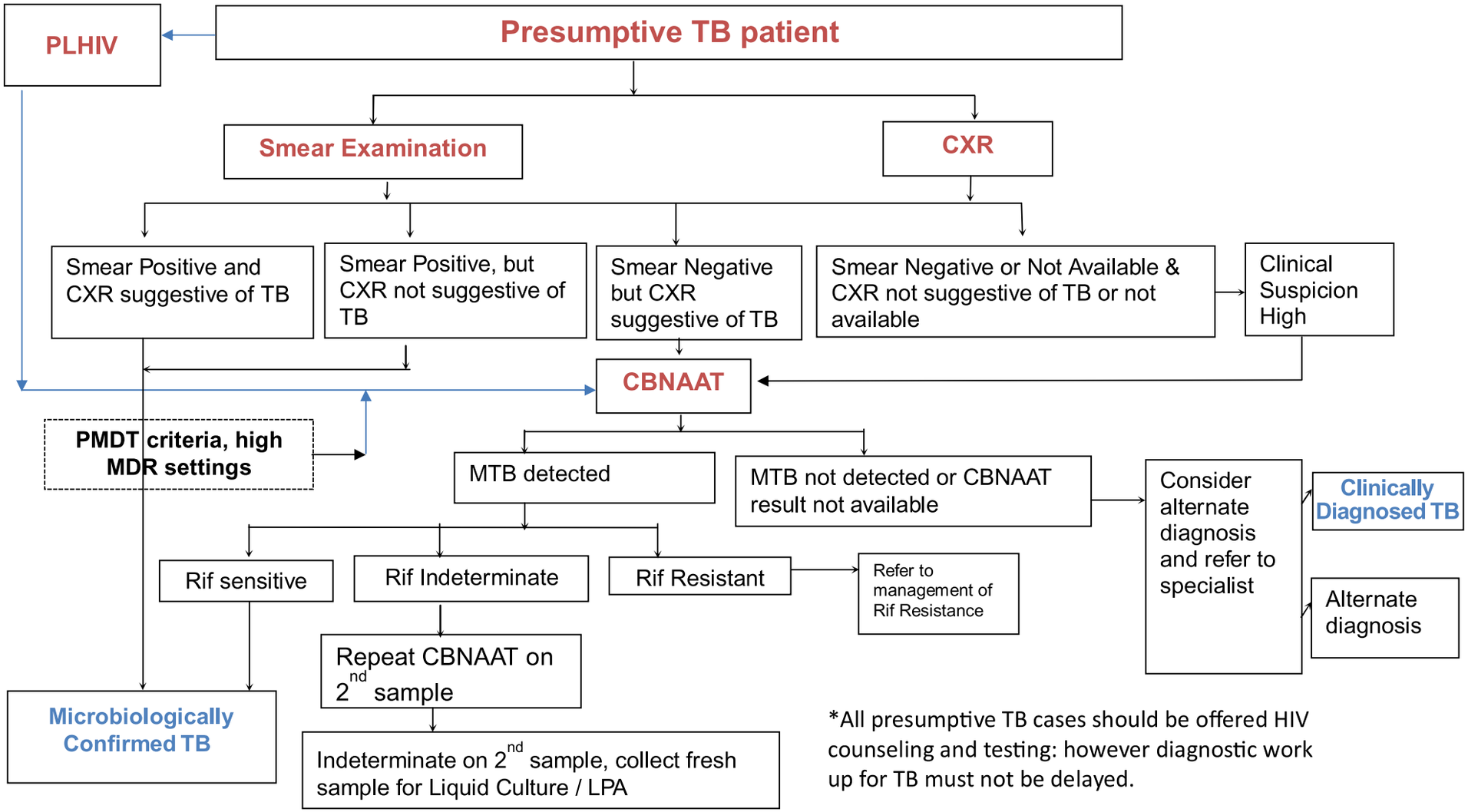
Smear preparation, Staining and Reading

Refer to SOPs of ZN Staining Techniques or Fluorescence Staining Techniques in (**Annexure 1 & 2)**

Diagnostic algorithm for pulmonary TB

All persons identified as presumptive TB patients in the health facility or those referred by other health care providers from the public / private health sector should be subjected to diagnostic tests as per the diagnostic algorithm(s).

Diagnostic algorithm for pulmonary TB



*All presumptive TB cases should be offered HIV counseling and testing: however diagnostic work up for TB must not be delayed.

Note for diagnostic algorithm for pulmonary TB

A. All presumptive TB (specifically for PTB symptoms) will undergo sputum smear examination (ZN/LEDFM). Two specimens will be collected (spot-early morning or spot-spot). If the first smear is positive and the patient is not at risk for Drug Resistant (DR) TB, he will be categorized as microbiologically confirmed TB (sensitivity status not known)

B. Smear positive and presumptive MDR TB (as per PMDT guidelines) and in settings of high MDR TB (e.g. MDR TB rates >5% among new case and >20% among re-treatment cases), a CBNAAT will be performed to rule out rifampicin resistance before initiation of treatment where patients will be categorized as microbiologically confirmed Drug Sensitive (DST) TB or RIF resistant TB.

C. If the first smear is negative, CXR may be considered and if reported as suggestive of TB, the 2nd sample will be subjected to smear and CBNAAT simultaneously.

D. Based on CBNAAT results, patients will be categorized as microbiologically confirmed Drug sensitive TB or Rif resistant TB, if negative move to differential diagnosis for other etiology or point F.

E. A RIF indeterminate result will get an additional CBNAAT to get a valid result and in case of indeterminate on second occasion, an additional specimen will be collected and sent to the nearest Intermediate Reference Laboratory (IRL) or Culture & Drug Susceptibility Testing (C&DST) centre for LPA or Liquid Culture & DST as appropriate.

F. Wherever the facilities are available, efforts should be made to obtain DST results of all drugs by collecting additional samples and sending to nearest C&DST. (Subject to laboratory capacity).

G. If the both sputum smears and CXR are negative, and physician is still suspecting TB, he will refer patient to pulmonology expert / chest specialist.

H. All key population (PLHIV, Children, EPTB, etc.) will preferentially get an upfront CBNAAT as per approved algorithm for PLHIV and TB HIV patients, pediatric TB and Extra pulmonary TB.

I. The algorithm does not mandatorily decide the “order to DO” the tests / investigations. If needed / available, appropriate tests may be done simultaneously but “order of consideration” for different types of test / investigation results should be as per the algorithm. (e.g. If available, smear for AFB and CXR may be done simultaneously to avoid diagnostic delay / patient's day loss. But, smear results will be prioritized over CXR to make an early diagnosis). If patient walks in with the latest CXR, the same may be considered to reduce the diagnostic delay.

J. All diagnostic health care facilities should have TB labs that are quality assured by competent authority.

Diagnosis of Extra-pulmonary TB

Extra pulmonary tuberculosis (EPTB) refers to any microbiologically confirmed or clinically diagnosed case of TB involving organs other than the lungs such as lymph nodes, pleura, bones and joints, meninges of the brain, intestine, genitourinary tract, etc. A high level of suspicion of EPTB is important in patients with suggestive symptoms and signs.

All efforts should be made to establish microbiological confirmation in case of presumptive EPTB. Appropriate specimens from the presumed sites of involvement must be obtained from all presumptive EPTB patients for CBNAAT / Smear Microscopy / Culture & DST for *M. tuberculosis* / histo-pathological examination, based on type of specimen and availability of facilities. CBNAAT is preferred over other tests. Chest X-ray, Ultrasonography, Computerised Tomography (CT) Scan, Magnetic resonance imaging (*MRI*) are other investigations which can be used as supporting tools for diagnosing EPTB.

Sensitivity of CBNAAT for TB diagnosis, when compared to liquid culture as a 'Gold Standard', is high in FNAC / biopsy specimen from lymph nodes, biopsy specimen from other tissues and cerebrospinal fluid (CSF), but lower in pericardial, ascitic and synovial fluid samples and still lower in pleural fluid. A positive CBNAAT result provides useful confirmation but a negative test does not always rule out TB, since the sensitivity of liquid culture itself in extra-pulmonary specimen is not very high. The laboratory SOP should be referred while using CBNAAT for extra-pulmonary samples. Tissues, to be tested by CBNAAT should be collected **without** formalin. Tissue samples should only be processed at laboratories with appropriate bio-safety requirements. **(Annexure 5)**

Note on Diagnostic Algorithm for Extra Pulmonary TB

1. CBNAAT in specimen from extra-pulmonary sites provides the following results:
   a. *M. tuberculosis detected, Rifampicin sensitive*: Diagnosis of microbiologically confirmed EPTB is made.

   b. *M. tuberculosis detected Rifampicin indeterminate*: a repeat CBNAAT test is performed on the 2nd specimen. If found to be indeterminate on the repeat test, an additional specimen should be collected and sent to the nearest RNTCP certified lab for culture and DST.

   c. *M. tuberculosis detected, Rifampicin resistance*: patient should be treated as per PMDT guidelines;

   d. *M. tuberculosis not* detected: The patient should be evaluated for TB based on clinical, radiological findings and other investigations like histo-pathological examination, ultra sonogram etc. In the event of a decision to treat with anti TB drugs, a diagnosis of clinically diagnosed TB can be made. Otherwise, an alternate diagnosis should be sought.

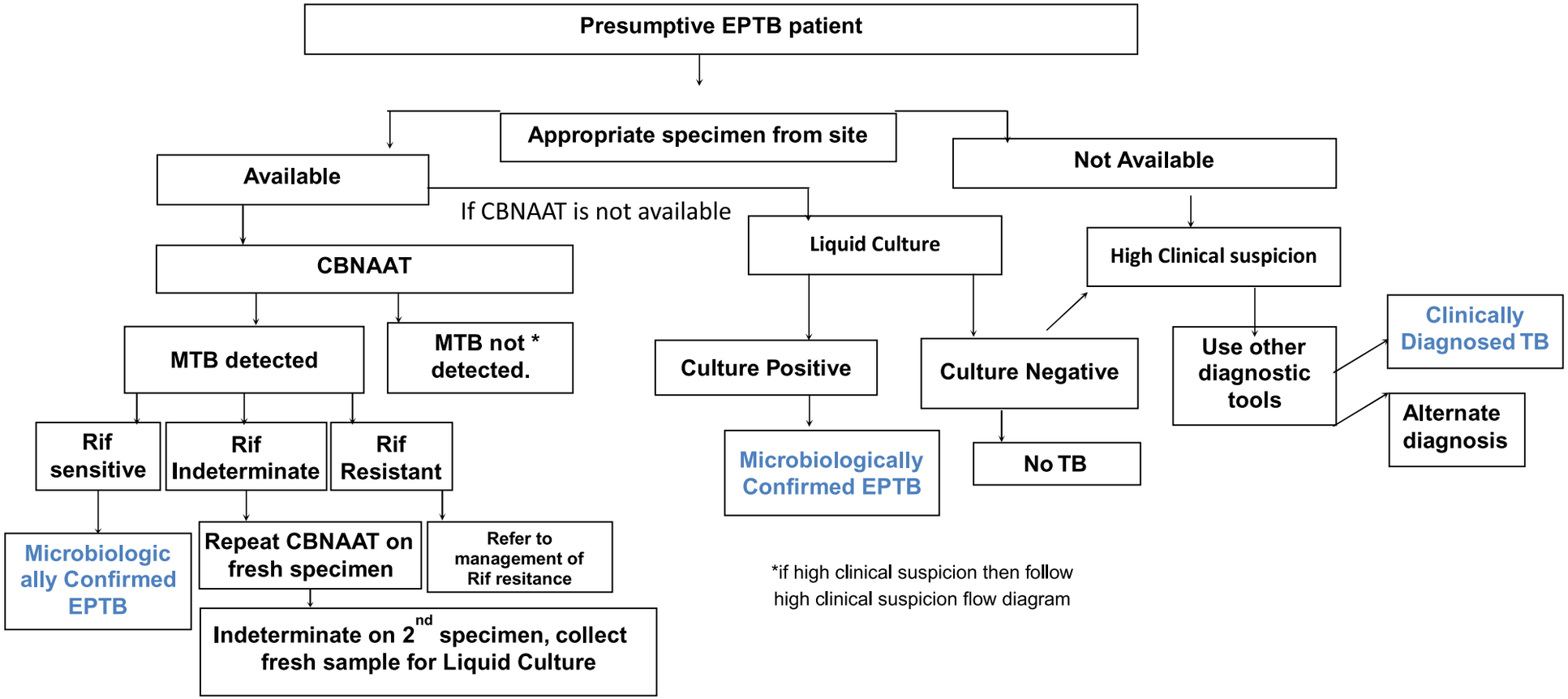
   e. Invalid test: a repeat CBNAAT test is performed on the 2nd specimen, if available.

   f. Error/No result: a repeat CBNAAT test is performed on the same sample.

2. In case CBNAAT is not available, liquid culture needs to be performed. If culture is positive then diagnosis of microbiologically confirmed EPTB is made. Further work up may be done for all EPTB patients if they fall under the criteria of presumptive DR TB.

3. If investigations like CBNAAT/smear microscopy/culture turn out to be negative or if appropriate specimen is not available for these investigations, consultation with a specialist followed by other tests such as histo-pathology, radiology, cytology, biochemical examinations, etc., may be undertaken. In the event of a decision to treat with a full course of anti-TB drugs, diagnosis of clinically diagnosed EPTB is made.

Diagnostic Algorithm for Extra Pulmonary TB



Diagnosis of Paediatric TB

In children with presumptive paediatric TB, every attempt must be made to microbiologically prove diagnosis through examination of appropriate respiratory / non-respiratory specimens with quality assured diagnostic tests. Diagnosis of tuberculosis should not be made only on clinical features and further investigations are always necessary to establish the diagnosis.

In case of suspicion of pulmonary TB, sputum examination should be carried out among children who are able to give good quality specimens. CBNAAT is the preferred investigation of choice. If CBNAAT is not readily available or testing is not possible even by referral, smear microscopy should be performed. If *M. tuberculosis* is detected, by either of methods patient is diagnosed as microbiologically confirmed pulmonary TB.In situations where *M. tuberculosis* is not detected or specimen is not available, chest X-ray and Tuberculin skin test (TST) by Mantoux technique using 2 TU of PPD RT 23 should be done. For interpretation and further course of action, refer to the diagnostic algorithm for childhood pulmonary TB.

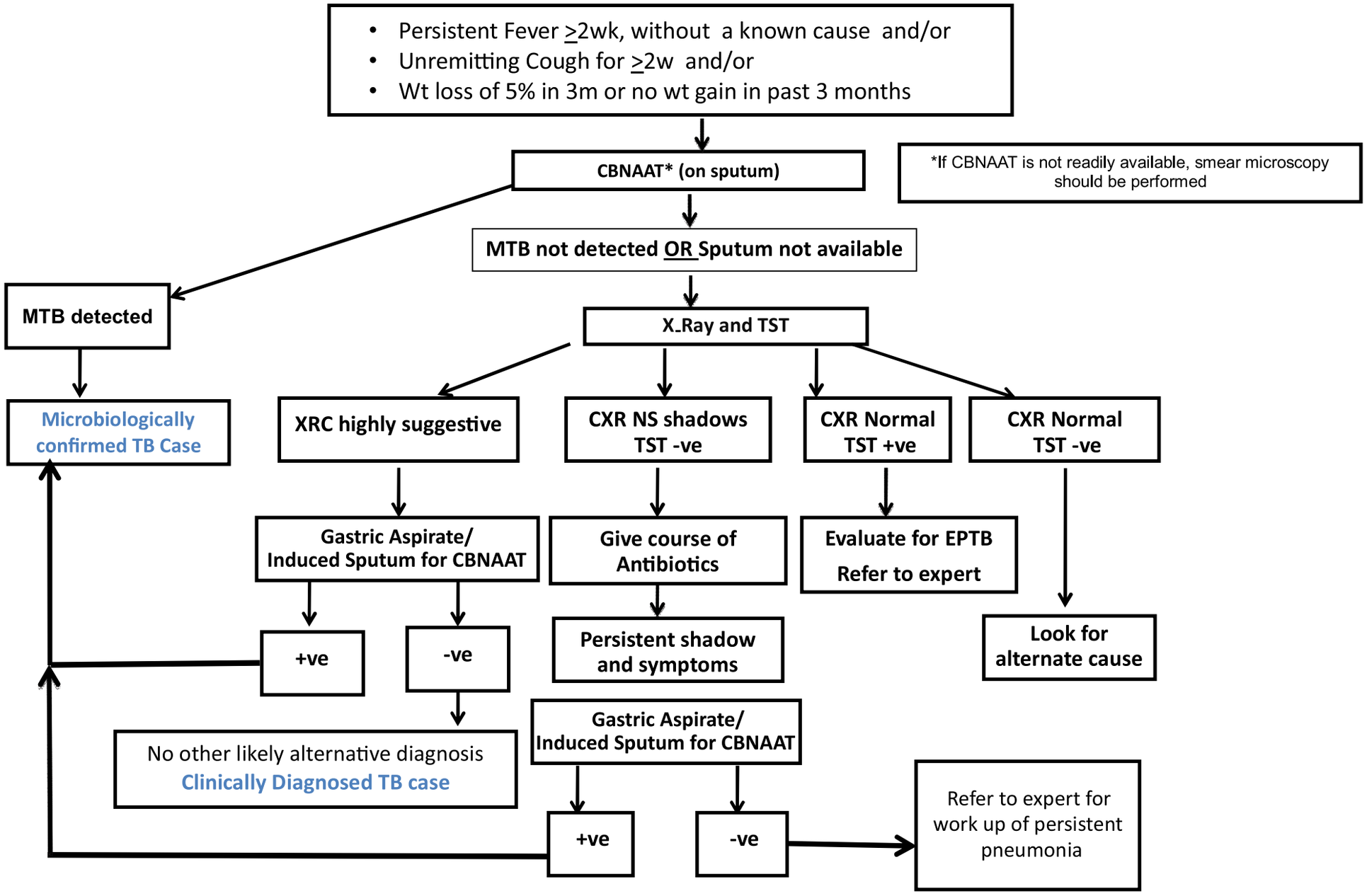
Notes on diagnostic algorithm

1. This algorithm is for children who are likely to have drug sensitive disease i.e. have not received ATT previously ever and are not presumptive drug resistant TB cases (lost to follow up, recurrent, treatment failure, HIV).
2. Proper Characterization of symptoms is very important starting point. Weight loss or not gaining weight should always be documented with appropriate and proper weighing.
3. Where CB NAAT is doable, smear examination may not be done. Whenever smear is used for diagnosis at least 2 samples should be sent while a single sample is subjected to CB NAAT. If a specimen is positive by any of these methods, the disease is labelled as Microbiologically confirmed TB.
4. Highly suggestive Chest X-ray refers to skiagrams showing either Miliaryor lymphadenopathy (hilar or mediastinal) or chronic fibro-cavitatory shadows. If the radiological picture is highly suggestive of TB, then proceed to do further investigations irrespective of the TST result as the sensitivity of the test is not 100%.
5. Non Specific Chest X-ray: Refer to patterns other than highly suggestive like consolidations, in homogenous shadows or bronchopneumonia, etc.
6. Whenever indicated, alternative specimens (Gastric aspirate/ Induced sputum/ broncho-alveolar lavage) should be collected by a skilled health care provider, depending upon available infrastructure and sample should be subjected to CBNAAT.
7. Antibiotics like linezolid or any quinolone or Amoxycilin-Clavulanic acid should not be used as they have anti-TB action.
8. Children with persistent symptoms, non specific shadows and negative smears and negative other samples (GA/IS) by CB NAAT should be referred to experts for further work up of persistent pneumonia.
9. All TB cases diagnosed must be offered testing for HIV.
10. Instructions for administering PPD vials are placed at (**Annexure 6)**
11. Whenever Rif Resistant result is reported on CBNAAT further management should be carried out as per the guidelines on Drug Resistant TB

All presumptive DR TB patients should be appropriately followed up with PMDT guidelines. In case of suspicion of Extra Pulmonary TB, the diagnostic algorithm as given in section above may be followed.

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

Diagnostic algorithm for Pediatric Pulmonary TB



Diagnosis of Drug Resistant TB

Drug resistant TB is a laboratory based diagnosis and is performed either by phenotypic Drug Susceptibility Testing using solid / liquid culture or genotypic testing for detection of resistance by Line Probe Assay / Cartridge Based Nucleic Acid Amplification Tests like Xpert MTB/Rif. CBNAAT detects resistance to only Rifampicin while LPA detects resistance to both Rifampicin and Isoniazid.

Genotypic testing is much faster than phenotypic methods, as these are not growth based tests. DST results by Solid LJ media has a turnaround time (TAT)of upto 84 days, Liquid Culture (MGIT) upto 42 days, LPA upto 72 hours and CBNAAT by 2 hours.

Under RNTCP, access to either CBNAAT or LPA is available **and should be used for diagnosis of DR-TB.**Refer to RNTCP Laboratory manual of Standard Operating Procedures for culture and DST, LPA and CBNAAT testing.

For CBNAAT, a single specimen is required for testing. The need for a second specimen for CBNAAT arises in case the result is "Invalid" or "Rif Indeterminate". For "Errors", "No Results" the test can be repeated on the same specimen after appropriate trouble shooting as per the user manual. Two specimens should be collected (spot-early morning or spot – spot) for examination by LPA which can be performed directly on sputum specimen which are positive on microscopy or on culture isolates of specimen which were negative on microscopy.

All efforts must be made to optimize the utilization of all locally available genotypic diagnostic capacity.

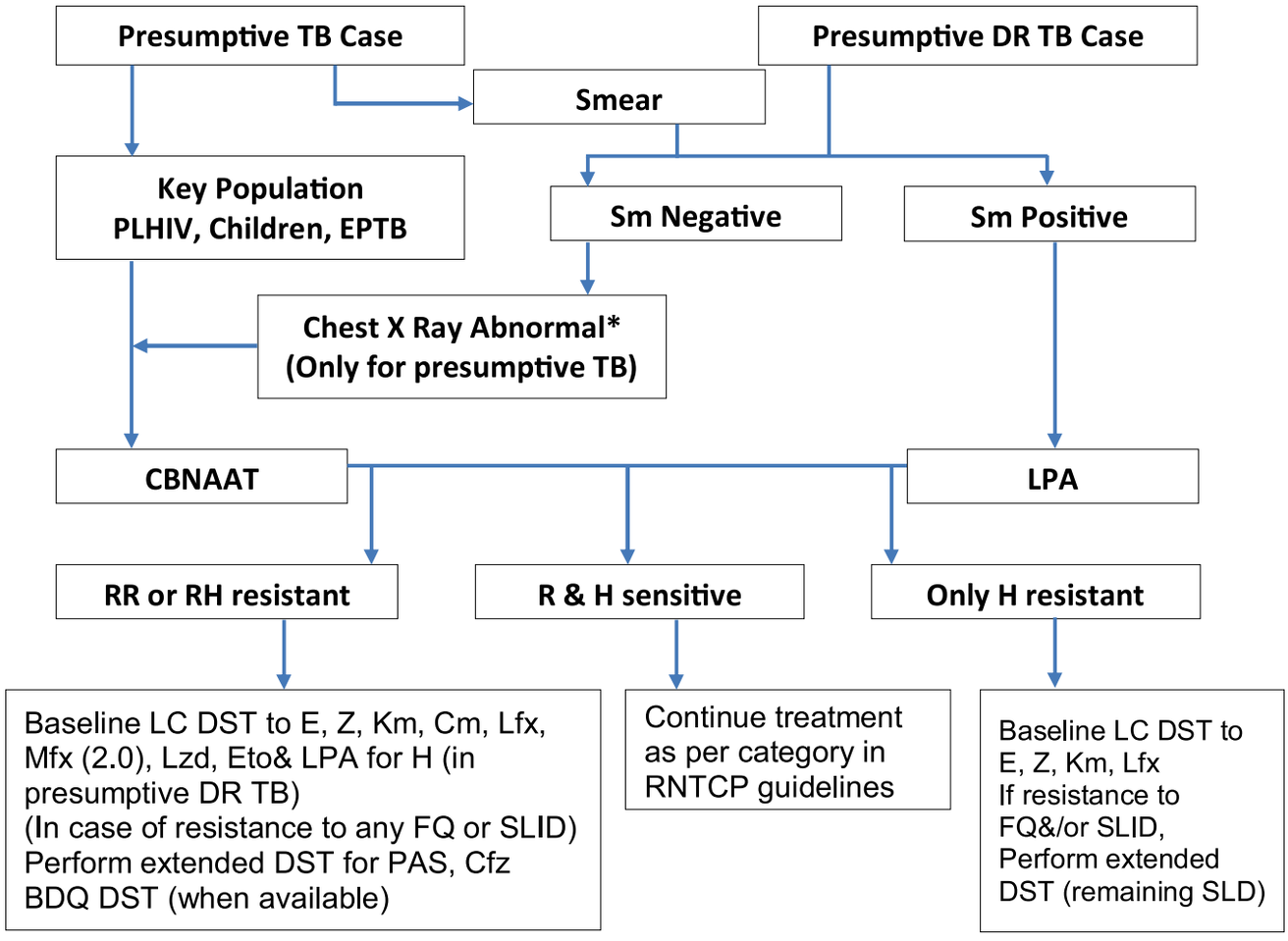
If Rifampicin Resistance is confirmed by CBNAAT or LPA, start Standardized Regimen for MDR TB and perform Liquid Culture DST at baseline to Levofloxacin and Kanamycin.

As guided by the diagnostic algorithm above, wherever the facilities are available, efforts should be made to obtain DST results of all the drugs intended to be used in regimen, by collecting additional samples and sending to nearest C&DST. (Subject to laboratory capacity which is dynamic and will be expanded in a phased manner).The programme has introduced Bedaquiline through conditional access programme initially at six sites with diagnostic protocol comprising of extended sets of DSTs. This diagnostic Algorithm for Bedaquiline containing and optimized background regimen is as follows

If Rifampicin Resistance is confirmed by CBNAAT or LPA, start Standardized Regimen for MDR TB and perform Liquid Culture DST at base line to Levofloxacin, Moxifloxacin, Kanamycin, Capreomycin, Ethambutol, Ethionamide, Linezolid and Pyrazinamide along with LPA for Isoniazid on sample /culture isolate (reported as KatG or inhA mutation to decide on use of INH) with the next available specimen.
If resistance is detected to any second line injectable and/or fluoroquinolones, extended DST is performed for Para Amino Salicylic acid, Clofazamine and Bedaquiline (whenever available) and treatment modified accordingly.

If Rifampicin sensitive is detected by CBNAAT among presumptive DR-TB cases, send sample for LPA or liquid culture. All Isoniazid sensitive patients after testing with LPA or those while awaiting results of LPA should continue treatment with first line drugs as per RNTCP guidelines. If Isoniazid resistance is detected by LPA, report of result must also mention Kat G or INH-A mutation. Furthermore, Liquid Culture DST will be performed for Ethambutol, Pyrazinamide, Kanamycin, and Levofloxacin. If resistance is detected to second line injectable and/or fluoroquinolones, perform DST for remaining second line drugs as mentioned above. Initiateor modify treatment as per Drug susceptibility test results.

Diagnostic Algorithm for Bedaquiline containing and optimized treatment regimen



- If RR by CBNAAT, in addition to other drugs, H resistance (by LPA) to be done and treatment modified accordingly.
- For samples reported by LPA – report must mention H- resistance by Kat G or INH A mutation.
- For new patients (those who do not fit in the definition of presumptive DR-TB case diagnosed as TB with RR by CBNAAT – a second CBNAAT test will be offered along with liquid culture DST

** Those who do not fit in the definition of presumptive DR-TB case*

Intensified TB Case Finding

Intensified case finding activity (ICF) is basically a provider initiated activity with the primary objective of detecting TB cases early by active case finding in targeted groups and to initiate treatment promptly. It can target people who anyway have sought health care with or without symptoms or signs of TB and also people who do not seek care. Increased coverage can be achieved by focusing on clinically, socially and occupationally vulnerable populations who have greater risk of TB. It must be remembered that 'Screening' is a dynamic process and the prioritization of vulnerable groups, choice of screening approach and screening interval should be regularly reassessed by the programme. Decisions on when and how to screen for TB, which vulnerable groups to prioritize and which screening tool to use will depend on the vulnerable group, the capacity of the health system, and the availability of resources.

Screening Tools

The most sensitive screening tool needs to be used to improve the pre-test probability of the subsequent diagnostic test and to reduce the number of people who need to undergo further diagnostic evaluation; and it may be different for different vulnerable groups or settings. Options for the screening tools include symptom screening and chest radiography. The following table shows the sensitivity and specificity of the screening tool options.

Pooled sensitivity and specificity of different screening tools for Pulmonary tuberculosis (TB), using culture-confirmed pulmonary TB as the gold standard

	Screening tests		Sensitivity %	Specificity %
	Primary Screening	Cough >= 2 weeks	56.2 (46.7, 65.4)	95.3 (94.4, 96.1)
		Any symptom	66.0 (56.3, 74.5)	93.8 (92.7, 94.8)
		Any symptom OR history of ATT	71.2 (64.8, 76.75)	92.7 (91.7, 93.6)
		CXR as initial screening tool	76.6 (70.8, 81.6)	97.3 (96.5, 97.9)
		Cough >= 2 weeks OR CXR any abnormality	94.3 (91.1,96.4)	93.1 (92.3,93.8)
	Secondary screening	CXR among those having Cough >= 2 weeks	66.8 (60.5, 72.7)	87.8 (83.7, 91.0)
		CXR among those having any symptom	65.0 (58.8, 70.7)	89.8 (85.8, 92.7)
		CXR any abnormality among those having any symptom OR H/o ATT	67.1 (61.7-72.1)	86.7 (82.3-90.2)

Screening strategies

1. Community screening can be done by:
Inviting people to attend screening at a mobile facility or a fixed facility. Invitations may target specifically people within a given vulnerable group, those

- who have had recent close contact with someone who has TB and people with symptoms of TB
- Going door to door to screen households

2. **Institutional screening**

- In Health care facilities : Systematically perform active screening of vulnerable individuals attending hospitals and other health care institution
- In congregate settings: Systematically perform active screening of vulnerable individuals in shelters, old age homes, refugee camps, correctional facilities and other specific locations such as workplaces.

Recommendations on Vulnerable groups to be screened

A vulnerable group is any group of people in which the prevalence or incidence of TB is significantly higher than in the general population. The recommended vulnerable groups to be considered for intensified case finding may be classified as follows:

Clinical	Social	Geographical
Clients attending HIV Care Settings	Prisoners	Urban Slums
Substance abuse including smokers	Occupations with risk of developing TB	Hard to reach areas
Co-morbidities like Diabetes Mellitus, Malignancies, patients on dialysis and on long term immunosuppressant therapy	People in Congregated settings – night shelters, De-addiction centres, Old age homes	Indigenous and tribal populations
Health Care Workers		
Household & Workplace Contacts		
Patients with Past History of TB		
Malnourished		
Antenatal mothers attending antenatal clinics/MCH clinics		

For the groups classified above; the rationale of intensified case finding activities in the particular vulnerable group, the screening tool recommended and the strategy for screening are discussed in **Annexure 7.**

In all settings where intensified case finding is undertaken, systematic TB **recording and reporting** needs to include the following:

- A special register with individual-level information for each person screened may be used to obtain refined data about subcategories of persons within a vulnerable group.
- A register of all presumptive TB cases (Presumptive TB register) who undergo further diagnostic evaluation (if a register is used to collect individual-level information for all people who are screened, then this information can be included in it)
- A column in the laboratory registers for noting whether the tested patient was identified through screening, and to which risk group the patient belongs;
- A column in the treatment registers to note whether the patient was identified through screening, and to which risk group the patient belongs

Adopting a well thought **ACSM** strategy and integrating it with the planning process for ICF will result in a multiplier effect in case finding efforts.

Utilizing Mobile Medical Units for screening presumptive TB patients in identified and hard to reach areas. Using Information, Communication &Technology (ICT) tools to enhance case finding are some the examples of innovation in ICF which can be adapted.

Laboratory Quality Assurance

Quality Assurance (QA): A System designed to continuously improve the reliability and efficiency of laboratory services. The Quality Assurance activities include:

- Internal Quality Control (IQC)
- External Quality Assurance (EQA)
- Quality Improvement (QI)

For Smear Microscopy

The nationwide network of designated sputum smear microscopy laboratories provide appropriate and accessible quality assured TB diagnostic services. To meet the recommended standards of diagnostic practices for TB, the programme provides quality reagents and equipment to the laboratory network. A system has been designed for EQA of sputum smear microscopy and for supervision and monitoring of the diagnostic systems by the RNTCP which is carried out by Senior TB Laboratory Supervisor (STLS) locally and by the Intermediate (State level) and National Reference Laboratory at higher levels.

The NRLs work closely with the IRLs, monitor and supervise the IRL's activities and also undertake periodic training for the IRL staff in EQA, Culture & DST activities. Three microbiologists and four laboratory technicians have been provided by the RNTCP on a contractual basis to each NRL for supervision and monitoring of laboratory activities. The NRL microbiologist and laboratory supervisor / technician visit each assigned state at least once a year for 3 to 4 days as a part of on-site evaluation under the RNTCP EQA protocol

The IRL ensures the proficiency of staff in performing smear microscopy activities by providing technical training to district and sub-district laboratory technicians and STLSs. The IRLs undertake on-site evaluation and panel testing to each district in the state, at least once a year.

Designated Microscopy Centre (DMC) is the most peripheral laboratory under the RNTCP network. For DMC and its supervisory staff, quality improvement trainings conducted periodically focus on issues such as human resources, trainings, AMC for binocular microscopes, quality specifications for ZN stains, RBRC blinding and coding issues, bio-medical waste disposal, infection control measures etc.

Internal Quality Control (IQC): of microscopy is a process of effective and systematic internal monitoring of the performance of bench work in the microscopy laboratory against established limits of acceptable test performance. This is accomplished by checking:

a) Instruments: binocular/fluorescence microscopes, weighing machines, water baths etc.
b) New lots of staining solutions.
c) Smear preparation, staining, examination, grading, recording, reporting and storage.
d) Appropriate disinfection and disposal.

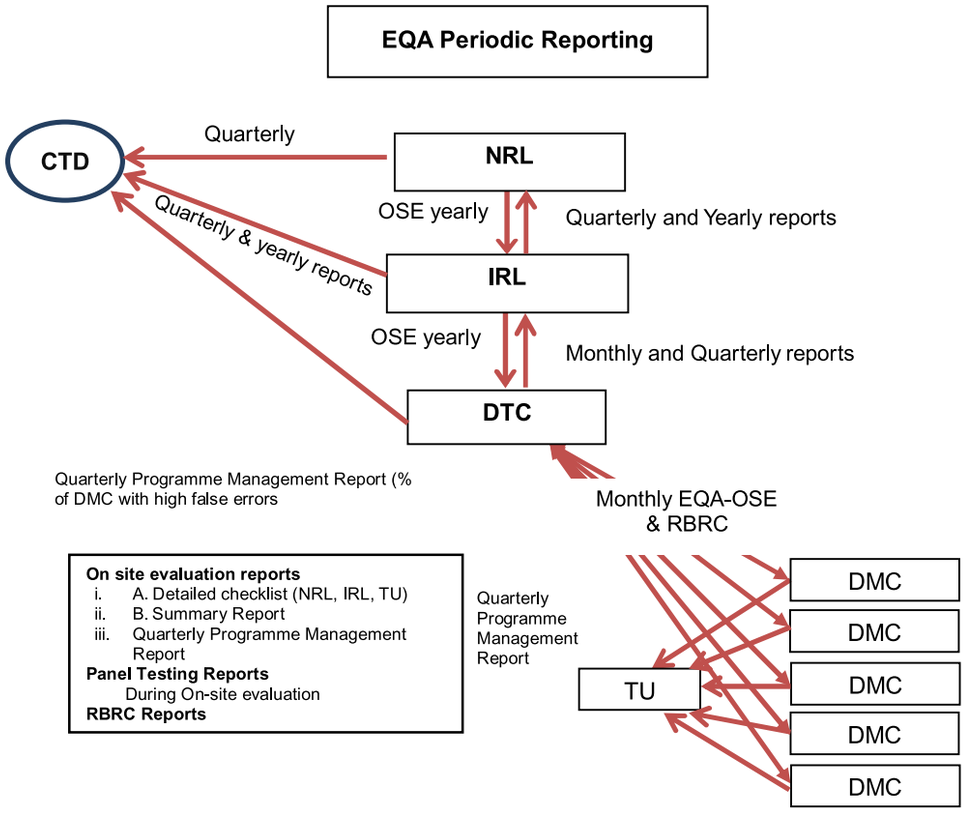
External Quality Assessment (EQA): EQA is a process to assess laboratory performance which includes:

- On-site evaluation (unblinded reading of smears, QC and process of smear microscopy)
- Panel Testing (PT of lab personnel during OSE)
- 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

Quality Improvement (QI): A continuous process by which all components of smear microscopy are carefully analyzed for improving the diagnostic services. Data Collection, analysis and problem solving are the key components of this process.

The schematic representation of the EQA reporting process is shown below:



Quality assessment methods under RNTCP have been implemented for more than a decade now and it is therefore necessary to revise the modalities to the present day scenario as well as to have mechanisms to routinely monitor the quality parameters. Monitoring quality of sputum smear microscopy depends on the:

- Evaluation of entire process of smear microscopy.
- Quality of data collection, analysis and correct interpretation of the results.
- Identifying defects, followed by remedial action.
- Quality Improvement largely relies on effective on-site evaluations.

The mechanisms involved as well as appropriate data collection is revised periodically in consultation with the National Reference Laboratories. For further details refer to Guidelines for Quality Assurance of Smear Microscopy.

Quality Assurance for Culture and DST:

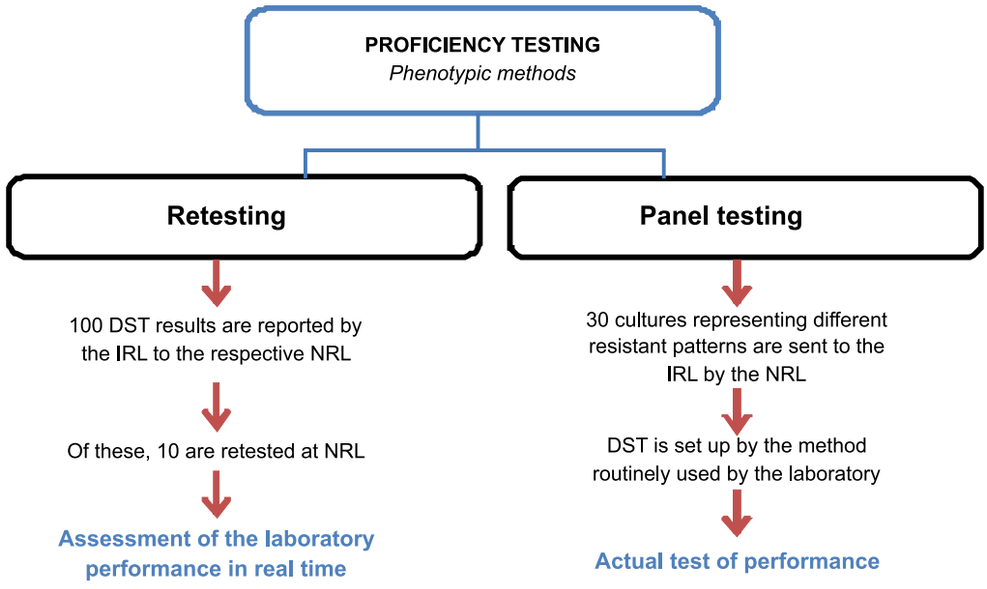
The components of quality assurance for Culture and DST include Internal Quality Control (IQC) and External Quality Assessment mechanisms.

Internal Quality control of LJ media is performed as a routine laboratory protocol and involves testing each batch of media for contamination as well as the use of control strain (H37RV) for growth parameters. IQC for MGIT is instrument guided. External quality assessment is not performed for culture.

Internal quality control of DST involves use of control strain (H37RV) as well as mono resistant strains (R mono and H mono) with every batch of DST performed.

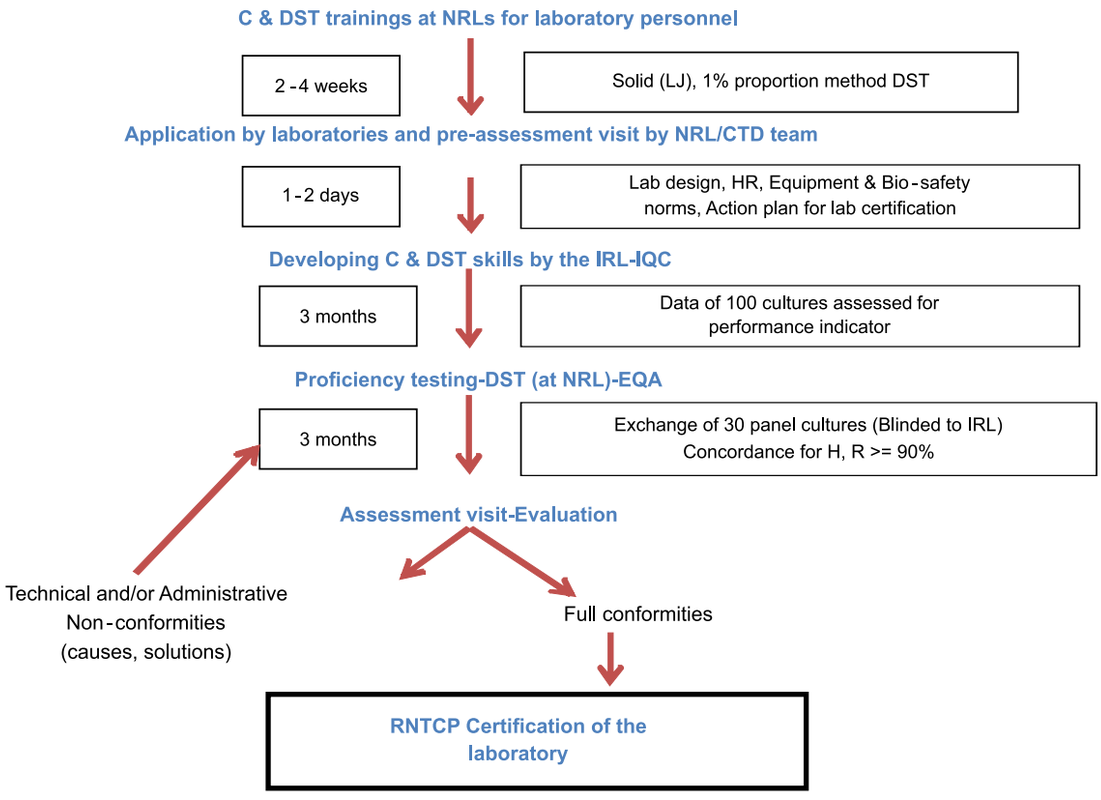
External quality control for both LJ as well as MGIT is performed in two stages, initial retesting as one time activity where the NRL retests ten strains out of hundred performed by the participating laboratory. This is assessment of the laboratory in real time. As a second stage the participating laboratory is required to perform DST for thirty panel strains received annually from the NRL. This is the actual test of performance. For further details refer to Guidance for accreditation of laboratories under RNTCP for Mycobacterial Culture & DST.

Schematic representation of Proficiency Testing:



Schematic representation of the process of Certification:

RNTCP Certification process for TB culture and DST laboratories



Quality assurance for LPA:

Initially, the NRL retests DNA extracts of twenty strains out of 50 performed in duplicates at the participating laboratory. This is followed by annual proficiency testing with panel strains.

PT Benchmark:

- Invalid LPA results – Less than 10%
- Contamination of negative control – Clean in all runs
- Internal Concordance – Greater than 95%
- External Concordance – Greater than 95%

Quality assurance for CBNAAT:

Each CBNAAT cartridge contains internal controls: Sample Processing Control (SPC) and Probe Check Control. If Probe Check fails, then the test is stopped, and an Error result is obtained. Troubleshooting is required based on the error code generated. Error rates higher than 5% should be investigated.

SPC must be:

- Positive when the result is **MTB Not Detected.**
- SPC can be negative or positive when the result is **MTB Detected.**
- The test result is **invalid** if the SPC is negative.

On site visits to CBNAAT sites should be planned at regular intervals to assess laboratory performance by district, state, IRL, NRL, CTD using the available standardized supervisory checklist for CBNAAT. CBNAAT sites in the districts should be visited by IRL/NRL during their EQA visits. Poorly performing sites should be prioritized for on-site visits.

Treatment of TB

Goal of TB Treatment

The goals of Tuberculosis treatment are:

- To decrease case fatality and morbidity by ensuring relapse free cure
- To minimize and prevent development of drug resistance
- To render patient non-infectious, break the chain of transmission and to decrease the pool of infection

Case definitions

I. **Microbiologically confirmed TB case** refers to a presumptive TB patient with biological specimen positive for acid fast bacilli, or positive for Mycobacterium tuberculosis on culture, or positive for tuberculosis through Quality Assured Rapid Diagnostic molecular test.

II. **Clinically diagnosed TB case** refers to a presumptive TB patient who is not microbiologically confirmed, but has been diagnosed with active TB by a clinician on the basis of X-ray abnormalities, histopathology or clinical signs with a decision to treat the patient with a full course of Anti-TB treatment.

In children, clinically diagnosed TB case is diagnosed based on the presence of abnormalities consistent with TB on radiography, a history of exposure to an infectious case, evidence of TB infection (positive TST) and clinical findings suggestive of TB in children in event of negative or unavailable microbiological results

Microbiologically confirmed or clinically diagnosed cases of TB are also classified according to:

- anatomical site of disease;
- history of previous treatment;
- drug resistance;

Classification based on anatomical site of disease

a) **Pulmonary tuberculosis (PTB)** refers to any microbiologically confirmed or clinically diagnosed case of TB involving the lung parenchyma or the tracheo-bronchial tree.

b) **Extra Pulmonary tuberculosis (EPTB)** refers to any microbiologically confirmed or clinically diagnosed case of TB involving organs other than the lungs such as pleura, lymph nodes, intestine, genitourinary tract, joint and bones, meninges of the brain etc.

Miliary TB *is classified as PTB because there are lesions in the lungs. A patient with both pulmonary and extrapulmonary TB should be classified as a case of PTB.*

Classification based on history of TB treatment

a) **New case -** A TB patient who has never had treatment for TB or has taken anti-TB drugs for less than one month is considered as a new case.

b) **Previously treated patients** have received 1 month or more of anti-TB drugs in the past.

I. **Recurrent TB case**- A TB Patient previously declared as successfully treated (cured/treatment completed) and is subsequently found to be microbiologically confirmed TB case is a recurrent TB case.

II. **Treatment After failure** patients are those who have previously been treated for TB and whose treatment failed at the end of their most recent course of treatment.

III. **Treatment after loss to follow-up** A TB patient previously treated for TB for 1 month or more and was declared lost to follow-up in their most recent course of treatment and subsequently found microbiologically confirmed TB case

IV. **Other previously treated patients** are those who have previously been treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented.

c) **Transferred In:** A TB patient who is received for treatment in a Tuberculosis Unit, after registered for treatment in another TB unit is considered as a case of transferred in.

Classification based on drug resistance

a. **Mono-resistance (MR):** A TB patient, whose biological specimen is resistant to one first-line anti-TB drug only.

b. **Poly-Drug Resistance (PDR):** A TB patient, whose biological specimen is resistant to more than one first-line anti-TB drug, other than both INH and Rifampicin.

c. **Multi Drug Resistance (MDR):** A TB patient, whose biological specimen is resistant to both isoniazid and rifampicin with or without resistance to other first line drugs, based on the results from a quality assured laboratory.
Rifampicin Resistance (RR): Resistance to rifampicin detected using phenotypic or genotypic methods, with or without resistance to other anti-TB drugs excluding INH. Patients, who have any Rifampicin resistance, should also be managed as if they are an MDR TB case.

d. **Extensive Drug Resistance (XDR):** A MDR TB case whose biological specimen is additionally resistant to a fluoroquinolone (ofloxacin, levofloxacin, or moxifloxacin) and a second-line injectable anti TB drug (kanamycin, amikacin, or capreomycin) from a quality assured laboratory.

Drug regimen

Drug sensitive TB-

The RNTCP adopted thrice weekly regimen for treatment of drug sensitive TB until now. The programme is now introducing daily regimen for treatment of drug sensitive Tuberculosis among PLHIV and Pediatric TB patients in the entire country and for all TB patients in 104 districts initially. Rest of the country will follow intermittent regimen as per existing guidelines until the daily regimen in scaled up to the entire country. For detailed guidelines on intermittent treatment regimen for drugs sensitive TB, RNTCP training module 1-4 for programme managers may be referred to.

The principle of treatment for tuberculosis (other than confirmed Drug Resistant forms of TB) with daily regimen is to administer daily fixed dose combinations of first – line anti-tuberculosis drugs in appropriate weight bands.

For new TB cases, the treatment in intensive phase (IP) will consist of eight weeks of Isoniazid, Rifampicin, Pyrazinamide and Ethambutol in daily dosages as per four weight band categories. There will be no need for extension of IP. Only Pyrazinamide will be stopped in the Continuation Phase (CP), while the other three drugs will be continued for another 16 weeks as daily dosages.

For previously treated cases of TB, the IP will be of 12 weeks, where injection Streptomycin will be stopped after 8-weeks and the remaining four drugs (INH, Rifampicin, Pyrazinamide and Ethambutol) in daily dosages as per weight bands will be continued for another 4-weeks. There will be no need for extension of IP. At the start of CP, Pyrazinamide will be stopped while the rest of the drugs – Rifampicin, INH and Ethambutol will be continued for another 20 weeks as daily dosages in the CP.

The CP in both new and previously treated cases may be extended by 12-24 weeks in certain forms of TB like CNS TB, Skeletal TB, Disseminated TB etc. based on clinical decision of the treating physician.Extension beyond 12 weeks should only be on recommendation of experts of the concerned field. Loose Drugs would be needed as substitutions in case of adverse drug reaction or with co-morbid conditions.

Type of TB Case	Treatment regimen in IP	Treatment regimen CP
New	(2) HRZE	(4) HRE
Previously treated	(2) HRZES + (1) HRZE	(5) HRE

Prefix to the drugs stands for number of months

MDR/RR-TB cases (without additional resistance)

These patients are to be treated with standard treatment regimen for MDR-TB that contains 6 to 9 months of IP with Kanamycin, Levofloxacin, Ethambutol, Pyrazinamide, Ethionamide and Cycloserine and 18 months of CP with Levofloxacin, Ethambutol, Ethionamide and Cycloserine.

Type of TB Case	Treatment regimen in IP	Treatment regimen CP
Rifampicin resistant + Isoniazid sensitive or unknown[2]	(6-9) Km LfxEto Cs Z E H	(18)LfxEto Cs E H
MDR TB[1]	(6-9) Km LfxEto Cs Z E *(Modify treatment based on the level of INH resistance as per the footnote)*	(18)LfxEto Cs E

All MDR-TB isolates would be subjected to LC DST at baseline for Kanamycin and Levofloxacin, the results of which would be received after 6-8 weeks. Appropriate modifications of the treatment regimens can be done in the presence of additional resistance.

XDR TB

XDR TB cases will be treated with the STR for XDR TB comprising of Injection Capreomycin, Moxifloxacin, Linezolid, PAS, Clofazimine High Dose INH & Co-Amoxyclav.

The duration of IP will be for 6-12 months. Only the injectables will be stopped in CP and the remaining medicines will continue for another 18 months in CP.

All DR-TB treatment regimen are to be given on daily basis under supervision.

Type of TB Case	Treatment regimen in IP	Treatment regimen CP
XDR	(6-12) Cm, PAS, Mfx, High dose- H, Cfz, Lzd, Amx/Clv	(18) PAS, Mfx, High dose-H, Cfz, Lzd, Amx/Clv

Whenever DST pattern of extended panel of drugs would be available to guide the treatment like at six sites where Bedaquiline is introduced initially; the management protocol will follow essentially optimized regimen in case patients are diagnosed with drug resistance other than or in addition to MDR and XDR. Management of such patients is as follows.

Mono/Poly Drug resistant TB

On receiving the reports showing Mono/ Poly DRTB from the quality assured CDST laboratory, patients and their family members are counselled. Patient is referred for evaluation & initiation of the regimen for mono/ poly DR TB to the DR TB center. Repeat rifampicin DST is to be done in case, result of mono or poly drug resistant TB is available after 6-8 weeks.

The DR TB Center committee carries out the pre-treatment evaluation (including clinical and radiological evaluation) of the patient and initiates him/her on the treatment regimen.

- **Mono Drug Resistant TB-**The treatment regimen is consisting of Injectable SLD + FQ + Rifampicin + two out of the first line drugs (from H,E & Z) to which the patient is sensitive to make a total of 5 effective drugs regimen given daily.

- In case of **reported baseline additional resistance to other FLDs**, the regimen is Inj SLD + FQ + Rifampicin + any FLD to which patient is sensitive + one of the remaining Group 4 drugs (Ethionamide, Cycloserine ,PAS).

In addition, High Dose INH is added to the regimen if LPA shows inhA mutation or culture reports show low level INH resistance.

The total duration of treatment will be 9 to 12 months. The Intensive Phase (IP) is for 3 months with scope for extension to a maximum of 6 months. The Continuation phase (CP) is for a fixed duration of 6 months. The patient is initiated on treatment at DR-TB Centre, and then sent back for ambulatory treatment to the DTO for continuation of treatment regimen and regular follow-up.

Type of TB Case	Treatment regimen in IP	Treatment regimen CP
Rifampicin Sensitive INH Resistant[1] TB & DST of SEZ not known	(3-6) Km Lfx R E Z *(modify treatment based on baseline DST report to E,Z,KM, CM,Lfx, Mfx)*	(6) Lfx R E Z

In certain circumstances, the committee can decide to continue same treatment on which the patient was, if patient is clinically, radiologically & microbiologically better while recommending an extension in the duration of the regimen and more frequent sputum smear and/or cultures in follow-up.

After 6 to 8 weeks the CDST reports of the patient sent before the initiation of treatment becomes available. The DTO continues the treatment regimen if no additional drug resistance is detected on culture DST report. However if the CDST report shows additional Drug resistance, the DTO once again performs Sputum smear and if the Sputum smear is positive, the patient must be once again tested for Rifampicin resistance by LPA/CBNAAT before referring the patient to DR TB Center for further evaluation.

MDR/RR-TB cases with additional resistance

In case of additional drug resistance, the treatment can be modified as follows:

- In case of resistance to Ethambutol, it is to be omitted.
- In case of resistance to Pyrazinamide, it is to be omitted.
- In case of resistance to both Ethambutol and PZA, PAS to be added in IP and CP
- In case of resistance to Levofloxacin or Moxifloxacin, the sensitive one is to be used along with PAS and clofazimine.
- In case of resistance to both Levofloxacin and Moxifloxacin, these drugs are to be replaced with Clofazimine, Linezolid and PAS in IP and CP. The duration of IP will be from 6 to 12 months.
- In case of resistance to any second line injectable (Kanamycin or Capreomycin), use one of the sensitive injectables.
- In case of resistance to all second line injectable, replace them with Clofazimine, Linezolid and PAS in IP and CP. The duration of IP will be from 6 to 12 months.

Type of TB Case	Treatment regimen in IP	Treatment regimen CP
MDR or Rifampicin Resistant TB + Ethambutol resistance[1,2]	(6-9) Km Lfx Eto Cs Z	(18) Lfx Eto Cs
MDR or Rifampicin Resistant TB + Pyrazinamide resistance[1,2]	(6-9) Km Lfx Eto Cs E	(18) Lfx Eto Cs E
MDR or Rifampicin Resistant TB + Ethambutol + Pyrazinamide resistance[1,2]	(6-9) Km Lfx Eto Cs PAS	(18)Lfx Eto Cs PAS
MDR or Rifampicin Resistant TB + Levofloxacin	(6-9) Km Mfx Eto Cs Z E PAS Cfz	(18)Mfx Eto Cs E PAS Cfz
MDR or Rifampicin Resistant TB + Moxifloxacin	(6-9) Km Lfx Eto Cs Z E PAS Cfz	(18)Lfx Eto Cs E PAS Cfz
MDR or Rifampicin Resistant TB + Resistance to all Fluoroquinolones	(6-12) Km Eto Cs Z E PAS Cfz Lzd	(18) Eto Cs E PAS Cfz Lzd
MDR or Rifampicin Resistant TB + Resistance to Km only	(6-9) Cm Lfx Eto Cs Z E	(18)Lfx Eto Cs E
MDR or Rifampicin Resistant TB + Resistance to all SL Injectable	(6-12) Lfx Eto Cs Z E PAS Cfz Lzd	(18)Lvx Eto Cs E PAS Cfz Lzd

MDR-TB with mixed patterns of resistance

In MDR-TB cases with mixed patterns of resistance (any FLD/ Inj SLD/ FQ/ Ethionamide, PAS, LZ, CF), Standardised Treatment Regimen (STR) for MDR TB will be modified in the following way:-

Type of TB Case	Treatment regimen in IP	Treatment regimen CP
Mixed resistance pattern (any FLD/Inj SLI/FQ / Ethionamide, PAS, LZ, CF)[3]	(6-9) Km LfxEto Cs Z E **Modify based on resistance pattern:** Use any SLIand FQ as per recommendation above. Consider other oral drugs as per DST pattern and **Duration:** *If SLI& FQ are included:* Minimum 6 Drugs in IP. *If SLI and /or FQ are not included:* Minimum 8-9 drugs are to be given in IP. *In pre-XDR/XDR patients, duration of IP will be 6-12 months*	(18)LfxEto Cs E **Duration:** If SLI& FQ are included: Minimum 4 Drugs in CP If SLI and /or FQ are not included: Minimum 7-8 drugs in CP

These regimen will be scaled up when DST guided treatment guidelines will be implemented for the entire country.

Notes-

1. *For Isoniazid resistance, decision on use of Isoniazid in the regimen depends on following:*
   - If High level resistance detected by Liquid culture - omit INH.
   - If low level resistance detected by Liquid culture - add high dose INH.
   - If LPA reports INH resistance by Kat G mutation- Omit INH
   - If LPA reports INH resistance by INH A mutation- Use High dose INH. Ethionamide in the treatment regimen will be replaced with PAS
2. *If RR by CBNAAT, add INH in the standard doses to the treatment regimen till results of LPA or Liquid culture DST are known.*
   - ☞ For new patients diagnosed as TB and RR by CBNAAT, put up both a repeat CBNAAT & send sample for liquid culture. Till then - following will be the treatment:
     - If second CBNAAT also shows RR - start standard MDR-TB treatment regimen with INH till the results from culture DST are known. Perform DST to H & SLDST on the liquid culture.
     - If second CBNAAT shows R sensitive- Start regimen for new TB cases and wait for report of Liquid culture DST.
       - If Liquid culture shows R Sensitive - Continue regimen for new TB cases.
       - If Liquid culture shows R resistance-refer the patient to DR TB center committee for Clinical, Radiological & microbiological assessment and decision regarding starting standard MDR-TB treatment regimen or continuing regimen for new TB cases depending upon the response to treatment given so far.
3. For mixed resistance pattern, consider oral drugs in following sequence of preference - Pyrazinamide (If Sensitive), Ethambutol, Ethionamide, Cycloserine, Pas, Clofazimine,Linezolid, Co-Amoxyclav, High Dose INH& Clarithromycin
4. The regimen designing / modification will be the prerogative of the DR-TB centre committee only.
5. Surgery in M/XDR-TB patients:
   - All patients of M/XDR-TB should be evaluated for surgery at the initiation of treatment and/or during follow up.

Bedaquiline Conditional Access Programme: Introduction of new anti TB drug under RNTCP

Bedaquiline (BDQ): is a new class of drug, diarylquinoline that specifically targets mycobacterial ATP synthase, an enzyme essential for the supply of energy to *Mycobacterium tuberculosis* and most other mycobacteria. Strong bactericidal and sterilizing activities against *M. tuberculosis* have been shown in pre-clinical, laboratory and animal experiments. The drug has a high volume of distribution, with extensive tissue distribution, highly bound to plasma proteins and hepatically metabolized. The drug has an extended half-life, which means that it is still present in the plasma up to 5.5 months post stopping BDQ. The dosing schedule has been established after extensive pharmacokinetic / pharmacodynamic (PK/PD) studies in animals and humans and hence needs to be administered as per the manufacturer's advice. BDQ demonstrates no cross-resistance with existing first- and second-line anti-TB drugs and has shown significant benefits in improving the time to culture conversion in MDR-TB patients. In June 2013, WHO published interim policy guidance for the use of BDQ in conjunction with the WHO-recommended MDR-TB treatments. RNTCP is introducing BDQ through conditional access programme at 6 sites in the country initially.

Criteria For Patients To Receive Bedaquiline

Basic criteria: The criteria for patients to receive BDQ as approved by the Apex Committee is: adults aged ≥ 18 years having pulmonary MDR-TB.

Additional requirements

- Females should not be pregnant, or should be using effective non-hormone-based birth control methods. They should be willing to continue practicing birth control methods throughout the treatment period, or have been post-menopausal for the past 2 years.
- Patients with controlled stable arrhythmia can be considered after obtaining cardiac consultation.

Treatment with Bedaquiline Containing Regimen

Pre-treatment evaluation of patients

All eligible patients would be subjected to a thorough pre-treatment evaluation at the DR-TB centres as per the RNTCP PMDT Guidelines. In addition, some additional pre-treatment evaluations would be added for patients eligible for BDQ containing regimen:

Each of the DR-TB centres must ensure that the necessary laboratory capacity and consultancy services from various specialists are available in the sites, either in-house or through an outsourced mechanism supported under institutional/state govt. mechanisms.

Treatment initiation

While waiting for the results of baseline SLDST as detailed above, all patients diagnosed as MDR-TB/RR-TB using various technologies will be initiated on standard regimen for MDR-TB as per RNTCP PMDT Guidelines. Once the results of baseline SLDST are available, the patients eligible and consented to be treated with BDQ containing regimen will be identified and an appropriate regimen will be designed by the DR TB center committee.

All eligible patients need to be offered counseling along with a patient education booklet which will give details of the nature and duration of treatment including information on the new drug BDQ; need for regular treatment; possible side-effects of these drugs; drugs to be avoided with BDQ and the consequences of irregular treatment or premature termination of treatment. Female patients will receive special counselling on family planning. After this, a written informed consent will be obtained from patients before administration of BDQ containing regimen.

All patients would be counseled and managed indoor for a mandatory period of 2 weeks (14 days) to complete the initial 2 weeks of BDQ doses. The final decision of further duration of indoor management of the patients rests with the DR-TB Centre committee and must be well-documented for every patient. After discharge the treatment will be continued on ambulatory basis as per RNTCP PMDT guidelines with strict adherence of treatment and the follow up schedule.

All measures for airborne infection control must be implemented as per the national AIC guidelines while managing all TB patients.

The RNTCP PMDT treatment register has been updated. Once the BDQ CAP is initiated, this new format of the register will be used for all DR-TB patients by the concerned DR-TB centers. The patient would be registered in this updated register and all necessary records would be maintained as detailed in the guidelines.

Please refer to The Guidelines for use of Bedaquiline in RNTCP through conditional access under the Programmatic Management of Drug Resistant Tuberculosis (PMDT) in India for details of BDQ Conditional Access Programme

Drug Dosage

Drug Dosage for Adult TB

Weight category	Number of tablets (FDCs)		Inj. Streptomycin
	Intensive phase	Continuation phase	
	HRZE	HRE	
	75/150/400/275	75/150/275	gm
25-39 kg	2	2	0.5
40-54 kg	3	3	0.75
55-69 kg	4	4	1
>=70	5	5	1

**Inj. Streptomycin to be added in IP phase for 2 months in the previously treated regimen of drug sensitive patients. In patients above 50 years of age, maximum dose of streptomycin should be 0.75gm.*
Adults weighing less than 25 kg will be given loose drugs as per body weight. Dosages of loose drugs are given in appendix

Drug Dosage for Pediatric TB

Weight category	Number of tablets (dispersible FDCs)			Inj. Streptomycin
	Intensive phase		Continuation phase	
	HRZ	E	HRE	
	50/75/150	100	50/75/100	mg
4-7 kg	1	1	1	100
8-11 kg	2	2	2	150
12-15 kg	3	3	3	200
16-24 kg	4	4	4	300
25-29 kg	3 + 1A*	3	3 + 1A*	400
30-39 kg	2 + 2A*	2	2 + 2A*	500

A=Adult FDC (HRZE = 75/150/400/275; HRE = 75/150/275)

Dosage for DR-TB for adults

S.No	Drugs	16-25 Kgs	26-45 Kgs	46-70 Kgs	>70 Kgs
1	Rifampicin*	300	450	600	600
2	Isoniazid[$]	200	200	300	450
3	Ethambutol	400 mg	800 mg	1200 mg	1600 mg
4	Pyrazinamide	500 mg	1250 mg	1500 mg	2000 mg
5	Kanamycin	500 mg	500 mg	750 mg	1000 mg
6	Levofloxacin	250 mg	750 mg	1000 mg	1000 mg
7	Ethionamide	375 mg	500 mg	750 mg	1000 mg
8	Cycloserine	250 mg	500 mg	750 mg	1000 mg
9	Na-PAS (80% weight/vol)[1]	7.5 gm	10 gm	12 gm	16 gm
10	Pyridoxine	50 mg	100 mg	100 mg	100 mg
11	Moxifloxacin (Mfx)	200 mg	400 mg	400 mg	400 mg
12	Capreomycin (Cm)	500 mg	750 mg	1000 mg	1000 mg
13	Amikacin (Am)	500 mg	500 mg	750 mg	1000 mg
14	High dose INH (High dose-H)	400 mg	600 mg	900 mg	900 mg
15	Clofazimine (Cfz)	100 mg	200 mg	200 mg	200 mg
16	Linezolid (Lzd)	300 mg	600 mg	600 mg	600 mg
17	Amoxyclav(Amx/Clv)(In child: WHO 80mg/Kg in 2 divided doses)	875/125 mg BD	875/125 mg BD	875/125 mg 2 morn +1 even	875/125 2 morn +1 even
18	Clarithromycin (Clr)	250 mg BD	500 mg BD	500 mg BD	750 mg BD

**For mono-H resistant TB; [$]For Rifampicin Resistant TB*

[1]In case of PAS with 60% weight/volume the dose will be increased to 10 gm (16-25 Kg); 14 gm (26-45 Kg); 16 gm (46-70 Kg) and 22 gm (>70 Kg)

Dosage for MDR-TB in pediatric Patients (less than 30 kg body weight)

Drug	Daily Doses*
Kanamycin / Capreomycin	15-30 mg/kg (SM 20-40 mg/kg)
Levofloxacin / Moxifloxacin	Levo<5 yrs: 15-20 mg/kg split dose Levo>5 yrs: 10-15 mg/kg once day Moxi 7.5-10 mg/kg
Ethionamide	15-20 mg/kg
Cycloserine	10-20 mg/kg
Ethambutol	15-25 mg/kg
Pyrazinamide	30-40 mg/kg
Na-PAS	<30 kg: 200-300 mg/kg

Drug dosage for XDR TB paediatric patients

Drugs	Daily Dose*
Inj. Capreomycin (Cm)	15-30 mg/kg
PAS	<30 kg: 200-300 mg/kg
Moxifloxacin (Mfx)	7.5-10 mg/kg
High dose INH (High dose-H)	15-20 mg/kg#
Clofazimine (Cfz)	1 mg/kg (max. 200 mg / day) limited data
Linezolid (Lzd)	10 mg/kg TDS (max. 600mg /day) with pyridoxine
Amoxyclav(Amx/Clv)	80 mg/kg (based on amoxicillin component) in two divided doses (max.4gm amox + 0.5gm clav)
Clarithromycin (Clr)	7.5 mg/kg every 12 hours

** as per companion handbook to the WHO guidelines for the programmatic management of drug-resistant TB.*

 # Till the time data are available, adult dose is used

Operational guidelines for treatment initiation

By suspecting TB in a patient, the clinician assumes an important role of providing complete care to the patient including long-term relapse free cure from TB. S/he also assumes an important public health responsibility of preventing the transmission of disease. If the clinician is waiting passively for the patient to report with the result of diagnostic test, it may cause significant delay in initiation of treatment or the patient may be lost to follow up. Hence, clinicians who refer the presumptive TB/ drug resistant TB case for diagnosis are encouraged to actively trace the patients. Health facilities that diagnose patients who do not reside in their service delivery area have to refer the patient to the facility where the patient would undergo monitoring of treatment.

All TB patients are offered quality assured anti-TB drugs under RNTCP. Treatment should be initiated by a trained medical officer. In most of the situations, treatment process may be initiated in the peripheral health institution which caters to the patient's residential area. In special circumstances, patients may have to be initiated on treatment in institutions outside their residential areas. eg. patient admitted in medical college hospital.

The information required for treatment initiation of TB patients are drug sensitivity pattern and history of anti-TB treatment. Based on it, decision on treatment to be taken as follows:

History of treatment	Drug sensitivity status	Type of regimen
New	Drug sensitive or DST unknown / awaited	Regimen for new case
Previously treated	Drug sensitive or DST unknown* / awaited	Regimen for previously treated case
New or previously treated	Drug resistant	Regimen based on DST pattern

**If DST is unknown, the patient should be offered DST based on current criteria of presumptive DR-TB patient. Four sets of drug sensitivity patterns may be offered based on availability of DST services.*

- Rifampicin alone, where a CBNAAT is used for diagnosis.
- Isoniazid and Rifampicin where a LPA is used for diagnosis.
- A detailed first line pattern with Isoniazid, Rifampicin, Ethambutol and Streptomycin if a first line liquid DST is used.
- A second line DST pattern for second line drugs as may be available

The medical officer should record the weight of the patient. It is ideal to record the height also, to assess the Body Mass Index (BMI), which would provide a good indicator for prognosis of the disease. The patients should be given dosages depending on body weight in weight bands.

The medical officer of peripheral health facility can initiate treatment based on abovementioned information. However, all DR-TB patients should be treated with active involvement of DR-TB centre.

A proper pre-treatment evaluation is essential for each DR-TB patients (Rifampicin resistant / mono-/poly- resistant TB / MDR / XDR. For pre-treatment evaluation, a patient needs to be referred to appropriate health facilities where clinical competency to carry out such assessment is available. The pre-treatment evaluation includes a thorough clinical evaluation by a physician, chest radiograph, and relevant haematological and bio-chemical tests detailed in the box below.

Pre-treatment evaluation for DR-TB patients

1. Detailed history (including screening for mental illness, seizer disorder, drug/alcohol abuse etc.)
2. Weight
3. Height
4. Complete Blood Count with platelets count
5. Blood sugar to screen for Diabetes Mellitus
6. Liver Function Tests
7. Blood Urea and S. Creatinine to assess the Kidney function
8. TSH levels to assess the thyroid function (TSH levels alone are usually sufficient to assess the thyroid function of the patient)
9. Urine examination – Routine and Microscopic
10. Pregnancy test (for all women in the child bearing age group)
11. Chest X-Ray
12. ECG (if Moxiflocaxin is to be used)
13. Serum electrolytes (if Capreomycin is to be used)

- All DR-TB cases will be offered referral for HIV counselling and testing at the nearest centre if the HIV status is not known or the HIV test is found negative with results more than 6 months old. If patient is HIV positive refer her/him to ART centre (if not on ART)
- Surgical evaluation should be added to the pre-treatment evaluation wherever indicated
- Preferably, pre-treatment evaluation should be carried out at DR-TB centre where DR-TB committee with group of experts are available. In this case, the patient should be referred to the DR TB center for admission & initiation of treatment with their DST result and referral for treatment form. Alternatively, district TB Officer can arrange pre-treatment evaluation at district level linked DR-TB centre or even at sub-district level health facility, in case the patient is unable to get hospitalized and to avoid any delay in initiation of treatment. In such case, the results of pre-treatment evaluation are communicated to DR-TB Centre Committee and on approval; the regimen for DR-TB can be initiated at the DTC.

Patient Flow in case of TB patients

- Before initiating the treatment, all the TB patients should be counselled thoroughly. It is advisable to involve close family members during the counselling, since family support is an essential component in the management.
- Educate the patient and family members about the disease (type of disease and mode of spread) and the treatment (dosage schedule, duration, common side-effects and methods to prevent them).
- Counsel the patient and family members to ensure treatment adherence (importance of need for regular treatment and consequences of irregular treatment or premature cessation of treatment, monitoring of progress until completion of treatment).
- Explain patients on prevention of transmission of disease (cover cough, proper disposal of sputum) and encourage him to get all his close contacts (especially household contacts) screened at the earliest.
- It is important to look for co-morbidities like diabetes, liver or renal diseases, neurological disorders etc. It is also important to look for substance abuse especially tobacco (in any form) & alcohol. Socioeconomic status of the patient may be assessed to link him/her with appropriate treatment support schemes.
- Medical Officer needs to open a treatment card (in duplicate when required) for each patient at the time of initiation of treatment. Each patient must be given TB Identity Card.
- Drugs should be made available at the treatment centre along with the TB treatment Card. Appropriate treatment adherence and monitoring mechanisms should be planned by the MO at the time of treatment initiation in consultation with the patient and the peripheral health worker who is responsible for monitoring treatment adherence.
- Assure the patient that s/he will be supported during the entire course of treatment by the MO and peripheral health care workers.
- Medical officer should make efforts to get HIV testing done in all cases of TB. This is important to ensure all HIV positive TB patients receive ART and CPT. Ideally all presumptive TB patients have to undergo HIV screening. If not, offer HIV screening. All HIV positive TB patients have to be referred to ART centre for initiation of ART and CPT.

Patient Flow in case of DR-TB patients

- DR-TB Centre should be involved actively in management of all DR-TB patients.
- DR-TB Centre will be the reporting unit for catering districts and will register all DR-TB cases of respective districts in DR-TB treatment registered with issue of unique DR-TB number.
- Treatment card of DR-TB patients admitted at DR-TB centre for pre-treatment evaluation will be opened by Medical Officer of DR-TB Centre.
- In case, a patient is not evaluated at DR-TB centre, results of the pre-treatment evaluation will be communicated to the DR-TB Centre committee for a decision to initiate the patient on treatment.
    - On receiving an affirmation from the DR-TB Centre committee the DTO will open the treatment card and start the patient on treatment.
    - A copy of the treatment card will be sent to the DR-TB Centre for their record and registration in the PMDT register.
    - On registration the DR-TB Centre will inform the PMDT TB number to the DTO.
- After pre-treatment evaluation and initiation of treatment, the patient should be referred back to the residence district / PHI with up to a maximum of one week's supply of drugs, arrangements for injections in transit, and a copy of the treatment card and referral form.
- The respective DTO / MO-PHI should be informed by the MO DR-TB centre / DTO on referral of patients for ambulatory care in advance, by means of the RNTCP PMDT referral for treatment form via email.
- Drugs provided to the patients to cover for transit period may be counted as unsupervised doses. However, as far as possible efforts should be made by the district staff to restrict these transit doses
- The DTO arranges for availability of the monthly IP drug box (from the TU) and the patient records at the identified treatment support Centre with information to the respective MO-PHI.
- This MO-PHI is responsible for supplying the treatment records and the drugs to the designated Treatment supporter. The MO-PHI will need to make suitable arrangements during the intensive phase of the treatment for daily injections including free needles and syringes.
- The overall responsibility of the patient on treatment including follow up is with the MO-PHI from where the patient is taking the treatment

Treatment support program

Adherence to regular and complete treatment is the key to relapse free cure from TB. To assess and foster adherence, a patient-centred approach to administration of drug treatment, based on the patient's needs and mutual respect between the patient and the provider, should be developed for all patients.

A good treatment support plan should be developed at the time of initiation of treatment. This plan should include initial and frequent follow-up counselling of the patient and family members, supervision of treatment by a trained treatment supporter (a health worker or community volunteer), locally managed additional nutritional support, retrieval of treatment interrupters, screening for adverse reactions, psycho-social support, co-morbidity management and follow up laboratory investigations.

Direct observation of treatment is one of the best practices to promote adherence. It ensures that the patient consumes every dose of the treatment before a trained health worker and provides additional opportunity to support treatment. *However, the principle of direct observation is to be applied logically and judiciously.*

A treatment supporter who is acceptable, accessible to the patient and accountable to the health system should be identified and trained. A health worker in the hospital/health centre may be the best person to provide all the envisaged components of treatment support program. However, access to such a health worker in person, place and time may be limited since the centre may be far away from patient's residence, working hours may be restricted and the worker may be away on field visits. Compelling the patient to travel long distance to avail directly observed treatment is against the principles of patient centric approach. Hence all efforts must be put in to find a treatment supporter close to the patient's residence. Accumulating evidence has pointed to the effectiveness of a wide variety of approaches including community and family-centered DOT, which is more achievable for most developing healthcare systems and produce comparable outcomes to DOT by healthcare worker.

Wherever appropriate, a family member can also be assigned with the responsibility of observing treatment. Such situations may arise with sick and bed ridden patients, children, long-day workers etc. In such situations, the family member who is assigned with the responsibility to observe treatment should be trained well and supported during the process by a health worker by frequent visits to the house.

Each patient and his/her treatment supporter should be supervised by a health worker. It may be a peripheral health worker in the public health system. If the patient is initiated on treatment by a private health care provider, public health system may offer this supportive role when requested.

While observing treatment is one of the best modalities of promoting treatment, other modalities also may be deployed to further enhance adherence to treatment. Intelligent deployment of information communication technologies (ICT) is an example of such modalities. A patient who is unable to undergo supervised treatment should not be denied treatment. Frequent on-job travellers, truck drivers, sailors etc may require identification of proper treatment supporter. To promote treatment adherence among these patients, ICT modalities like frequent calls, SMS reminders, IVRS etc. may be deployed. [Box: Choices for ICT based Treatment adherence support]

Patient may require mobility support if s/he prefers observation of treatment outside his residence. Counselling may be required to quit substance abuse. Nutritional assessment & support, ancillary drugs, co-morbidity management, compensation for lost wages etc. are some other requirements.

To avail these, Healthcare providers should endeavor to derive synergies between various social welfare support systems like RSBY, TB pension schemes, national rural employment guarantee scheme,corporate social responsibility (CSR) initiatives, counselling centres etc.to mitigate out of pocket expenses such as transport and wage loss incurred by people affected by TB.

All individuals with active TB should receive (i) an assessment of their nutritional status and (ii) appropriate counselling based on their nutritional status at diagnosis and throughout their treatment. (iii)If malnutrition is identified, it should be managed according to WHO recommendations. Linkages for extra nutritional support for TB patients or of his/her contacts on IPT may be explored with existing Govt. schemes like public distribution system (PDS) or Food security act.

Under the programme, compensation is provided for transport costs incurred by DR TB patient for sending specimen for follow upor for travel to DR-TB centre. In addition, TB patients in tribal and difficult areas get Rs. 750.Treatment supporters are also provided incentive to ensure completion of treatment as below:

Category I	Rs. 1000 per patient
Category II	Rs. 1500 per patient
Category IV / V	Rs. 5000 per patient

The compensation may be given to TB HIV patients for visits to ART centers. For enablers or incentives refer to **Annexure 8**. If required, linkages with various social support systems to be explored and ensured, for additional treatment support. Capacity building and engaging with local community based organizations, self-help groups, patient support groups, PRI could prove to be effective intervention to promote treatment adherence.

All patients, should have free or affordable quality assured diagnostic and treatment services, which should be provided at locations and times so as to minimize workday or school disruptions and maximize access.

Box: Choices for ICT based Treatment adherence support

Mobile based "Pill-in-Hand" adherence monitoring tool In this mechanism, each time a patient takes a dose of medication, a hidden number appears which is printed on the strip behind the drug. The patient need to send a missed call to a particular contact number with the digits appeared on drug package. This will be documented at a centralized ICT unit. And thus, an electronic treatment record of each patient will be maintained to monitor the treatment adherence.

Because the sequence of hidden numbers cannot be predicted by patients, but are known by the system for each month of medication prescribed, the system offers high confidence that patients who respond correctly have indeed dispensed their medication.

S/he can also be providing the option of where in the patients treatment would be remotely followed up with help of Interactive Voice Response (**IVR**), **SMS** reminders.

Specially designed **electronic pill boxes** or strips with GSM connection and pressure sensor can be used to monitor the pill consumption by tracking the weight of the remaining pills.

The treatment provider can use the **Patient Compliance toolkit;** a mobile app for patients to report treatment compliance using video, audio or text message.

Automated pill loading system, which will load the dosage as per the pre-programmed settings. Medication dispenser: a color-coded reminder system built in the dispenser that will hold drugs.

Treating doctors can be provided with **innovatively designed cards** to educate them on correct TB prescription methods. Doctors will then give these cards to TB patients, instructing them to SMS the server/ customer care centre (CCC) the unique code on the card which will register them on the network and also SMS the unique codes printed on their TB drugs as they take them. The CCC will then deliver phone interventions like reminders to take medicines, financial incentives, follow up calls, and TB health tips via SMS and phone balance recharge, mobile APP for scheduled dose reminders and alerts.

A Short Messaging service **(SMS) gateway** to be made available by which the patient can report day to day events like pill consumption, minor side effects or his need for help through simple and shortcut SMS templates. The gateway can allow incoming services in pre-recorded or Interactive Voice Response (IVR) mode to inform patients about their test results, as follow up reminders and as periodic counselling messages.

Follow up of Treatment

Patients should be closely monitored for treatment progress and disease response. There are two components of follow up: (1) Clinical follow up and (2) Laboratory follow up

1. **Clinical follow up** should be done at least monthly. Patient may visit the clinical facility for reviews or the medical officer may conduct the review when he visits the house of the patient. Improvement on chest symptoms, increase in weight etc. may indicate good prognosis. Control of co-morbid conditions like HIV and diabetes by appropriate treatment is essential for getting a better prognosis to TB treatment. Symptoms and signs of adverse reactions to drugs should be specifically asked. Detailed description of symptoms and signs of adverse reaction to anti-TB drugs and pharmacovigilance program is described in relevant section.

2. **Laboratory investigations** may be those to assess the prognosis of the disease or to manage co-morbidities or adverse reaction. In case of pulmonary tuberculosis, sputum smear microscopy should be done at the end of IP and end of treatment. A negative sputum smear microscopy result at the end of IP may indicate good prognosis. However, in the presence of clinical deterioration, the medical officer may consider repeating sputum smear microscopy even during CP. This will provide the patient an early opportunity to undergo drug susceptibility testing if s/he is found to be sputum smear positive. At completion of treatment, a sputum smear and/or culture should be done for every patient. This is very important because, culture is a more sensitive and specific test compared with smear microscopy to detect the presence of M.tb in biological specimens.

   Chest x-ray may be a good tool to assess the progress and it is to be offered to drug sensitive pulmonary TB patients whenever required and available. For drug resistant TB patients, it is to be carried out at end of IP, at end of treatment and whenever required.

   Response to treatment in extrapulmonary TB may be best assessed clinically. Help of radiological and other relevant investigations may be taken.

   Response to treatment in children: In children in their early ages are unable to produce sputum, the response totreatment among them may be assessed clinically. The help of radiological andother relevant investigations may also be taken.

Long term follow up: After completion of treatment, the patients should be followed up at the end of 6, 12, 18& 24 months. In presence of any clinical symptoms and/or cough, sputum microscopy and/or culture should be considered. This is important in detecting recurrence of TB at the earliest.

In case of DR-TB patients, the DTO will ensure that an updated copy of the treatment card is sent to the designated DR-TB Centre, preferably electronically, every month for updating the DR-TB Register. Clinical follow-up should be done monthly. For collection of the follow-up samples for culture, the patient will need to go to their respective sputum collection centre, where the DTO will arrange for the samples to be collected and transported to the respective RNTCP-certified Culture and DST laboratory. The patient will need to go to the DR-TB Centre for the decision to end treatment, for managing severe adverse drug reactions, and for any change of regimen or dosage. All referrals from the DTC to the DR-TB Centre or vice versa should be made on Referral for Treatment Form. The receiving health facility should communicate the receipt of patient to the referring centre through an e mail.

Type of Case	Follow up schedule	Extension of treatment	Action on follow up positive	Long term follow up
Drug sensitive Pulmonary TB (New & Previously treated TB)	**Microbiological**: One specimen at the time of completion of the intensive phase of treatment, and at the end of treatment. **Weight:** Monthly **Chest X-Ray: if required** **Physician evaluation** : whenever required	Extension of IP is not required	If the sputum smear is positive in follow-up at any time during treatment, DST should be done as per presumptive DR-TB case	After completion of treatment the patients should be followed up with clinical and/or sputum examination at the end of 6, 12, 18 and 24 months.
Multi Drug resistant Pulmonary TB *(with or without additional drug resistance)*	**Microbiological:** One sputum specimen will be collected and examined by culture at least 30 days apart from the 3rd to 7th month of treatment (i.e. at the end of the months 3, 4, 5, 6 and 7) and at 3-monthly intervals from the 9th month onwards till the completion of treatment (i.e. at the end of the months 9, 12, 15, 18, 21 and 24). If any culture during CP or end of treatment is positive then it should be followed by monthly culture for 3 months. **Weight:** Monthly **Chest X-Ray** at end of IP, end of treatment and whenever clinically Indicated **Physician evaluation** including adverse drug reaction monitoring every month for six months, then every three months for two years **S. Creatinine** monthly for first 3 months,	In MDR TB cases IP can be extended for maximum three months (maximum duration of IP – 9 months). In all MDR TB with additional drug resistant cases (including XDR TB) patients, IP can be extended for maximum 6 months (maximum duration of IP – 12 months)*.	On follow up if sputum culture is found to be positive at 6 months or later, repeat DST for second-line drugs to decide on further course of action. DST to other additional second line drugs may also be done if laboratory facilities are available to guide treatment.	

	then every 3 months during the injectable phase **Thyroid Function Test** during pre-treatment evaluation and whenever indicated **For additional drug resistance** :- ECG: once a month in IP whenever Moxifloxacin is used **Complete Blood Count with Platelets Count:** weekly in first month, then monthly to rule out bone marrow suppression and anaemia as a side effect of Linezolid **Kidney Function Test**- monthly creatinine and addition of monthly serum electrolytes to the monthly creatinine during the period that Inj. Capreomycin is being administered **Liver Function Tests**: monthly in IP and 3 monthly during CP **Chest X-Ray:** every 6 months in XDR-TB patients			
Mono- / Poly-Drug resistant Pulmonary TB	**Microbiological**: One sputum specimen is collected and examined with smear and culture at 2nd and 3rd months & then culture examination at 3-monthly intervals till completion of the treatment. **Weight:** Monthly **Chest X-Ray: if required** **Physician evaluation** : whenever required	IP can be extended for maximum three months (maximum duration of IP – 6 months).	If the sputum /culture is positive in follow-up at any time during treatment, DST should be done as per presumptive DR-TB case	After completion of treatment the patients should be followed up with clinical and/or sputum examination at

				the end of 6, 12, 18 and 24 months.
Extra Pulmonary TB	In patients with extra-pulmonary tuberculosis the treatment response is best assessed clinically. The help of radiological and other relevant investigations may also be taken as above.	-Extension of IP or and/or CP in DS EPTB may be required in consultation with the specialist concerned. -Extension of IP DR-TB EPTB may be required in consultation with the specialist concerned. - Refer to guidelines for EPTB duration of treatment.		
Pediatric TB	In children, who are unable to produce sputum, the response to treatment may be assessed clinically. The help of radiological and other relevant investigations may also be taken.	Same as above		

***Extension of IP in DR-TB patients**

MDR TB patients

IP should be given for at least six months. After 6 months of treatment, the patient will be reviewed and the treatment changed to CP if the 4th or 5th month culture result in solid or liquid culture is negative respectively. If the 4th or 5th month culture result remains positive, the treatment is extended by 1 month. Extension of IP beyond 1 month will be decided on the results of sputum culture of 5th or 6th and 6th or 7th months. If the result of the 4th month culture is still awaited after 6 months of treatment, the IP is extended until the result is available, with further treatment being decided according to the culture result. The IP can be extended up to a maximum of 3 months after which the patient will be initiated on the CP irrespective of the culture result. The recommended duration for CP is 18 months.

***Schedule for sputum culture examinations for MDR-TB**

IP extension	Intensive phase				Extension of IP (1-3 months)			Continuation phase					
No	3	4	5	6	-	-	-	9	12	15	18	21	24
1 month	3	4	5	6	7			10	13	16	19	22	25
2 months	3	4	5	6	7	8		11	14	17	20	23	26
3 months	3	4	5	6	7	8	9	12	15	18	21	24	27

** For MDR TB with additional drug resistance (including XDR TB) patients and XDR-TB IP extension can be upto 1-6 months.*

MDR TB with additional drug resistance (including XDR TB) patients

The change from IP to CP will be done only after achievement of culture conversion i.e., 2 consecutive negative cultures taken at least one month apart. In case of delay in culture conversion, the IP can be extended from 6 months up to a maximum of 12 months. In case of extension, the DR -TR Centre Committee, which will be responsible for initiating and monitoring the regimen for XDR TB, can decide on administering second line injectable intermittently (3 times/week) for the months 7 to 12.In case of extension of IP, the follow up culture months will shift by every month of extension of IP

Mono/poly DR TB patients

IP should be given for at least 3 months. After 3 months of treatment, the patient will be reviewed. If after the 3rdmonth smear result remains positive, the sputum sample is sent for genotypic DST to Rifampicin by CBNAAT or LPA and Liquid/solid culture & DST to see for resistance amplification. Shifting of IP to CP will be based on result of culture. The IP can be extended up to a maximum of 3 months after which the patient will be initiated on the CP irrespective of the culture result. The recommended duration for CP is 9 months.

At any time during treatment, if and when the results of additional DST are available, the patient must be referred to the DR TB center for complete clinical review by the committee and possible treatment modification.

Contact investigation

- All close contacts, especially household contacts should be screened for TB.
- In case of paediatric TB patients, **reverse contact tracing** for search of any active TB case in the household of the child must be undertaken.
- Particular attention should be paid to contacts with the highest susceptibility to TB infection

The highest priority contacts for active screening are:

- Persons with symptoms suggestive of tuberculosis
- Children aged < six years
- Contacts with known or suspected immune-compromised patient, particularly HIV infection
- Contacts with Diabetes Mellitus
- Contacts with other higher risks including pregnancy smokers and alcoholics etc.
- Contacts of patients with DR-TB.

All close contacts of DR-TB cases should be identified through contact tracing and evaluated for active TB disease as per RNTCP guidelines. If the contact is found to be suffering from pulmonary TB disease irrespective of the smear results, he/she will be identified as an "Presumptive MDR-TB". The patient will be initiated on regimen for new or previously treated case based on their history of previous anti-TB treatment. Simultaneously two sputum samples will be transported for culture and DST to a RNTCP-certified C&DST laboratory.

Isoniazid Preventive Therapy

Children are more susceptible to TB infection, more likely to develop active TB disease soon after infection, and more likely to develop severe forms of disseminated TB. Children < 6 years of age, who are close contacts of a TB patient, should be evaluated for active TB by a medical officer/paediatrician. After excluding active TB he/she should be given INH preventive therapy irrespective of their BCG or nutritional status. The dose of INH for preventive therapy is 10 mg/kg body weight administered daily for a minimum period of six months. The INH tablets should be collected on monthly basis. The contacts should be closely monitored for TB symptoms.
In addition to above, INH preventive therapy should be considered in following situation:-

- For all HIV infected children who either had a known exposure to an infectious TB case or are Tuberculin skin test (TST) positive (>=5mm induration) but have no active TB disease.
- All TST positive children who are receiving immunosuppressive therapy (*e.g.* Children with nephrotic syndrome, acute leukemia, *etc.*).
- A child born to mother who was diagnosed to have TB in pregnancy should receive prophylaxis for 6 months, provided congenital TB has been ruled out. BCG vaccination can be given at birth even if INH preventive therapy is planned.

Close contacts of index cases with proven DR-TB should be monitored closely for signs and symptoms of active TB as isoniazid may not be prophylactic in these
cases. Although alternative prophylaxis treatments have been suggested, there is no consensus regarding the choice of the drug(s) and the duration of treatment. Prompt treatment of MDR-TB is the most effective way of preventing the spread of infection to others. The following measures should be taken to prevent spread of DR-TB infection:

1. Early diagnosis and appropriate treatment of MDR-TB cases;
2. Screening of contacts as per RNTCP guidelines

Further research into effective and non-toxic chemoprophylaxis in areas of high MDR-TB prevalence is required.

Death Audit

The Medical Officer should conduct an in-depth audit of all the deaths occurring amongst the TB patients irrespective of initiation of treatment. Similarly, DTO should conduct death review of all MDR-TB patients died. This would be beneficial inunderstanding the causes leading to the deaths and guide the programme in taking appropriateaction to prevent them.

Prevention and management of adverse drug reactions

Most TB patients on first line drugs complete their treatment without any significant adverse drug effects. However, a few patients do experience adverse effects and some of the drug induced side effects can be prevented. Moreover, many second line drugs are associated with more side effects during long duration of treatment. It is therefore important that patients be clinically monitored during treatment so that adverse effects can be detected promptly and managed properly. All Health personnel should monitor patients about adverse drug effects and inform patients to report to health system in case of any of the side effects. Health-care workers need to be informed and trained about the methodology and channels for reporting ADRs.

Adverse effects of Anti TB drugs

Anti-TB treatment with first-line drugs is generally safe and well tolerated. Side effects to anti-TB drugs are common. Trivial side effects may lead to reduced compliance with treatment. These adverse effects must be recognized early, to reduce associated morbidity and mortality. Following table shows the side effects-of essential first line anti TB drugs :-

Drug	Main effects	Rare effects
Isoniazid	Peripheral neuropathy Skin rash Hepatitis Sleepiness and lethargy	Convulsions Psychosis Arthralgia Anaemia
Rifampicin	Gastrointestinal: abdominal pain, nausea, vomiting Hepatitis Generalised cutaneous reactions Thrombocytopenic purpura	Osteomalacia Pseudomemberanous colitis Pseudoadrenal crisis Acute renal failure Haemolytic anaemia
Pyrazinamide	Arthralgia Hepatitis Gastrointestinal	Cutaneous reactions Sideroblastic anaemia
Ethambutol	Retrobulbar neuritis	Generalised cutaneous reactions Arthralgia Peripheral neuropathy Heapatitis (very rare)

Following table shows the side effects-of second line anti TB drugs :-

Drugs	Side effects
Injectables– *Kanamycin / Capreomycin*	• Ototoxicity • Nephrotoxicity • Vertigo • Electrolyte imbalance
Quinolones– *Ofloxacin, Levofloxicin, Moxifloxacin*	• Gastro Intestinal symptoms: diarrhoea, vomiting, and abdominal pain • Central nervous system (CNS): dizziness and convulsions • Phototoxicity and photosensitivity • Tendinopathy and tendinitis • Skin rash • Cardiotoxicity – QT prolongation • Arthralgia
Ethionamide	• Gastro-intestinal: epigastric discomfort, anorexia, nausea, metallic taste, vomiting, • excessive salivation, and sulfurous belching • Psychiatric: hallucination and depression • Hepatitis • Hypothyroidism and goitre with prolonged administration • Gynaecomastia, menstrual disturbances, impotence, acne, headache, and peripheral • neuropathy
Cycloserine	• CNS: dizziness, slurred speech, convulsions, headache, tremor, and insomnia • Psychiatric: confusion, depression, altered behaviour, and suicidal tendency • Hypersensitivity reaction
PAS	• Gastro-intestinal: anorexia, nausea, vomiting, and abdominal discomfort • Skin rash • Hepatic dysfunction • Hypokalemia • Hypothyroidism and goitre with prolonged administration

Management of ADRs

What to do if symptoms of adverse effects occur

If symptoms of adverse effects occur the following should be done:

- the dose of drugs should be checked
- all other causes of symptoms should be excluded
- the seriousness of the adverse effects should be estimated

- the adverse effects should be registered
- the drugs may need to be stopped and should eventually be reintroduced gradually when symptoms disappear
- development of drug resistance should be avoided.

A symptom-based approach to the management of the most common adverse effects is adopted. These side effects are classified as major or minor. In general, a patient who develops minor adverse effects should continue the TB treatment and be given symptomatic treatment. If a patient develops a major side-effect, the responsible drug or the entire regimen may need to be stopped and the patient should be urgently referred to a clinician or health care facility for further assessment and treatment. Patients with major adverse reactions should be managed in a hospital. States need to identify such facilities with sufficient infection control measures and expertise. In DR-TB patients, the DR-TB committee needs to be involved in the management and modification of the regimen if required.
Management of ADRs by medical practitioners and health workerare detailed in Annexure 9 & 10

Pharmacovigilance in TB control programme

Pharmacovigilance is defined by the World Health Organization (WHO) as the *"science and activities relating to the detection, assessment, understanding and prevention of adverse e ects or any other drug-related problem".*
It is a fundamental activity to inform the management of patient safety measures in health care. Pharmacovigilance is a *public health surveillance activity*. There are 3 methods for reporting on pharmacovigilance activities

- Spontaneous reporting- Spontaneous (or voluntary) reporting means that no active measures are taken to look for adverse effects other than the encouragement of health professionals and others to report safety concerns. Reporting is entirely dependent on the initiative and motivation of the potential reporters. This is the most common form of pharmacovigilance, sometimes termed passive reporting

- Targeted reporting- It focuses on capturing ADRs in a well-defined group of patients on treatment. Health professionals in charge of the patients are sensitized to report specific safety concerns.

- Active surveillance- It is a pro-active efforts made to elicit adverse events. Events detected by asking patients directly, screening patient records, laboratory & clinical tests. It is best done prospectively

Causality assessment- "Estimating the probability of a relationship between exposure to a medicine and the occurrence of an adverse reaction".For assessing the causality the causality assessment committee.Establishing causality is a process which begins by examining the relationship between the medicine and the event. Two basic questions need to be addressed separately:

- Is there a convincing relationship between the drug and the event?
- Did the drug actually cause the event?

The relationship of a single case-report can be established, but it may not be possible to establish a firm opinion on causality until a collection of such reports is assessed or new knowledge is gained. Causality for individual reports, even those with a close relationship, can seldom be established beyond doubt and our assessments are based on probability. A causality assessment should be seen as provisional and subject to change in the light of further information on the case, or new knowledge coming from other sources. For details "a practical handbook on the pharmacovigilance of medicines used in the treatment of tuberculosis" by WHO may be referred.

Under the Pharmacovigilance Programme of India (PvPI) set up by the Ministry of Health and Family Welfare (MoHFW), Govt. of India in July 2010 routine reporting and monitoring of ADRs will be continued. Simultaneously, the pharmacovigilance activity will be implemented in phase-wise manner.

Priority is given to establishing pharmacovigilance at DR-TB centres for drug resistant Cases. The DR-TB centres would be linked with ADR monitoring centres established under PvPI in medical colleges to initiate reporting of ADR in systematic manner. With introduction of daily anti-TB treatment regimen priority will be given to establish pharmacovigilance at ART centres for TB-HIV patients. It will be further expanded in districts / health institutions along with expansion of daily regimen to other TB patients. The standardized suspected ADR reporting form (Annexure 11) and needs to be filled by the treating doctor.

Treatment in special situations

TB in Pregnant and Lactating women

Before initiating treatment for tuberculosis, women of childbearing age should be asked about current or planned pregnancy and counseled appropriately. A successful treatment of TB is important for successful outcome of pregnancy. With the exception of streptomycin, the first line anti-TB drugs are safe for use in pregnancy. Streptomycin is ototoxic to the fetus and should not be used during pregnancy.

A breastfeeding woman should receive a full course of TB treatment. Correct chemotherapy is the best way to prevent transmission of TB to baby. Breast feeding has to be continued. After ruling out active TB, the baby should be given 6 months of isoniazid preventive therapy, followed by BCG vaccination. Breast feeding should not be discouraged. The mother should be advised about cough hygiene measures such as covering the nose and mouth while coughing, sneezing or any act which can produce sputum droplets.Mothers receiving INH and their breastfed infants should be supplemented with vitamin B6 (pyridoxine), recommended dose of Pyridoxine in infants is 5 mg/day.

DR-TB in pregnancy

Teratogenicity has been demonstrated with only some of the drugs used to treat MDR-TB. Women of child bearing age identified as presumptive MDR TB case should be advised to use a reliable and appropriate contraceptive method till the results of culture and DST are available. And if a woman is diagnosed with DR-TB and receiving second line treatment, she should be intensively counselled to use birth control measures because of the potential risk to both mother and foetus. All women of childbearing age should be tested for pregnancy as part of the pre-treatment evaluation and whilst on treatment if there is a history of amenorrhea of any duration. MDR-TB patients found to be pregnant prior to treatment initiation or whilst on treatment are evaluated in consultation with a Gynaecologist/Obstetrician taking into consideration the following factors:

- Risks and benefits of MDR-TB treatment
- Severity of the MDR-TB
- Gestational age
- Potential risk to the foetus

Further management of MDR-TB patients who are pregnant prior to initiation of treatment or whilst on treatment are based on the duration of pregnancy.

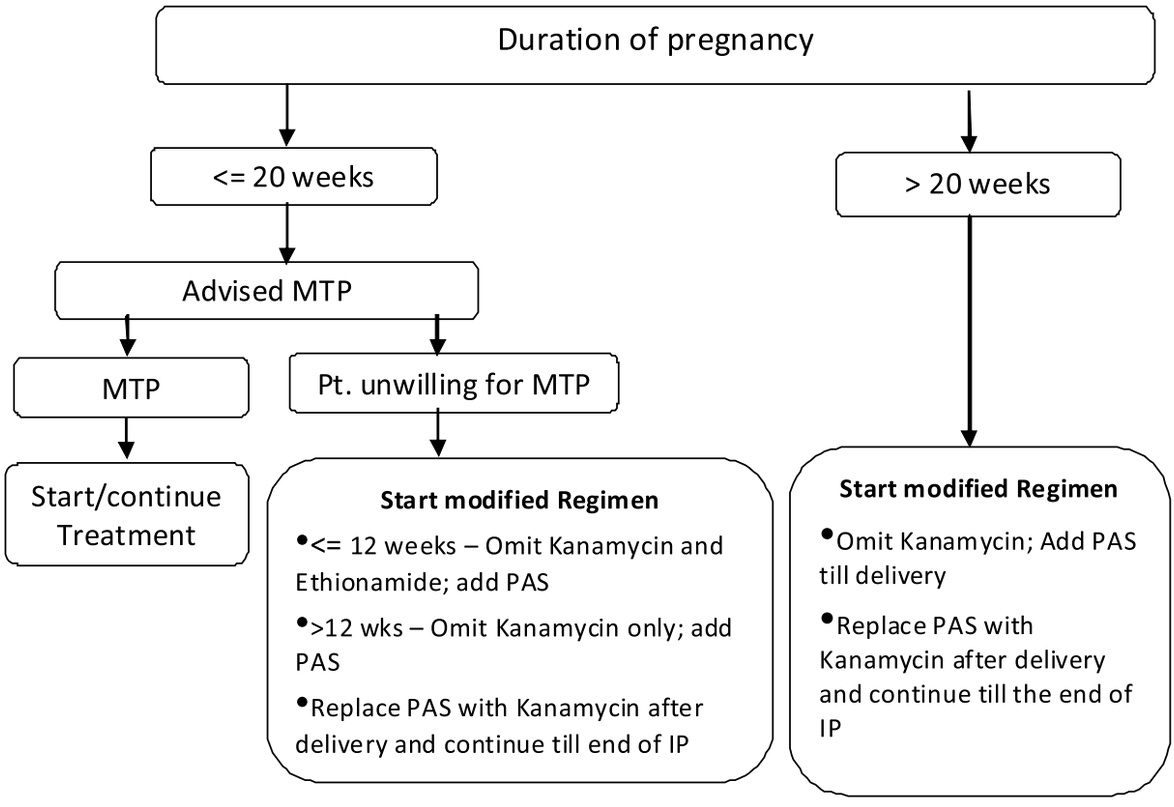
- If the duration of pregnancy is <20 weeks, the patient should be advised to opt for a Medical Termination of Pregnancy (MTP) in view of the potential severe risk to both the mother and foetus. If the patient is willing, she should be referred to a Gynaecologist/Obstetrician for MTP following which treatment can be initiated (if the patient has not started treatment) or continued (if the patient is already on treatment) by the DR-TB Centre Committee.

- For patients who are unwilling for MTP or have pregnancy of >20 weeks (making them ineligible for MTP), the risk to the mother and foetus needs to be explained clearly and a modified Regimen for MDR TB should be started as detailed below:

  – For patients in the first trimester (⩽ 12 weeks), Kanamycin and Ethionamide are omitted from the regimen and PAS is added.
  – For patients who have completed the first trimester (>12 weeks), Kanamycin is replaced with PAS. Post-partum, PAS may be replaced with Kanamycin and continued until the end of the Intensive Phase.

Pregnant MDR-TB patients need to be monitored carefully both in relation to the treatment and the progress of the pregnancy. This approach should lead to good results, since the patient should be smear-negative at the time of parturition, and mother and infant do not need to be separated. Breast-feeding should be encouraged as long as the patient is sputum negative.

The management of MDR-TB patients with pregnancy is summarised in the flow chart:



TB and Contraceptive pills usage

As Rifampicin is a potent inducer of hepatic enzymes, the protective efficacy of oral contraceptive pills may be decreased. Oral contraceptives might have decreased efficacy due to vomiting and drug interactions with second line anti-TB drugs. Hence, women suffering from TB and using contraceptive pills should be advised to use some alternative anti-contraception method. Use of barrier methods (Condoms/diaphragms), IUDs (CuT) or depot-medroxyprogesterone (Depo-provera) are recommended based on
individual preference and eligibility.

Management of TB in patients with liver disorders

Patients with hepatitis virus carriage, a past history of acute hepatitis, current excessive alcohol consumption can receive the usual TB regimens provided that there is no clinical evidence of chronic liver disease. However, hepatotoxic reactions to anti-TB drugs may be more common among these patients and should therefore be anticipated. In patients with unstable or advanced liver disease, liver function tests should be done at the start of treatment. If the liver disorder is severe, lesser hepatotoxic drugs have to be used. Expert consultation is advisable in treating patients with advanced or unstable liver disease. Clinical monitoring (and liver function tests, if possible) of all patients with pre-existing liver disease should be performed during treatment. If the serum alanine aminotransferase level is more than 3 times normal before the initiation of treatment, the following regimens should be considered:

- ***Containing two hepatotoxic drugs:***
  9 months of isoniazid and rifampicin, plus ethambutol (until or unless isoniazid susceptibility is documented);
  2 months of isoniazid, rifampicin, streptomycin and ethambutol, followed by 7 months of isoniazid and rifampicin;
  6–9 months of rifampicin, pyrazinamide and ethambutol.
- ***Containing one hepatotoxic drug:***
  2 months of isoniazid, ethambutol and streptomycin, followed by 10 months of isoniazid and ethambutol
- ***Containing no hepatotoxic drugs:***
  18–24 months of streptomycin, ethambutol and a fluoroquinolone.

DR-TB in patients with pre-existing liver disease

Pyrazinamide, PAS and Ethionamide are potentially hepatotoxic drugs. Hepatitis occurs rarely with the fluoroquinolones. The potential for hepatotoxicity is increased in elderly, alcoholics and in patients with pre-existing liver disease. In general, most of second line drugs can be safely used in presence of mild hepatic impairment, as they are relatively less hepatotoxic than the first-line drugs. However, pyrazinamide and ethionamide should be avoided in such patients. Once a patient on second line drugs develops hepatitis, other aetiologies should also be excluded such as viral hepatitis, alcoholic hepatitis, drug induced hepatitis by non-TB drugs etc. The further management should be on the same guidelines as in non- MDR-TB patients. MDR patients having deranged liver function test (LFT) during pre-treatment evaluation should be strictly monitored through monthly LFTs while on treatment. However routine LFT is not recommended in all cases.

TB patient with renal failure and severe renal insufficiency

Patients suffering from Chronic Kidney Diseases (CKD) are at an increased risk of developing Tuberculosis. Active TB should be excluded in patients with CKD by appropriate investigations in patients who have an abnormal chest x-ray or a history of prior pulmonary or extrapulmonary TB that has been either inadequately or not previously treated. Chemoprophylaxis in standard doses should be given. TB should be considered in all patients with unexplained systemic or system-specific symptoms as extrapulmonary TB is common, particularly in patients on dialysis, with peritoneal TB being common in patients on chronic ambulatory peritoneal dialysis.

Any patient with active TB, either pulmonary or extrapulmonary, should receive standard chemotherapy agents, albeit with dose interval modifications where appropriate. Isoniazid and rifampicin are eliminated by biliary excretion, so no change in dosing is necessary. There is significant renal excretion of ethambutol and metabolites of pyrazinamide, and doses should therefore be adjusted. For patients with stages 4 and 5 chronic renal disease and on hemodialysis, dosing intervals should be increased to three times weekly for ethambutol, pyrazinamide and the aminoglycosides.

Treatment can be given immediately after haemodialysis to avoid premature drug removal. With this strategy there is a possible risk of raised drug levels of ethambutol and pyrazinamide between dialysis sessions. Alternatively, treatment can be given 4 to 6 hours before dialysis, increasing the possibility of premature drug removal but reducing possible ethambutol or pyrazinamide toxicity. Three times per week administration of these two drugs at the following doses is recommended: pyrazinamide (25 mg/kg), and ethambutol (15 mg/kg). These doses are the ones used in daily regimens. While receiving isoniazid, patients with severe renal insufficiency or failure should also be given pyridoxine in order to prevent peripheral neuropathy. Because of an increased risk of nephrotoxicity and ototoxicity, streptomycin should be avoided in patients with renal failure. If streptomycin must be used, the dosage is 15 mg/kg, two or three times per week, to a maximum of 1 gram per dose, and serum levels of the drug should be monitored. In post renal transplant cases, Rifampicin in particular can interact with immunosuppressive regimens, increasing the chance of graft rejection, and doses of mycophenolate mofetil, tacrolimus and cyclosporine may need adjustment. Corticosteroid doses should be doubled in patients receiving rifampicin.

DR-TB in patients with renal impairment

Renal insufficiency due to longstanding TB disease itself, previous use of aminoglycosides or concurrent renal disease is not uncommon. Great care should be taken in the administration of second-line drugs in patients with renal impairment. Consideration needs to be taken that MDR-TB patients require aminoglycosides for 6 months or more. In patients with mild renal impairment, the dose of aminoglycosides may be reduced. In the presence of severe renal failure, the aminoglycoside therapy should be discontinued and replaced with other potent non-nephrotoxic antituberculosis drugs. Other drugs, which also might require dose or interval adjustment in presence of mild to moderate renal impairment, are: Ethambutol, Quinolones, Cycloserine and PAS. In the presence of severe renal impairment many other drugs may also require adjustments (refer table as below).

Adjustment of anti-TB drugs in renal insufficiency[a]

Drug	Recommended dose and frequency for patients with creatinine clearance < 30 ml/min or for patients receiving haemodialysis (unless otherwise indicated dose after dialysis)
Isoniazid	No adjustment necessary
Rifampicin	No adjustment necessary
Pyrazinamide	25-35 mg/kg per dose three times per week (not daily)
Ethambutol	15-25 mg/kg per dose three times per week (not daily)
Rifabutin	Normal dose can be used, if possible monitor drug concentrations to avoid toxicity.
Rifapentine	No adjustment necessary
Streptomycin	12-15 mg/kg per dose two or three times per week (not daily)
Capreomycin	12-15 mg/kg per dose two or three times per week (not daily)
Kanamycin	12-15 mg/kg per dose two or three times per week (not daily)
Amikacin	12-15 mg/kg per dose two or three times per week (not daily)
Ofloxacin	600-800 mg per dose three times per week (not daily)
Levofloxacin	750-1000 mg per dose three times per week (not daily)
Moxifloxacin	No adjustment necessary
Cycloserine	250 mg once daily, or 500 mg / dose three times per week
Terizidone	Recommendations not available
Prothinamide	No adjustment necessary
Ethionamide	No adjustment necessary
Para-aminosalicylicacid	4 g/dose, twice daily maximum dose
Bedaquiline	No dosage adjustments required in patients with mild to moderate renal impairment (dosing not established in severe renal impairment, use with caution).
Linezolid	No adjustment necessary
Clofazimine	No adjustment necessary
Amoxicillin/clavulanate	For creatinine clearance 10-30 ml/min dose 1000 mg as amoxicillin component twice daily; For creatinine clearance <10 ml/min dose 1000 mg as amoxicillin component once daily
Imipenem / cilastin	For creatinine clearance 20-40 ml/min dose 500 mg every 8 hours; For creatinine clearance <20 ml/min dose 500 mg every 12 hours
Meropenem	For creatinine clearance 20-40 ml/min dose 750 mg every 12 hours; For creatinine clearance <20 ml/min dose 500 mg every 12 hours
High dose isoniazid	Recommendations not available

[a] source: Companion Handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis 2014.
Estimated creatinine clearance calculations:
Men: Ideal Body Weight (kg) x (140-age) / 72 x serum creatinine (mg/dl)
Women: 0 85 x Ideal Body Weight (kg) x (140-age) / 72 x serum creatinine (mg/dl)

TB in patients with seizure disorders

The use of isoniazid and rifampicin may interfere with many of the anti-seizure medications. Drug interactions should be checked before their use.High dose isoniazid also carries a high risk of seizure and should be avoided in patients with active seizure disorders.

The prophylactic use of oral pyridoxine (vitamin B6) can be used in patients with seizure disorders to protect against the neurological adverse effects of isoniazid or cycloserine. The suggested prophylactic dose for at risk patients on isoniazid is 10 to 25 mg/day and for patients on cycloserine is 25 mg of pyridoxine for every 250 mg of cycloserine daily. The optimal prophylactic dose of pyridoxine for children has not been established, nonetheless 1–2 mg/kg/day has been recommended in some reports with a usual range of 10–50 mg/day for paediatric patients at risk for neurological sequel.

DR-TB in patients with seizure disorders

Some patients requiring treatment for DR-TB will have a past or present medical history of a seizure disorder. The first step in evaluating such patients is to determine whether the seizure disorder is under control and whether the patient is taking anti-seizure medication to control the disorder. If the seizures are not under control, initiation or adjustment of anti-seizure medications will be needed prior to the start of DR-TB therapy. In addition, if other underlying conditions or causes for seizures exist, they should be corrected.

Among second line drugs, Cycloserine, Ethionamide and fluoroquinolones have been associated with seizures, and hence should be used carefully amongst MDR-TB patients with history of seizures. Pyridoxine should be given with Cycloserine to prevent seizures. Cycloserine should however be avoided in patients with active seizure disorders that are not well controlled with medication. In cases where no other drug is appropriate, Cycloserine can be given and the anti-seizure medication adjusted as needed to control the seizure disorder. The risk and benefits of using Cycloserine should be discussed with the patient and the decision on whether to use Cycloserine are made together with the patient.

Antiepileptic drugs may have drug interactions with Cycloserine and fluoroquinolones. Hence close monitoring of serum levels of anti-epileptic drugs should be done. One should remember that TB itself might involve central nervous system and may cause seizures. However when seizures are present for the first time during anti-TB therapy, they are likely to be the result of an adverse effect of one of the anti-TB drugs.

DR-TB in patients with psychosis

For DR-TB patients with a concurrent psychiatric illness, it is advisable to have an evaluation carried out by a psychiatrist before the start of treatment for DR-TB. The initial evaluation documents any pre-existing psychiatric condition and establishes a baseline for comparison if new psychiatric symptoms develop while the patient is on treatment. Any identified psychiatric illness at the start or during treatment should be fully addressed. There is a high baseline incidence of depression and anxiety in patients with DR-TB, often connected with the chronicity and socioeconomic stress factors related to the disease. If a health care worker with psychiatric training is not available, the treating healthcare provider should document any psychiatric conditions the patient may have at the initial evaluation.

Treatment with psychiatric medication, individual counselling, and/or group therapy may be necessary to manage the patient suffering from a psychiatric condition or adverse psychiatric effect due to medication. Group therapy has been very successful in providing a supportive environment for DR-TB patients and may be helpful for patients with or without psychiatric conditions (adequate measures to prevent infection risk should be in place for the group therapy). Fluoroquinolones and Ethionomide have been associated with psychosis. Pyridoxine prophylaxis may minimize risk of neurologic and psychiatric adverse reactions.

Cycloserine may cause severe psychosis and depression leading to suicidal tendencies. However the use of Cycloserine is not absolutely contraindicated for the psychiatric patient. Adverse effects of Cycloserine may be more prevalent in the psychiatric patient, but the benefits of using this drug often outweigh the potential higher risk of adverse effects. Close monitoring is recommended if Cycloserine is used in patients with psychiatric disorders.

If patient on Cycloserine therapy develops psychosis, anti-psychotic treatment should be started and Cycloserine therapy should be temporarily suspended. Once symptoms resolve and patient is stabilized Cycloserine therapy may be resumed. Such patients may require anti-psychotic treatment till anti-TB treatment is completed. When any patient on MDR-TB treatment develops psychosis, other aetiologies such as psycho- social stresses, depression, hypothyroidism, illicit drug and alcohol use, should also be looked for.

All healthcare workers treating drug-resistant TB should closely work with a psychiatrist and have an organized system for psychiatric emergencies. Psychiatric emergencies include psychosis, suicidal ideation, and any situation involving the patient's being a danger to him/her self or others. Mechanisms to deal with psychiatric emergencies (often inpatient psychiatric hospital admissions) should be available on twenty-four hours basis. Proper infection control measures must be taken for the smear-positive patient who requires any hospitalization.

Extra pulmonary TB

The burden of EPTB ranges from 15-20% of all TB cases in HIV-negative patients while among PLHIV, it accounts for 40-50% of new TB cases. With advent of diagnostics cases of drug-resistant EPTB are likely to be identified more in the country.

All EPTB patients should be tested for HIV. All patients suspected of EPTB should have clinical assessment for active PTB. All patients should receive an appropriate treatment regimen, and the provider should monitor adherence and address factors leading to interruption/discontinuation of treatment. All patients with a diagnosis of EPTB should be risk-assessed for drug resistance prior to starting treatment, and drug susceptibility testing should be available for all patients at risk of drug-resistant tuberculosis.

Extra pulmonary TB should be treated with the same regimens as pulmonary TB. The duration of continuation phase may be extended by 3 to 6 months in special situations like TB meningitis, Bone & Joint TB, Spinal TB with neurological involvement and neuro- tuberculosis. Unless drug resistance is suspected, adjuvant corticosteroid treatment is recommended for TB meningitis and pericarditis. In tuberculous meningitis, ethambutol should be replaced with streptomycin.

Although sometimes required for diagnosis, surgery plays little role in the treatment of extra pulmonary TB. It is reserved for management of late complications of disease such as hydrocephalus, obstructive uropathy, constrictive pericarditis and neurological involvement from Pott's disease (spinal TB). For large, fluctuant lymph nodes that appear to be about to drain spontaneously, aspiration or incision and drainage appear beneficial. For further details on management of EPTB, refer to Index-TB guidelines on management of EPTB.

Treatment regimen and schedule for EP MDR-TB cases will remain the same as for pulmonary MDR-TB. EP MDR-TB patients will undergo all those pre -treatment investigations as done for pulmonary MDR-TB patients. In addition, ultrasound of abdomen of the patient will also be done, if necessary, to rule out involvement of other organs and abdominal nodes. Unlike microbiological follow up examination schedule in pulmonary DR-TB, culture from the affected EPTB site can bedone only till the specimen is available. The follow up is mainly based on clinical parameters.

Clinical Monitoring and follow up of DR-TB patients:

1. Weight Gain
2. Decrease or increase in symptoms (e.g. healing of ulcer / scrofuloderma)
3. Increase or Regression in size of nodes (possibility of Immune Reconstitution Inflammatory Syndrome (IRIS) should be considered and differentiated from disease progression)
4. Appearance of new nodes
5. If chest symptomatic, monthly sputum for AFB and chest X- ray (to rule out pulmonary involvement)
6. Other Extra-pulmonary sites should be monitored (USG abdomen if necessary)
7. Serum Creatinine – monthly for the first three months of treatment and then quarterly till the patient receives Kanamycin and further when clinically indicated
8. Liver function test – as clinically indicated
9. USG -abdomen – if necessary
10. Monitoring for drug adverse reactions

Treatment outcome will depend on availability of culture reports of specimens taken from affected site, treatment completion and clinical improvement of the patient.

Hospitalization

The usual mode of TB treatment is domiciliary, but in patients with pneumothorax or large accumulations of pleural fluid leading to breathlessness; massive haemoptysis etc. the patients might need hospitalization. These patients can be managed in general hospitals preferably in wards where adequate air borne infection control measures are taken to prevent the spread.

Role of surgery in management of MDR-TB

In DR-TB patients with localized disease, surgery, as an adjunct to chemotherapy, can improve outcomes provided skilled thoracic surgeons and excellent post-operative care are available. When unilateral resectable disease is present, surgery should be considered for the following cases:

- Absence of clinical or microbiological response to chemotherapy despite six to nine months of treatment with effective anti-tuberculosis drugs;
- High risk of failure or relapse due to high degree of resistance or extensive parenchymal involvement;
- Morbid complications of parenchymal disease e.g. haemoptysis, bronchiectasis, bronchopleural fistula, or empyema;
- Recurrence of positive culture status during course of treatment; and
- Relapse after completion of anti-tuberculosis treatment.

If surgical option is under consideration at least six to nine months of chemotherapy is recommended prior to surgery.

Latent Tuberculosis Infection (LTBI)

Latent tuberculosis infection (LTBI) is the presence of Mycobacterium tuberculosis in the body without signs and symptoms, or radiographic or bacteriologic evidence of tuberculosis (TB) disease. Studies have demonstrated that Isoniazid (INH) taken for at least 6 months in persons with LTBI reduced subsequent TB incidence by 25 to 92 per cent, the differences in effectiveness largely explained by differences in treatment completion. Recently WHO has published detailed guidelines for management of LTBI. (WHO Guidelines on the management of latent tuberculosis infection) There was consensus of the WHO Panel on the equivalence of 6-month INH, 9-month INH, and 3-months once a week Rifapentine plus high dose INH as treatment for LTBI.

India, with one-fourth of the global burden of TB, has 40 per cent of the population infected with M.Tb. Treating 40 per cent of the population for LTBI based on Tuberculin Skin Test (TST) positivity or Interferon Gamma Release Assay is neither rational nor practicable, thus emphasizing the need for a focussed approach. In clinical situations, the most obvious group for LTBI treatment would include high-risk patients such as those receiving long term corticosteroids, immunosuppressants, HIV-infected and juvenile contacts of sputum-positive index cases.

Treatment of Nontuberculous Mycobacterial (NTM) Lung Diseases

Under programme conditions sometimes the report of culture examination shows presence of Nontuberculous Mycobacteria (NTM). NTM represent a broad array of organisms that have been isolated from soil and water, and exposure to these reservoirs is thought to be the source of human infection. A review of several studies observed that in India 1-4% of laboratory isolates among presumptive TB cases or presumptive MDR-TB cases are NTMs. In TB-HIV co-infected cases the probability of NTM may be increased. The clinician (DTO/MOPHI/DR-TB Committee etc.) should not ignore such reports. A careful clinical correlation is required in such cases as some of these patients may be wrongly put on MDR/XDR-TB regimen as these patients may be found to be resistant to all commonly used first line and second line anti-TB drugs. One should not diagnose NTM based on single culture report. In presence of NTM the commonly used molecular tests, such as LPA or CBNAAT will be negative, which should prompt the clinician to think of NTM. Such cases should be referred to DR-TB committee for further management through general health services.The American Thoracic Society (ATS) Guidelines (An Official ATS/IDSA Statement: Diagnosis, Treatment, and Prevention of Nontuberculous Mycobacterial Diseases) may be referred for the management of patients suffering from NTM infection.

Treatment outcomes

The treatment outcome definitions make a clear distinction between three types of patient groups ("cohorts"):

1. Patients treated for drug-susceptible TB;
2. Patients treated for RR-/MDR-TB/XDR-TB
3. Patients treated for mono-/poly- DR-TB

The groups are mutually exclusive. Any patient found to have DR-TB and placed on second-line treatment is removed from the rifampicin-susceptible TB treatment cohort. DR-TB patients who were not started on a Mono/Poly/MDR-TB regimen are assigned an outcome from those for rifampicin-susceptible TB. This means that the basic TB register and the Second-line TB treatment register need to be coordinated to ensure proper accounting of treatment outcomes.

Treatment outcomes for drug-susceptible TB patients

Cured: Microbiologically confirmed TB patients at the beginning of treatment who was smear or culture negative at the end of the complete treatment

Treatment completed: A TB patient who completed treatment without evidence of failure or clinical deterioration BUT with no record to show that the smear or culture results of biological specimen in the last month of treatment was negative, either because test was not done or because result is unavailable.

Treatment Success: TB patients either cured or treatment completed are accounted in treatment success

Failure: A TB patient whose biological specimen is positive by smear or culture at end of treatment.

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

Lost to follow up: A TB patient whose treatment was interrupted for 1 consecutive month or more

Not Evaluated - A TB Patient for whom no treatment outcome is assigned. This includes former "transfer-out"

Treatment Regimen Changed - A TB patient who is on first line regimen and has been diagnosed as having DRTB and switched to drug resistant TB regimen prior to being declared as failed

Died: A patient who has died during the course of anti-TB treatment

Outcomes for RR-/MDR-TB and /or XDR-TB patients

Cure: Treatment completed as recommended by the national policy without evidence of failure AND three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase

Treatment completed: Treatment completed as recommended by the national policy without evidence of failure BUT no record that three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase

Treatment success: The sum of cured and treatment completed.

Treatment failed : Treatment terminated or need for permanent regimen change of at least two or more anti-TB drugs in CP because of:

- Lack of microbiological conversion by the end of the intensive phase or
- Microbiological reversion in the continuation phase after conversion to negative or
- Evidence of additional acquired resistance to fluoroquinolones or second line injectable drugs or
- Adverse drug reactions (ADR)

Conversion and reversion

Conversion (to negative): culture is considered to have converted to negative when two consecutive cultures, taken at least 30 days apart, are found to be negative. In such a case, the specimen collection date of the first negative culture is used as the date of conversion.

Reversion (to positive): culture is considered to have reverted to positive when, after an initial conversion, two consecutive cultures, taken at least 30 days apart, are found to be positive. For the purpose of defining *Treatment failed*, reversion is considered only when it occurs in the continuation phase.

Died: A patient who dies for any reason during the course of treatment

Loss to follow up: A patient whose treatment was interrupted for one consecutive month or more

Not Evaluated - A patient for whom no treatment outcome is assigned.

Treatment Regimen Changed - A TB patient need for permanent regimen change of at least one or more anti-TB drugs prior to being declared as failed

Outcomes for mono-/ poly-drug resistant TB patients

Cure: A microbiologically confirmed TB at the beginning of treatment who was culture-negative in the last month of treatment and on at least one previous occasion

Treatment completed: A patient who has completed treatment according to guidelines but does not meet the definition for cure or treatment failure due to lack of microbiological results.

Failure: Treatment terminated or need for permanent regimen change of at least two or more anti-TB drugs in CP because of:

- Evidence of additional acquired resistance to rifampicin, fluoroquinolone or second line injectable during treatment
- Severe ADR
- Culture positive during CP or at end of treatment

Died: A patient who dies for any reason during the course of M/XDR-TB treatment

Loss to follow up: A patient whose treatment was interrupted for one month or more for any reasons.

Not Evaluated - A DR-TB Patient for whom no treatment outcome is assigned, this includes former "transfer-out".

Treatment outcome is defined 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. Details of Treatment outcome should be updated in NIKSHAY.

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 should be handed over to the STS during his routine monthly visits. Every patient started on treatment has to be given one and only one treatment outcome.

TB Comorbidities

Several medical conditions are risk factors for TB and poor TB treatment outcomes. Similarly, TB can complicate course of some diseases. It is therefore important to identify these comorbidities in people diagnosed with TB in order to ensure early diagnosis and improved outcome. When these conditions are highly prevalent in the general population they can be important contributors to the TB burden. Consequently, reducing the prevalence of these conditions can help prevent TB. TB share underlying social determinants with many of these conditions. Addressing the social determinants of health is a shared responsibility across disease programmes and other stakeholders within and beyond the health sector.

TB and HIV

The primary impact of HIV on TB is that the risk of developing TB becomes higher in patients with HIV. Overall, HIV-infected persons have approximately an 8-times greater risk of TB than persons without HIV infection. The risk of TB in HIV-infected persons continues to increase as HIV disease progresses and CD4 cell count decreases. While anti-retroviral treatment can substantially decrease the risk of TB, this risk always remains higher than that in HIV negative individuals. Furthermore, among cured TB survivors with HIV infection, the risk of recurrent TB is also quite high.

Similarly, Tuberculosis is the most common opportunistic infection amongst HIV-infected individuals. It is a major cause of mortality among patients with HIV and poses a risk throughout the course of HIV disease.

The presentation of TB in the HIV-infected patient may vary with degree of immune suppression. The diagnosis of TB in PLHIV can be more difficult and may be confused with other pulmonary or systemic infections. As the HIV disease progresses and the individual become more immune-compromised, the clinical presentation is proportionately more likely to be extra-pulmonary or smear-negative than in HIV-uninfected TB patients. This can result in misdiagnosis or delays in diagnosis, and in turn, higher morbidity and mortality.

It is estimated that there are 2.1 million people living with HIV in India with an estimated adult HIV prevalence of 0.27% (range: 0.2%–0.4%).TB accounts for 25% of deaths among People Living with HIV and AIDS (PLHIV) in India. Although only 5% of incident TB patients are HIV-infected, in absolute terms it means more than 100,000 cases annually, ranks second in the world and accounts for about 10% of the global burden of HIV-associated TB. HIV positivity among PLHIV varies from states /districts in the country, the proportion of HIV positive among TB patients over 10% in high HIV burden states to up to 40% in some high burden districts.

NACP and RNTCP Coordination in India:

To mitigate the effect of dual burden of HIV and TB co-infection, the ministry of Health and Family Welfare, Government of India through its NACO and Central TB Division (Department of Health and Family Welfare) has been undertaking joint collaborative efforts since 2001. While joint HIV/TB activities started with differential strategies based on underlying HIV burden initially, the programme evolved over the years and currently implements uniform HIV/TB collaborative activities across the country. NACP and RNTCP have developed a policy of HIV/TB collaborative interventions based on experience gained during programme implementation in initial years.

The mechanism for collaboration includes coordinated service delivery at field level, and oversight and advisory groups at the district level in the form District Coordination Committee chaired by District Collector. At the state level, a similar mechanism exists in the form of the State Technical Working Group chaired by Director Health Services and State Coordination Committee chaired by Principle Secretary Health. At the National level, TB-HIV coordination committee chaired by Additional Secretary, National AIDS Control Organization [NACO] and technical working group [NTWG] chaired by DDG regularly monitor and provide suggestions on key policy matters related to TB/HIV Collaborative activities. To enable effective coordination, joint trainings, standard recording and reporting, joint monitoring and evaluation and operational research are strategically implemented.

Milestones of TB-HIV collaborative activities in India

- 2001- Basic HIV/TB activities started in six high-HIV burden states.
- 2003 - Pilot for HIV-TB cross-referral in four districts of Maharashtra.
    - Cross-referral started in six HIV high prevalence states.
- 2004 - Cross referral of activities expanded to eight additional states.
- 2005 - Joint training modules developed, joint surveillance initiated.
- 2007- Pilot for Routine referral of TB patients for HIV testing and CPT.
    - National (policy) framework for TB/HIV developed.
- 2008 - National Framework revised.
    - All-India implementation of HIV-TB activities.
    - Intensified Package (IP) rolled out in nine states.
- 2009 - National Framework revised.
    - Intensified Package rolled out in eight more states.
    - Uniform activities at ART centers and ICTCs nationwide for intensified TB case finding and reporting, established.
- 2010 - Intensified package launched in 11 states.
- 2012 - Nationwide coverage achieved.
- 2013 - National Framework for HIV/TB collaborative activities in India developed

National Framework for HIV/TB in India:

Latest revision of National Framework Nov 2013 aimed to incorporate recent policy updates in NACP and RNTCP and align with respective national strategic plan for next 5 year along with recommendations in WHO HIV/TB policy guidelines 2011

The salient features are as below.

1. Emphasis on Integrated TB and HIV services e.g. HIV screening at RNTCP DMC.

2. Focus on early detection and early care:

   a. Early detection of TB in PLHIV:
      i. Early suspicion of TB–symptoms of any duration among PLHIV
      ii. Use of an expanded clinical algorithm for TB screening that relies on presence of four clinical symptoms (current cough, weight loss, fever or night sweats) instead of only cough, to identify patients with presumptive TB
      iii. Strengthen ICF at ART, Link ART centre (LAC) and Targeted intervention projects (TI) for High Risk Group (HRG) specially Injection Drug Users (IDU)
      iv. Offering upfront CBNAAT among presumptive TB cases among PLHIV
      v. Early detection HIV/TB

   b. Enhance HIV testing facilities in settings with lack of co-located HIV and TB testing facilities, by establishing HIV screening services using whole blood finger prick test (WBT)
      i. Strengthen HIV testing of TB patients in high HIV prevalent settings by promoting establishment of Facility Integrated Counselling and Testing Centre(F-ICTC) where DMC exists
      ii. PITCamong patients being evaluated by diagnostic smear microscopy presumptive TB cases in high HIV prevalent settings

   c. Early Care:
      i. Promotion of 'single window delivery services' where in all HIV/TB patients get their TB medications from the ART centres along with ART drugs.
      ii. Strengthened linkage of HIV/TB patients to ART centres through travel support by RNTCP as per NSP (2012-2017) etc.
      iii. ART for HIV infected TB cases irrespective of CD4 count
      iv. Prompt ART initiation- within first 8 weeks of commencing Anti-TB treatment.
      v. Monitoring of timeliness of ART initiation through expanded ART reporting formats

3. Early detection and care of HIV infected Drug Resistant TB patients (DR-TB/HIV):
      i. Strengthen HIV testing in presumptive DR-TB cases (Criteria C)
      ii. Ensure access to culture and drug susceptibility testing for HIV infected TB patients
      iii. Prompt linkage of HIV infected DR-TB cases to ART centres
      iv. Prompt initiation of ART in HIV infected DR-TB cases

4. Prevention of TB among HIV infected adults and children:
      i. Implementation of IPT for all PLHIV (On ART + Pre-ART)
      ii. Strengthen implementation of air borne infection control strategies.

5. Strengthen HIV/TB activities among children and pregnant women

6. Promotion of participation of private, NGO, CBO health facilities and affected communities working with NACP and RNTCP to strengthen HIV/TB collaborative activities.

HIV Screening for TB Patients/ Presumptive TB cases-

1. Presumptive / Diagnosed TB patients coming to the ICTCs will be offered counselling and testing as per the norms and standard operating procedures of the National AIDS Control Programme (NACP).
2. All referrals will be recorded in the ICTC counselling register as referrals from RNTCP
3. For patients with HIV positive results, the counselor will link the patient to the nearest ART centre available in the district/state .This will be done by giving a referral form and explaining the patient on how to access the centre. The patient will be given the contact details of the district programme managers for any assistance needed
4. The counsellor will document the HIV status, date of HIV testing and PID number in the RNTCP laboratory form as a feedback to LT of DMC. The counselor will also assist the DMC LT to update the laboratory register with information on HIV status.

Intensified TB case finding (ICF) at ICTCs, ART and Community Support Centres (CSCs)
Intensified TB case finding at HIV care settings is an important strategy for early diagnosis of TB among PLHIV.

ICF at ICTCs
All ICTC clients should be screened by ICTC counsellors for presence of TB symptoms at every encounter (pre, post, or follow-up counselling). Clients who have symptoms or signs, irrespective of their HIV status, should be referred to RNTCP diagnostic and treatment facility located in same institution. Therefore, NACP and RNTCP promote establishing co-located facilities, for better coordination between the two programmes. Hence, as network of HIV testing facilities is being expanded, consideration should be given to establish them at sites, which already have RNTCP, designated microscopy centres (DMC).

The referrals of presumptive TB cases from ICTCs to TB diagnosis facility should be recorded on a line list (**Annexure 12A)** to facilitate exchange of information with RNTCP and track the client through the process of TB diagnosis and initiation of TB treatment. To streamline this process further RNTCP programme staff should stay in touch with ICTC counsellors to complete the exchange of information in time**.** In addition, ICTC counsellors and RNTCP programme staff participate in monthly HIV/TB coordination meeting at district level to validate line-lists and Monthly HIV/TB reports (**Annexure 12B**) and resolve operational issues if any.

ICF at ART Centres
HIV-infected persons attending ART centres for pre-ART registration have a high prevalence of TB disease (6 to 8%). The incidence of TB among ART clients is also very high, even when on ART. Although ART reduces risk of incident TB, it remains many times higher compared to general population. In addition, HIV-infected clients having undiagnosed or untreated TB may seek care at ART centres and thus exposing other HIV-infected persons to the risk of acquiring TB. Therefore active efforts for intensified TB case finding (ICF) at ART centres is critical for early suspicion and detection of TB, linkage to treatment and thus for prevention of transmission of infection to other clients. The national ART guidelines clearly state that all patients coming to ART centres should be actively screened for opportunistic infections, particularly tuberculosis. All people living with HIV should be regularly screened for four symptoms viz., current cough of any duration, fever of any duration, significant weight loss or drenching night sweats, during every visit to a health facility and every contact with a health-care provider. Those with history of coughing blood and sputum and with any pulmonary abnormality in chest X-ray should also be evaluated for TB. Similarly, children living with HIV who have one or more of the following symptoms – failure to thrive, fever or cough of any duration or history of contact with a TB patient should be evaluated for TB.

Screening for TB is important regardless of whether the PLHIV is receiving IPT or ART. The presumptive TB cases identified at ART centres or Link ART centres should be prioritized and "fast-tracked" for evaluation by SMO/MO to minimize opportunities for airborne transmission of infection to other PLHIV.

PLHIVs suspected to have TB by MO, should be subjected to testing of sputum / appropriate specimen from a relevant extra-pulmonary site by CBNAAT at the nearest facility. CBNAAT is the frontline test for diagnosis of TB among PLHIV. If CBNAAT is not available, arrangements have to be made for collection and transportation of sputum specimen to the nearest CBNAAT site. If CBNAAT linkage is not available, then the patient should be evaluated with microscopy and Chest-X ray on the same day.

Clinically dignosed TB and extra pulmonary TB is more common among people living with HIV and therefore a high level of suspicion is required. In the event of suspicion of Extra Pulmonary TB, the diagnostic algorithm as for HIV negative presumptive EPTB patients may be followed. Similarly, refer to diagnostic algorithm for paediatric pulmonary TB.

Preferably, PLHIVs should be offered TB and HIV diagnostic facility at the same premises as a "one-stop service" in order to reduce diagnostic delay and to link those not having any of the four symptom complex to IPT services.

In addition, the referrals presumptive TB cases should be recorded on an ART centre TB-HIV line list (**Annexure 13 A**) to facilitate coordination with RNTCP programme staff and to track the patient closely through the process of TB diagnosis and TB treatment initiation. It is also crucial that ART Centre staff members attend monthly HIV/TB coordination meeting. The HIV/TB monthly reporting format to be generated at ART centres is incorporated into the ART centre monthly report (CMIS) (**Annexure 13 B**).

Information of all HIV infected TB patients in HIV care should be recorded in the ART centre HIV/TB register (**Annexure 13 C**). These include TB patients detected by ART centre staff as well as those TB patients found HIV infected while on TB treatment and referred to ART centre by the RNTCP. TB-HIV register is an important monitoring tool to track timeliness of initiation of CPT and ART the TB treatment outcome to modify ARV regimens as per guidelines. It is also important that ART centre staff carry this register when they attend monthly HIV/TB coordination meeting to update information on TB treatment outcome from RNTCP staff and share information pertaining to CPT and ART with them for recording into RNTCP TB registers.
PLHIV diagnosed to be suffering from TB are presumptive MDR cases and need to follow the algorithm for diagnosis of drug resistant TB (Refer Section 5).

ICF at Link ART Centres (LAC)
The ICF activity is also implemented at all Link ART plus and Link ART centres in the country. As in ART centres LAC-Plus and LAC should 1) implement ICF using symptom screening on every encounter 2) promptly refer presumptive TB case to RNTCP diagnostic facilities, and 3) refer the patient to ART centre promptly if TB is detected for initiation of ART or modify current ARV regimen. Similar to ART centre, the LAC staff nurse /counsellor should maintain line-list, exchange with local RNTCP staff to seek information on TB diagnosis and treatment and complete the line-list.

The LAC Plus use same line-list format as the ART centre **(Annexure 13 A)** while at LAC the ICTC line-list format is used (since ICTC counsellor runs the LAC) **(Annexure 12A)**. The completed line-list from LAC-plus is merged with ART centre line-list whereas that from LAC is merged into ICTC line-list for the same period and monthly report is generated accordingly. These mechanisms are designed considering operational feasibility but key point is if TB is detected among patients at LAC plus of LAC, they **must be promptly referred to ART centre** for further management.

ICF among HIV high risk groups (HRG)

Operational research conducted in high HIV prevalent states have shown that HRG's like female sex workers (FSW), men having sex with men (MSM), injection drug users (IDU) etc. are more likely to have tuberculosis compared to general population. In addition, it is known that HIV prevalence among the HRG is several times higher than general population. While NACP provides HIV prevention interventions for the HRG through its targeted interventions, the ICF provides an opportunity to provide additional services to this population. This intervention is likely to help in detection HIV/TB cases early and link to care support and treatment. Among the HRG's, IDU have highest HIV prevalence therefore the programmes aim to provide ICF services and prompt linkage to care support and treatment to IDU as a priority.

ICF at Care and support centres:

TB symptom screening based on 4 symptom complex should also be done by counsellors and outreach workers at Care and support centre in collaboration with SACS.

Treatment of HIV-infected TB

Early diagnosis and effective treatment of TB among HIV-infected patients are critical for controlling the disease and minimizing the adverse impact of TB on the course of HIV. Hence, initiation of treatment is very important soon after the diagnosis of TB. Among HIV-infected persons, treatment of TB is same as that in the HIV-negative TB patients.

Anti-TB Treatment of HIV infected TB patients:

- Based on the clinical history and investigation reports ART MO will categorize patients as Rifampicin sensitive/ rifampicin sensitivity status not known/ clinically diagnosed TB cases, prior history of taking Anti-TB drugs (Cat I /Cat II) accordingly and initiate daily anti TB treatment in Fixed Dosage Combination as per RNTCP guidelines at ART Centre itself.

- All HIV-infected TB patients if not tested already should be tested for drug susceptibility before initiation of treatment. Staff nurse will refer the patient to the nearest drug resistant TB centre in coordination with to RNTCP and record the same in the line list as DRTB /Rif resistant patient. PLHIV with drug resistant TB should be managed by DR-TB center in consultation with ART centre.

- The STS of TU where ART Centre / CBNAAT site is located (nodal TU) will link the patient to the concerned TU based on the residence of the patient for TB treatment provision and follow up as per RNTCP guidelines. STS (nodal TU) will also be responsible to get the registration details from the concerned TU. Overall

- Responsibility of this linkage and coordination lies with District HIV –TB and PMDT coordinator.

- TB patients living with HIV infection should receive the same duration of TB treatment with daily regimen as HIV-negative TB patients.

- If drug sensitive TB patient and on second line ART, Rifampicin should be replaced with Rifabutin 300 mg three times a week or 150 mg daily.

- TB Treatment card for these patients will be prepared by staff nurse in duplicate and will be duly signed by medical officer. One copy of the TB treatment card is to be handed over to the patient. Patient will be registered , allotted TB Number and Nikshay ID by STS of the concerned TU as per the RNTCP guidelines within one month and nodal TU will be informed

- Pharmacist will maintain the inventory of stocks of Anti-TB drugs at ART centre. District HIV-TB and PMDT coordinator should ensure availability of adequate stock of Anti-TB drug and logistics in coordination with ART centre, District TB Officer ,District Drug store pharmacist.

- RNTCP will identify local treatment supporter for all HIV –TB co-infected patients. Anti TB treatment will be supervised by the local treatment supporter and any adverse drug reactions should be informed immediately to local medical officer at PHI and ART medical officer.

- Regular follow up of the patients, testing for sputum as per RNTCP Guidelines and adherence to ATT & ART treatment is to be ensured by the treatment supporter, STS, STLS, ART MO. ART Counsellor should ensure proper counselling in all the HIV-TB co-infected patients regarding adherence and possible side effects to ART and ATT.

- A mechanism of ensuring and checking adherence has been instituted by sending a missed call by patient to pre-printed phone numbers hidden behind selected pills after taking dose. As the sequence of hidden numbers cannot be predicted by patients, but are known by the system for each month of medication prescribed, the system offers high confidence that patients who respond correctly have indeed taken their medication.

- PLHIV with drug resistant TB should be managed by DR-TB center in consultation with ART centre. The treatment of HIV positive individual with MDR-TB is the same as for HIV negative patients. However treatment is more difficult and adverse events more common. Due to the increased frequency of adverse drug events, rigorous monitoring in this particular group of patients is required in order to ensure adherence to treatment, early identification and treatment of adverse events and reduce lost to follow up.

Anti-retroviral therapy and co-trimoxazole prophylactic therapy in HIV infected TB patients:

In addition to TB treatment, all HIV-infected TB patients must be provided access to care and support for HIV disease, including co-trimoxozole preventive therapy and antiretroviral therapy. ART reduces TB case fatality rates and the risk of recurrent TB. Co-trimaxazole preventative therapy has been shown to reduce mortality among PLHIV by preventing opportunistic infections.

- **Anti-retroviral therapy** must be offered to all patients with HIV and TB as well as drug-resistant TB, irrespective of CD4 cell-count, as early as possible (after 2 weeks) following initiation of anti-TB treatment. Appropriate arrangements for access to anti-retroviral drugs should be made for patients. However, initiation of treatment for TB should not be delayed.

Table: Initiation of first-line ART in relation to anti-TB therapy

Clinical staging	CD4 cell count (cells/mm3)	Timing of ART in relation to initiation of TB treatment	ART Recommendations
Start ART irrespective of any clinical stage	CD4 count of any value	• Start ATT first • Start ART as soon as TB treatment is tolerated(between2 weeks and 2 months)	Start ART Regimen TLE for patients not on ART. Forpatients already on 1st line ART, ZLN,shift to ZLE & continue ZLE even after ATT is stopped.
Rationale for ART recommendation during TB treatment : In the absence of ART, TB therapy alone does not significantly increase the CD4 cell count. Nor does it significantly decrease the HIV viral load. Thus, CD4 counts measured during active TB are likely to reflect the actual level of immune suppression The use of HAART in patients with TB can lead to a sustained reduction in the HIV viral load. It can also facilitate immunological reconstitution, and decrease AIDS-defining illness and mortality. This benefit is seen across different ranges of CD4 counts			

**The use of the standard 600mg/day dose of EFV is recommended for patients receiving EFV and Rifampicin.*
**In women of child-bearing age, the use of contraceptives should be ascertained because of drug reaction, as and when NNRTIs and Rifampicin are being used*
**Special Attention to be paid for monitoring hepatotoxicity*

Immune reconstitution inflammatory syndrome (IRIS)may occur in up to one-third of patients who have been diagnosed with TB and who have started ART. It typically presents within three months of the initiation of ART but can occur as early as five days. Patients with TB-associated IRIS most commonly present with fever and worsening of pre-existing lymphadenopathy or respiratory disease. The symptoms are similar to the paradoxical reactions seen in immuno-competent patients on ATT, but occur more frequently. Most cases resolve without any intervention and ART can be safely continued. Serious reactions, such as tracheal compression caused by massive adenopathy or respiratory difficulty, may occur. Therapy may require the use of corticosteroids.

First Line ART for HIV-TB

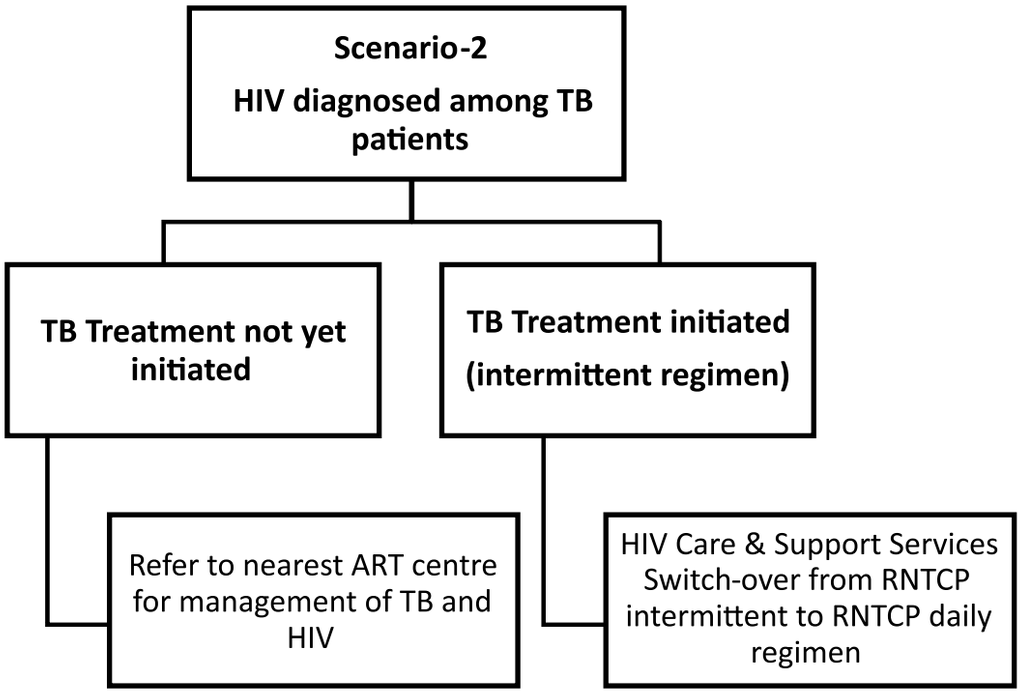
TENOFOVIR 300mg + LAMIVUDINE 300 mg + EFAVIRENZ 600 mg (FDC)		
Regimen	Tenofovir + Lamivudine + Efavirenz	All new co-infected patients should be initiated on FDC of TLE single pill based regimen irrespective of HB level/ CD4 count. Those patients who are already on ART on ZLN regimen at the time of TB diagnosis need to be changed to regimen ZL+E at the initiation of ATT due to interaction of ATT & NVP. Such patients will not be changed from EVF to NVP after ATT is completed and will continue on ZLE regimen. There is no change of regimen for patients who are already on ZLE at the time of TB diagnosis & treatment

Second Line ART for HIV-TB:
The following regimens are available under the National Programme currently for second line ART:
Tenofovir + Lamivudine + PI (Atazanavir / ritonavir or Lopinavir / Ritonavir)
Zidovudine + Lamivuidne+ PI (Atazanavir / ritonavir or Lopinavir / Ritonavir)
Stavudine+ Lamivudine + PI (Atazanavir / ritonavir or Lopinavir / Ritonavir)
Abacavir+ Lamivudine+ PI (Atazanavir / ritonavir or Lopinavir / Ritonavir)
Rifampicin alters the metabolism of Protease Inhibitors, including Atazanavir and Ritonavir and reduces their effectiveness in standard doses

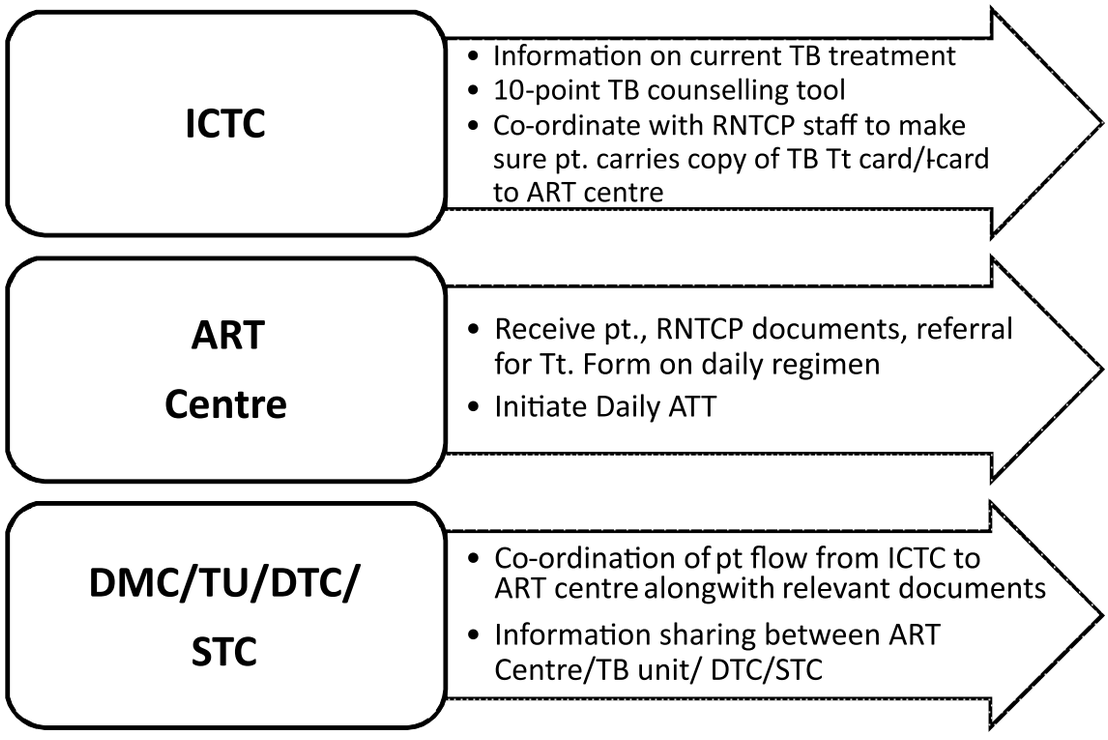
Initiating ART (Anti-Retroviral Therapy) in patients with DR- TB

- The use of ART in HIV infected patients with TB improves survival for both drug resistant and susceptible disease. However HIV infected MDR patients without the benefit of ART may experience mortality rates exceeding 90%. The likelihood of adverse effects could compromise the treatment of HIV or MDR TB if both treatments are started simultaneously. On the other hand undue delay in starting ART could result in significant risk of HIV related death amongst MDR patients.
- For patients who are already on ART at the time of DR-TB diagnosis be continued on ART when MDR-TB therapy is initiated. Occasionally, patients with HIV-related TB may experience a temporary exacerbation of symptoms, signs or radiographic manifestations of TB after beginning TB treatment. This paradoxical reaction occurs in HIV-infected patients with active TB and is thought to be a result of immune restitution due to the simultaneous administration of antiretroviral and tuberculosis medication (IRIS Syndrome).

Timing of referral to ART Centre
The following algorithm can be followed.



switch over from intermittent to daily regimen steps



- Patients who are not yet on ART should be provided with a referral to the ART centre immediately on identification as an HIV-infected TB patient. However, these patients (especially microbiologically confirmed pulmonary TB) should be counselled to attend the ART centre after at-least 2 weeks of anti-TB treatment have been completed, so that the risk of TB transmission to others is lessened.

- TB treatment should never be delayed, but it should be stressed to the patient to attend the ART centre as soon as possible, without delay. Patients who are on ART from a source other than NACO should be referred to an NACO ART Centre if they are willing or to their existing ART providers with information on TB treatment initiation otherwise.

Process at ART Centre

1. In view of advanced clinical stage of HIV disease, HIV-infected TB patients are to be evaluated for ART on priority (Fast-tracked). HIV-infected TB patients should be prioritized for CD4 testing.

2. The ART Centre Staff Nurse are to record patients' TB notification number and name of referring unit in the pre-ART register (along with 'entry point code') and ART- register.

3. The ART Centre Staff Nurses are to record the patient in the "ART Centre TB-HIV Register", and include information on whether or not ART was initiated.

4. If the HIV-infected TB patient is initiated on ART, they would also continue their CPT from the ART Centre.

5. The ART Centre staffs are expected to provide feedback to the referring physician. In particular, the ART Centre staff should communicate when they have assumed responsibility for CPT provision, so that the PHI Medical Officer can know if CPT is to be discontinued from that source.

6. The daily anti-TB regimen will be dispensed from ART centre on monthly basis to the patient by ART centre pharmacist.

Provision of Co-trimoxazole Prophylaxis Therapy (CPT) to HIV-Infected TB patients:

- Co-trimoxazole is a fixed dose combination of sulfamethoxazole and trimethoprim; it is a broad spectrum antibiotic that targets a range of gram-positive and gram-negative organisms, fungi, and protozoa. Co-trimoxazoleis given routinely for the prevention of opportunistic infections in HIV-infected persons; this strategy is called **Cotrimoxazole prophylaxis therapy.** CPT reduces morbidity and mortality of HIV-infected patients in general and HIV-infected TB patients in particular.Additional points to remember include:

- Dose for prophylaxis for adults (> 14 years old) and > 30 kg body weight): 960 mg (800 mg sulfamethoxazole + 160 mg trimethoprim) daily.

- For children and very low-weight adults (<30 kg), CPT for these patients is managed by ART centres as per separate protocol.

- CPT is provided to patients in monthly pouches.

- CPT is self-administered by the patient on a daily basis, and not under direct observation.

- CPT can be taken alongside anti-tuberculosis treatment (ATT) and ART. Many patients who are eligible for ART would also have CPT continued at ART center.

- Pregnant patients are also eligible, regardless of foetus gestational age.

- Patients should have no history of a serious drug allergy to sulpha drugs or glucose-6 phosphate dehydrogenase (G6PD) deficiency.

Isoniazid Preventive Therapy (IPT) For PLHIVs

IPT is one of the 3 I's globally recommended for prevention of incident TB among HIV infected individuals. Isoniazid is the most effective bactericidal, anti-TB drug available at currently. While it protects against progression of latent TB infection to active disease i.e. reactivation, it also prevents TB reinfection post the exposure to an open case of TB. In 2011 the World Health Organization (WHO) issued specific recommendations regarding the use of IPT in its guidelines on "Intensified TB case finding and isoniazid preventive therapy for people living with HIV in resource constrained settings". The key recommendations included the following:

a) Adults and adolescents living with HIV should be screened for TB with a clinical algorithm and those who do not report any one of the symptoms of current cough, fever, weight loss or night sweats are unlikely to have active TB and should be offered IPT. The guideline group strongly recommend use of Isoniazid 300 mg once daily for 6 months, in adult and adolescents,
b) Children living with HIV who do not have poor weight gain, fever or current cough are unlikely to have active TB
c) Children living with HIV who have any one of above symptoms may have TB and should be evaluated for TB and other conditions. If evaluation shows no TB, such children should be offered IPT regardless of their age.
d) Children living with HIV who are more than 12 months of age and who are unlikely to have active TB on symptom-based screening, and have no contact with a TB case should receive six months of IPT (10 mg/kg/ day) as part of a comprehensive package of HIV prevention and care services
e) All children living with HIV who have successfully completed treatment for TB disease should receive INH for an additional six months
f) Although IPT is more effective among Tuberculin Skin Test positive individuals (TST), it is not a requirement for initiating IPT intervention among the PLHIV considering difficulty in logistics and administration of the TST,
g) Providing IPT to people living with HIV does not increase risk of developing isoniazid (INH) resistant TB later. Therefore, concerns regarding development of INH resistance should not be a barrier to providing IPT

Steps in Provision of Isoniazid Preventive Therapy (IPT): The IPT provision involves following steps:

a) TB symptom screening at ART centre /Link ART-Plus and Link ART centres
b) Investigations for diagnosis of TB, if found symptomatic
c) If found Asymptomatic, assessment for the eligibility of Isoniazid Preventive therapy
d) If found eligible, initiation of IPT and Registration in IPT register maintained at the Nodal ART centre
e) Monthly collection of Isoniazid
f) Systematic recording and reporting
g) Continued TB symptom screening on each follow-up visits and reconsideration of IPT if symptoms develop

Monthly collection of Isoniazid: All eligible patients are to be initiated on IPT. The regimen prescribed are as below:

a) Adult and Adolescent: Isoniazid 300mg +Pyridoxine 50mg (Vitamin B6) per day for 6 months
b) Children above 12 months: Isoniazid 10mg/kg +Pyridoxine25 mg (Vitamin B6) per day for 6 months

The strategy for monthly collection of Isoniazid + Pyridoxine is as follows:

a) Patients on ART monthly collection from the ART centre, LAC-Plus or LAC along with monthly collection of the ART

b) Patients in pre-ART care visit the ART centre only once in six months. These patients may collect the monthly Isoniazid/ Pyridoxine packet from the designated stand-alone ICTC.

Systematic recording and reporting

All events in the cascade of IPT implementation including symptom screening at all contacts, IPT eligibility assessment, investigations, and the compliance with regimen are to be systematically recorded and reported.

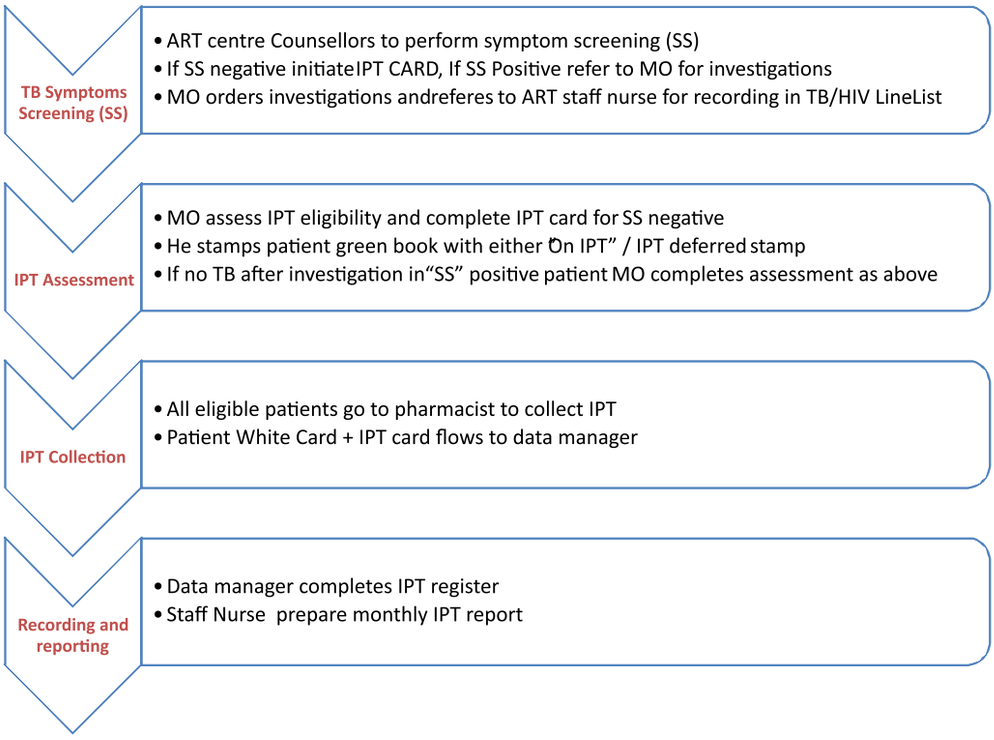
Mechanism of IPT implementation

The ART centre counsellor, staff nurse is to perform TB symptom screening (SS) among all the PLHIV attending the ART centre. If the SS is found negative, an IPT card is initiated, if the patient is found to be SS positive, s/he is referred to the ART centre Medical Officer for further opinion and investigations to rule out active TB disease. The MO prescribes the investigations and refers the patient to the ART centre staff nurse for inclusion in the TB/HIV Line-List

In rest of the patients, the MO undertakes assessment for eligibility of the patient for IPT and also completes the IPT card. He further stamps patient green book with either "On IPT" or IPT deferred stamp based on the situation. Also in patients found not suffering from TB after the investigations the MO undertakes the assessment as above.

All patients found to be eligible for IPT are referred to the pharmacist for collection of drugs. Concurrently the MO ensures that the Patients White Card and the IPT card are sent to the ART centre data manager so that the IPT register is updated. The data manager in turn updates the IPT register and Staff Nurse later prepares the monthly IPT report based on this register. This flow of patient and information is depicted pictorially in **Figure as follows.**

Figure: Mechanism of IPT implementation



TB and diabetes

As a consequence of urbanization as well as social and economic development, there has been a rapidly growing epidemic of Diabetes Mellitus (DM). India has second largest number of diabetic people in the world. As per recent estimates, there are around 66 million DM cases, with a further 77 million people having impaired glucose tolerance.

People with a weak immune system, as a result of chronic diseases such as diabetes, are at a higher risk of progressing from latent to active TB. Hence, people with diabetes have a 2-3 times higher risk of TB compared to people without diabetes.

- About 10% of TB cases globally are linked to diabetes.
- A large proportion of people with diabetes as well as TB is not diagnosed, or is diagnosed too late. Early detection can help improve care and control of both diseases.
- DM can lengthen the time to sputum culture conversion and theoretically this could lead to the development of drug resistance if a 4-drug regimen in the intensive phase of therapy is changed after 2 months to a 2-drug regimen in the presence of culture-positive TB.
- People with diabetes who are diagnosed with TB have a higher risk of death during TB treatment and a higher risk of TB relapse after completing treatment.
- DM is complicated by the presence of infectious diseases, including TB.
- It has been argued that good glycemic control in TB patients can improve treatment outcomes
- The precise biological mechanisms that result in this interaction between Diabetes and TB are still not clear. Epidemiological models have shown that DM accounts for 20% of smear-positive pulmonary TBand recent analyses have indicated that the increase in DM prevalence in India has been an important obstacle to reducing TB incidence in the country

National framework for joint TB- DM collaborative activities

The overall purpose is to articulate the national strategy for TB-Diabetes Mellitus Collaborative Activities between RNTCP and NPCDCS so as to ensure reduction of TB and Diabetes in India. Following strategy is proposed for collaboration between NPCDCS and RNTCP

1. Establishing joint planning and review committee for collaboration at National, State and District levels.
2. Establishment of service delivery protocols that address joint activities is as follows:

    a. Activities to improve diagnosis and management of Diabetes among TB patients:
    - Screening of all registered TB patients for DM
    - Ensuring DM management among TB patients

    b. Activities to improve diagnosis and management of TB among diabetic patients:
    - Intensified detection of active TB disease among DM patients
    - Ensuring TB infection control measures in health care settings where DM is managed
    - Ensuring TB treatment and management in comorbid patients

3. Joint monitoring and evaluation with standardized reporting shared between NPCDCS and RNTCP
4. Joint training of key programme and field staff in Diabetes/TB activities
5. Awareness and IEC activities
6. Operational research to strengthen implementation of DM/TB Collaborative Activities

Mechanisms for collaboration between RNTCP and NPCDCS

Mechanism for collaboration comprise at the National level, aNational TB-DM Co-ordination Committee (NCC) of key officials from NPCDCS and CTD, experts from WHO, national institutes and civil society; at the Stated level, State Coordination Committee on TB- DM, chaired by MD National Health Mission and at the district level, District Coordination Committee (DCC) under the chairmanship of District Collector. States may create Coordination committee on TB-Comorbidities and sub-committees (TB-DM, TB-Tobacco, TB-Alcohol) etc under the SCC for ease of functioning. Alternatively states may start with a separate committee till the systems are set and later on can be merged with the "one" body. These committees will ensure smooth coordination and oversight the collaborative activities.

Screening Intervention and Diagnosis of Diabetes among TB patients

- All TB patients who have been diagnosed and registered under RNTCP will be referred for screening for Diabetes. Referral of TB patients for screening for DM and its recording & reporting is responsibility of the Peripheral Health Institutions (PHI) where TB treatment is initiated.
- The screening for DM will follow the guidelines stipulated by NPCDCS in India. Those guidelines stipulate that fasting blood glucose (FBG) be carried out using a finger prick and glucometer with cut-off thresholds in line with those recommended by the NPCDCS.
- Screening TB patients for DM should be conducted as early as possible after diagnosis of TB; but can be done at any time during the course of TB treatment. Because of the difficulties in getting TB patients to first come to the clinic in a fasting state, TB patients will be initially screened with a random blood glucose (RBG) using a glucometer. If the RBG is less than 140 mg/dl, this is a normal result and no further tests need be carried out. If the RBG is at or greater than 140 mg/dl, this might indicate an abnormal glucose state and there is a possibility of DM. The patient will be asked to return in a fasting state, and a fasting blood glucose (FBG) will be carried out. FBG value at or greater than 126 mg/dl indicates DM.The criteria for diagnosing Diabetes will be as follows.

Diagnosis	Fasting Glucose (mg/dl)	2-hour Post-Glucose Load (mg/dl)
Diabetes Mellitus	>=126	>=200
Impaired Glucose Tolerance	<110	>140 to <200
Impaired Fasting Glucose	>=110 to <126	

- Criteria for suspected Diabetes case is reading of 140 mg/dl for Random Blood Glucose by glucostrip. The suspected case needs to undergo Fasting Blood Glucose test and Post Prandial tests to confirm diabetes
- The blood glucose testing will be done by a person designated and trained for the purpose at every peripheral health institution (PHI). Though, this would vary from site to site the following general principles would apply. Wherever, NPCDCS is being implemented, the Auxiliary Nurse Midwife (ANM) has been trained to use glucometer and screen people for DM. In case this mechanism is not available, the laboratory technician working in the PHI will be trained to do the test. If a PHI does not have a laboratory technician, then either the staff Nurse or any other staff designated by the MO-PHI will be trained to do the test.

Linkage of TB patients with DM for Diabetes care and management –

All Diabetic TB patients should be linked for diabetic care. In the districts where NPCDCS is being implemented, TB patients with DM or with a FBG at or higher than 126 mg/dl will be referred to diabetes care using a referral form for definite diagnosis and management. A referral and feedback mechanism will be developed to enable timely exchange of information. Good cooperation and collaboration will need to be developed between the two sets of staff working in the different service areas.

- At districts where NPCDCS is not implemented, TB patients should be referred to the nearest healthcare facility for further diagnosis and management of TB-DM comorbidity.
- TB patients diagnosed with Diabetes should receive the same duration of TB treatment with daily regimen as non- Diabetic TB patients.

Screening and referral of Diabetic patients for TB

- Four-symptom complex screening for active TB in Diabetes patients is to be done. Screening is expected to be carried out every time the patient visits the DM clinic. Patients will be asked whether they are on TB treatment, and if not, they would be screened for four-symptom complex, i.e.Cough of any duration, Fever, Weight loss, Night sweat.
- The Screening results for Diabetes are to be recorded in the patient NPCDCS register
- NCD clinic will implement basic infection measures as stipulated in RNTCP guidelines

Linkage of Diabetic patients with TB for TB case management-

On screening, patients with one or more symptoms will be referred to nearest diagnostic facility for diagnosis of TB.A referral and feedback mechanism will be developed to enable timely exchange of information. The patients diagnosed for TB would be initiated on TB treatment as per management guidelines stipulated in RNTCP.

TB and nutrition

Under nutrition is considered as one of the risk factors in the development of TB, since under nutrition is known to adversely affect the immune system. Still, there remains a question as to whether malnutrition predisposes to tuberculosis, or whether it is a consequence of the disease. There is as yet little evidence showing that additional nutrition support improves TB-specific outcomes, but low body mass index as well as lack of adequate weight gain during TB treatment are associated with an increased risk of TB relapse and death.

The basic recommendations to address nutritional needs of TB patients are discussed below:

1. Conducting an initial nutrition assessment of TB patients with further monitoring;
2. Providing ongoing counselling for patients on their nutritional status; Diet for TB patients starting treatment should include: cereals (maize, rice, sorghum, millets, etc.); pulses (peas, beans, lentils, etc.); oil; sugar, salt; animal products (canned fish, beef and cheese, dried fish); and dried skimmed milk.
3. Management of severe acute malnutrition should be treated according to national guidelines and WHO recommendations;
4. Management of moderate under nutrition for TB patients who fail to regain normal Body Mass Index (BMI) after two months of TB treatment or appear to lose weight during TB treatment should be evaluated for a proper treatment adherence and other comorbidities. If indicated, these patients should be provided with locally available nutrient- rich or fortified supplementary foods. Special categories of TB patients such as :
    - Children who are less than 5 years of age should be managed as any other children with moderate under nutrition. Pregnant women with active TB, patients with MDR TB should be provided with locally available nutrient- rich or fortified supplementary foods.

- Micronutrient supplementation for all pregnant women as well as lactating women with active TB. These women should be provided with iron and folic acid and other vitamin and minerals to complement their maternal micronutrient needs. In situations when calcium intake is low, calcium supplementation is recommended as part of antenatal care.

The Guidelines on Nutritional assessment and supplementation for the TB patients in India are being prepared so that the programme can adapt the basic principles of nutrition for better outcomes.

Under nutrition and underlying food insecurity are among the most important determinants of TB. Improving nutritional status at population level is important for TB prevention. This should be part of broader actions on social determinants. All efforts should be made to link TB patients for the nutritional support. It can be through the existing public distribution system, local self-government or NGO or donor agencies or through corporate sector under Corporate Social Responsibility (CSR).

Management of severe acute malnutrition: Children below 5 years, School-age children and adolescents (5 to 19 years), and adults, including pregnant and lactating women, with active TB and severe acute malnutrition should be managed for severe acute malnutrition.

TB and tobacco

India is the second largest consumer and the third largest producer of tobacco in the world(FAO, 2005). Nearly one million Indians die from tobacco use every year, which is much more than combined mortality resulting from HIV/AIDS, TB and Malaria. As per Global Adult Tobacco Survey, (GATS 2010, a household survey of persons 15 years of age and above) there are 275 million adult tobacco users in India. It is estimated that more than one- third (35%) of adults in India use tobacco in some form or the other. The prevalence of smokeless tobacco use (26%) is almost twice that of the prevalence of smoking tobacco (14%).

Tobacco smoke contains toxic chemicals which cause disturbances in the bronchial surface of the lung. It also weakens the immunity of the patient to fight with the TB bacteria.
The following evidence emerges from several studies conducted to look at the association of TB and tobacco in India:

- Almost 38% of TB deaths are associated with the use of tobacco.
- Prevalence of TB is 3 times as high among ever-smokers as compared to that of among never-smokers.
- Mortality from TB is 3 to 4 times as high among ever-smokers as compared to that among never-smokers.
- Smoking contributes to half the male deaths in 25-69 age groups from TB in India.

Exposure to tobacco smoke has also been found to affect TB in the following ways :

- Increase the risk of tuberculous infection and the risk of developing TB
- Affect clinical manifestations and increase risk of relapse among TB patients
- Affect microbiological conversion (sputum smear or culture) and outcome of treatment in TB patients
- Increase tuberculosis mortality and drug resistance to anti–tubercular drugs

Integrating Brief Advice for Tobacco Cessation

- When a patient gets registered as a tuberculosis case, the status of tobacco use is enquired.
- The information will be recorded in the TB treatment card in front portion using stamp
- If the TB patient is a smoker or tobacco user, he/she is offered 'Brief Advice' to quit tobacco used based on 5As and 5 Rs model
- The patient is assessed at every visit for follow up for TB and the status of tobacco use or quitting. At the end of treatment, his/her status of tobacco use is recorded in treatment card.
- If the patient has not quit tobacco use, he/she will be referred to the nearest Tobacco Cessation Clinic (TCC) or Quit line or m- cessation initiative.
- The information recorded in treatment card will be sent through the existing HMIS under RNTCP

Brief advice for quitting tobacco use consists of 5 'A's

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

If the tobacco user is not yet thinking about quitting tobacco use, the doctor/counsellor/treatment supporter will promote greater awareness of the **Relevance** to the patient of the advice to quit, the **Risks** of tobacco use and the **Rewards** (benefits) of quitting. Many tobacco users are largely unaware of the potential harm that continued tobacco use can do to them. If the patient is not ready to quit, the doctor/ counsellor/treatment supporter must not push the patient. People usually need time to change the mindset. If the patient is at least thinking about quitting, the doctor/ counsellor/treatment supporter can find out the patients' **Roadblocks** to quitting and help the patient see ways to overcome these. This process will assist the patient to get ready for quitting the tobacco use, without being forceful.

The 5 R's are :

- **Relevance** of quitting
- **Risks** of continuing
- **Rewards** of quitting
- **Roadblocks** to quitting
- **Repeat** at each visit

Awareness and IEC

- All the DOTS centre /Clinics will be made tobacco free
- IEC material will be displayed at TUs, DMCs and Tobacco Cessation Clinics.
- DMCs and TUs will display IEC material about the hazards of tobacco use, along with the brief advice.
- Tobacco Cessation Clinics will display hygiene and TB awareness related materials.
- Awareness building efforts will be done at both units for patients and staff.
- Sensitisation of all stakeholders (partners, policy-makers and administrators) will be done on regularly basis.
- Every effort will be made by both the programme divisions to sensitise the community about the ill effects of TB and tobacco use

Recording & reporting- Information on tobacco usage and its status is captured in treatment card.

Involvement of National Tobacco Control Programme in tuberculosis control

For enhancing active screening of TB patients through NTCP, the following process is indicated:

- Screening of four symptoms of active TB among tobacco users registered at the District TCC clinic and NCD Clinic at CHC- cough, fever, night sweat and weight loss
- Quit line established for tobacco cessation advice to conduct follow up of comorbid patients (TB patients with tobacco use) registered as TB cured, to identify TB relapse cases
- m-cessation initiatives to include TB-screening symptoms in cessation modules to identify active TB cases in people registered for tobacco cessation
- Ensure implementation of infection control guidelines in TCC Clinics
- Tobacco training modules prepared for teachers to include TB symptoms for increasing awareness among children and young adults

TB & Silicosis

Occupational high-risk group: Although reliable statistics are not available in India, it is known that thousands of workers and local residents are exposed to hazardous silica levels during stone crushing operations. Studies have shown increased morbidity and mortality rates among stone crushing mill workers from silicosis, lung cancer, and other lung diseases. Several other occupations also increase risk for tuberculosis including coal and other mining, tobacco (bidi rolling) and carpet weaving. Vulnerable and socially marginalised groups including tribal communities, children and migrant population are often used in these industries and do not have access to routine health services.

The RNTCP is in process of engaging with the Ministry of Labour and Mining to identify high priority districts with stone crushing units / mining industry. The specific guidelines will be developed to support persons with an occupational risk for TB and provide access, diagnosis and treatment services from the programme.

Human Resource Management

Most of the success that RNTCP has achieved can be attributed to its team of dedicated, hard-working and knowledgeable workers. Being under the overall umbrella of NHM, the HR policy and practice is mostly governed by the State NHM setup. The Central TB Division supplements this by provisioning contractual staff at strategic positions of the programme network, developing terms of reference for hiring of these staff and formulating standardized training material for creating a uniform knowledge base among workers. Apart from general health system staff, RNTCP has provisioned dedicated programme staff at various levels. The human resource structure given in next page enumerates key RNTCP positions at various levels.

Apart from these RNTCP positions, the States have been given the flexibility to create new structures and positions under their own health society mechanisms. Detailed terms of reference of these staff is provided at www.tbcindia.gov.in

Hiring of these staff is done by respective State/District Health Societies (other than National level positions). The compensation package for RNTCP contractual staff has to be decided by respective States, based on State specific situation, Job contents, Job responsibilities, and compensation for similar positions in other programmes under National Health Mission. Terms of reference of staff will be as per the programmatic guidelines.

RNTCP has adapted a cascading methodology to train its Staff, with National institutes and NRLs being involved as centres for training the trainers (STO, STDC Staff, IRL Staff, DTO, Medical College faculty, MO-STC -, etc.) on various components of the programme. These trainers come back and train the relevant cadre. The State TB Training and Demonstration Centres (STDCs) have been playing a major role in imparting State level RNTCP trainings. The MO-TCs and supervisory staff (STS, STLS) are trained at the STDCs who go on to train Treatment Supporters and lab technicians, respectively, at the district/Block/TB Unit level. DTOs with support of MO-TCs are entrusted with the responsibility of training the Medical Officers at district level.

The entire training process is reported under RNTCP programme management activities and closely monitored by National/ State / District officials.

Human Resource Structure

National Institutes

NTI Bengaluru - (TB Specialist, HR Consultant, Research Officer - IT, Documentation Assistant, Junior Epidemiologist, Sr. Microbiologist, Sociologist)

NITRD Delhi (NRL Staff)

NIRT Chennai (NRL Staff)

JaLMA Agra (NRL Staff)

Central TB Division (CTD)

Technical Officers, DEO, SA, Statistician, Data Analyst, Network Administrator, Administrative, Finance and Supply Chain Management Staff

National Reference Laboratories(NRL)

Consultant Microbiologist,

Senior LT

State TB Training and Demonstration Centre (STDC)

Microbiologist - EQA

State TB Cell

Epidemiologist, MO-STC, TB-HIV Co-ordinator, DRTB Co-ordinator, State PPM Co-ordinator, ACSM Officer, Accounts Oficer, Technical Officer-PSM, Treatment Monitor, SA, DEO-STC, DEO-STF, Driver

Intermediate Reference Laboratory (IRL) / CDST Lab

Microbiologist C&DST lab, Sr Lab Tech., DEO

State Drug Store (SDS)

Pharmacist cum Storekeeper, Store Assistant

District TB Centre (DTC)

MO-DTC, MO-Medical College, Sr MO-DRTB Centre, District Program Co-ordinator, District PPM Co-ordinator, District PMDT-TB-HIV Co-ordinator, DEO, Accountant, Driver

Drug Resistant TB Centre (DRTB Centre)

MO-DR-TB Centre, Counsellor, Statistical Assistant

Tuberculosis Unit

Senior Treatment Supervisor (STS), Senior TB Lab Supervisor (STLS),TBHV

Designated Microscopy Centre (DMC)

RNTCP LT/Sputum Microscopist

PHI

Treatment supporter

Capacity building

Capacity building is based on standardized modules which elaborate the technical and management components of the program. Special areas like pediatric TB, Drug resistant TB, TB with co-morbidities, Extra-pulmonary and other serious forms of TB, PPM, IPC, ACSM, SME etc are covered in these modules and also detailed as annexures to the main modules. Various categories of HR are trained/sensitized with the concise forms of these modules.The pharmacists, staff nurses, ANM, MPW, MPHS, Community volunteers are all trained with the same module for MPWs.

The customized modules for programme officials and staff, PPs,NGO functionaries, medical college faculties which include non-practicing TB teachers, non-practicing policy teachers, general practitioners, specialists, post graduates, researchers and professional associations are being developed using the advancement in ICT through capsular online e-training.The courses for each HR category ranging from the national policy makers and program managers to the community volunteers and patients' peer group are compiled based on their TOR and Job Responsibilities with clear focus on development of necessary skills to perform the tasks for each type of trainee. The curriculum matrix thus designed is available on www.tbcindia.gov.in

Training schedule

Induction training: Initial training before assuming the responsibilities of the programme

Update training: Newer initiatives or changes in the policy of the programme are to be conveyed to the health personnel

Re-training / refresher training: Based on training needs of the identified personnel focused on specific deficits of knowledge or skills

For duration and content of training for each cadre the matrix of training courses (with defined content) is to be used for need based scheduling of training which is placed on **www.tbcindia.gov.in** under HRD section. The first step for planning of each training and retraining is periodic training needs assessment.

Procurement & supply chain management

An uninterrupted supply of good quality Anti TB Medicines is an essential component of DOTS strategy under RNTCP. Managing the supply chain in a programme requires continuous monitoring at all levels.

Procurement

At Centre level – Anti-TB drugs, Binocular microscopes, LED Fluorescence microscope, CBNAAT equipment, CBNAAT cartridges, LPA, Solid and Liquid culture lab equipment and consumables, PDA/Tablet computers, barcode printers and scanners

At State / District level – Laboratory consumables and equipment, computers, vehicles, printing materials, IEC materials, PPD vials, refrigerator, air conditioners etc.

For **1st Line treatment**, RNTCP has two regimens: treating new and retreatment cases. The medicines for patients are available as independent Patient-Wise Boxes (PWBs) containing medicines for the entire treatment of the patient.

For **2nd line treatment**, monthly Patient Wise Boxes (Type -A, Type-B & Type-C PWBs) for the different patient weight bands are made available by the programme.

Further, Cap Rifabutin-150mg is also procured centrally for co-infected TB HIV patients, put on 2nd line ART regimen. With regard to distribution, supplies of Cap Rifabutin are also delivered at GMSDs by manufacturers and are further distributed to RNTCP State Drug Stores, based on the NACO requirement. Upon receipt of Rifabutin supplies at SDS, they are further distributed to respective SACS (State AIDS Control Societies) based on their monthly stock reports.

Procurement of 1st Line Anti TB Medicines is limited to 'Prequalified Suppliers' defined as GMP compliant manufacturers as assessed by WHO Pre-qualification Programme (PQP) whereas 2nd Line Anti TB Medicines are procured from suppliers having WHO GMP certification as a requirement for the bidding process. For GFATM, procurement of 2nd line medicines is through Global Drug Facility (GDF) of Stop TB Partnership.

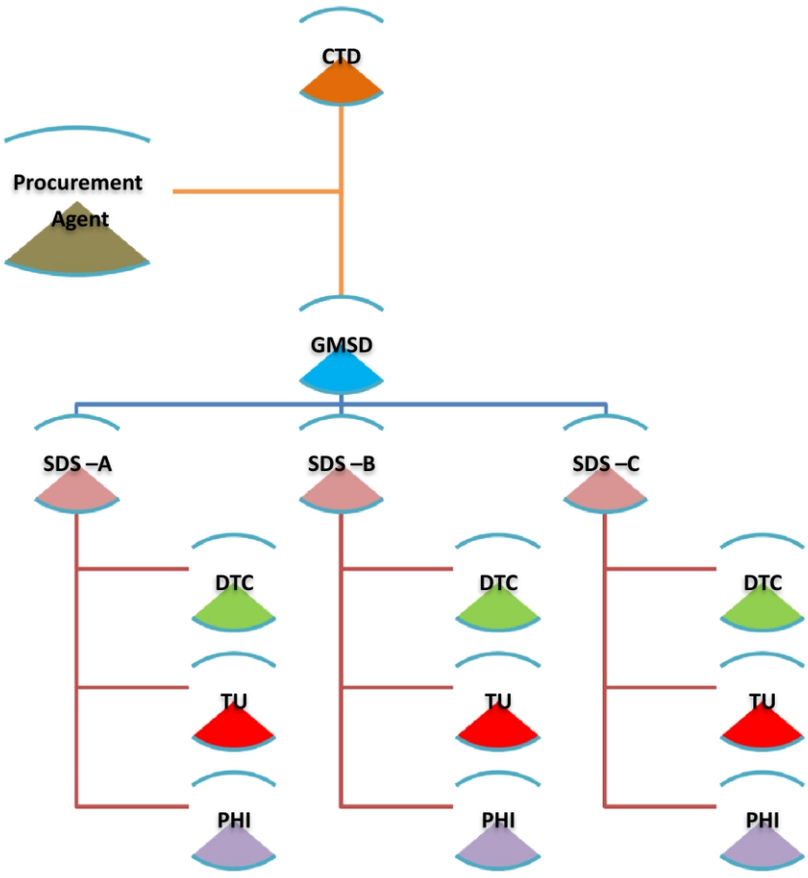
LED / Binocular Microscopes are also procured at the Central level by the Procurement Agency as per the General Finance Rules / World Bank procurement guidelines as funding for these is through Domestic Budget Support/World Bank credit.

Supply Chain Management

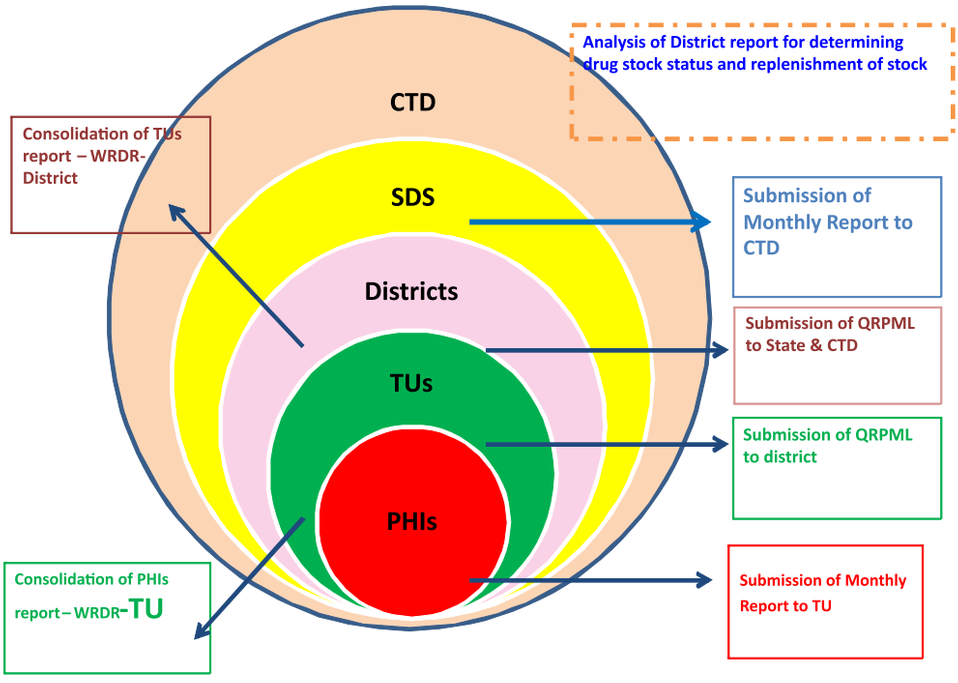
A good Supply Chain Management knows when to order or issue and how much to order or issue in order to maintain appropriate stock levels of all products to avoid stock outs and overstocking which can lead to product loss due to expiry. This is critical to the success of all health programs.

Distribution: The First Line Medicines are received at the GMSDs from the suppliers and based on the Monthly State Drug Stores and District Quarterly Programme Management and Logistics Report (QRPML), medicines are issued from the GMSDs.

For 2nd Line medicines, loose medicines are supplied at the GMSDs/SDS which have to be repacked into 1-monthly Type A, B and C Boxes for all the different weight bands. These Monthly boxes are then labelled, taken into record and distributed by the SDS as per requirement of the districts. The DTC in turn sends these boxes based on the quarter reports to its implementing TU to the PHI and finally to the DOT Centre/Provider, as the case may be.



Monitoring of Anti-TB Medicines is done based on Monthly and Quarterly Programme Management & Logistics Reports from PHIs and TU & Districts respectively. . The underlying presumption for consolidation of downline reports is that the QRPML should indicate accurate data on actual stock consumption and stock availability at all its downline medicine stores.



One of the important aspects of monitoring is Expiry Management wherein it is important that Principles of First-Expiry-First-Out (FEFO) are strictly adhered to by the drug stores at all levels to prevent expiry of medicines..

Reconstitution of medicine boxes is a process of retrieving residual medicines from PWBs of lost to follow up, dead and transferred-out patients and repacking them in quantities equivalent to and as per the description given on fresh PWBs for new & retreatment cases / Prolongation Pouches / loose medicines etc. It should be strictly centralized at the District Tuberculosis Center (DTC) or SDS for First line and Second Line medicines respectively.

Quality Assurance of Anti-TB Medicines has been accorded special importance by RNTCP and measures are taken at the time of procurement and also Post Procurement to maintain quality of Anti-TB Medicines. A comprehensive Quality Assurance (QA) Protocol is in place wherein samples from the field are regularly picked up for testing. This ensures continuous availability of good quality medicines at all stocking/ service delivery points under the programme.

Standard Operating Procedures (SOP) and Training Manuals have been developed for management of medicines. The SOP covers following aspects of supply chain management and provides detailed best practices to be followed by the State/ district/TU/PHI :-

- **Arrangement for transportation of Medicines-**. States should enter into a contract with these transporters for dispatches from SDS to districts and downline destinations.
- **Physical Verification** of inventory of anti-TB medicines and reconciliation thereof with store records should be carried out under the supervision of the concerned officer-in-charge at the State, DTC, TU & PHI drug stores, regularly at the end of each month.
- **Communication Infrastructure / Staffing** at the medicine stores
- **Location, Space and Storage arrangements** should be adequately available as per Good Storage Practices (GSP).
- **MIS for Medicines stock management**

For details, refer to SOP for district drug store and State drug stores available at tbcindia.gov.in.

Capacity building and Trainings on the SOPs are regularly conducted by CTD at the central & state level, as part of decentralization of this key area.

Stocking Norms for 1st Line Anti TB Drugs :-

Level	Stock for utilization	Reserve stock	Drug requirements
PHI	1 month	1 month	(Monthly consumption x 2) – (existing stock in PHI at end of the month)
TU drugstore	0 months	2 months	(Quarterly consumption / 3) x 4 – (existing stock in TU including PHI drug stores at end of the quarter)
DTC drugstore	0 month	3 months	(Quarterly consumption / 3) x 7 – (existing stock in DTC drug store including TU & PHI drug stores at end of the quarter)
SDS	0 months	3 months	(Quarterly consumption / 3) x 10 – (existing stock in SDS including stocks at all districts at end of the quarter)

Criteria for identification of short expiry Patient Wise Boxes (PWBs)

It is important that proactive measures be taken to ensure transfer of drugs to other districts/states to prevent expiry . The table below explains how to identify short-expiry drugs in the stores.

	Months				
Item	**Duration of treatment**	**Extension in IP**	**Possible Interruption**	**Max transit time for shifting of box**	**At risk of expiry, if less than ***
PC-1 PWB	6	1	2	1	10
PC-2 PWB	8	1	2	1	12

*** At the district level**

Stocking Norms for 2nd Line Anti TB Drugs

Flow of Drugs: At the beginning, the PHIs are supplied with a stock of two months (ie. stock for utilization in the first month along with a reserve stock of one month). Then every month, as per the monthly PHI report, they are supplied with stock from the TU which helps to maintain the reserve stock for a month at the PHI.

For the TU level to ensure that the PHIs have a month's utilization stock plus a reserve stock for one month, it needs to have a reserve stock of two months at the beginning of the quarter. District drug stores to replenish the stock at TU, upon the receipt of the drugs from their respective State Drug Stores, as per the stocking norms.

The district drug store should have at least a utilization stock of 1 month at the beginning of the quarter. Similarly the State Drug Stores should have at least a reserve stock of 3 months of consumption of the state.

It is expected that buffer stocks shall also be ensured at each level as per the stocking norms given in the table below.

Level	Stock for utilization	Reserve stock	Drug requirements
PHI	1 month	1 month*	(Monthly consumption x 2) – (existing stock in PHI at end of the month)
TU drugstore	0 months	2 months	(Quarterly consumption / 3) x 4 – (existing stock in TU including PHI drug stores at end of the quarter)
DTC drugstore	0 month	1 months	(Quarterly consumption / 3) x 5 – (existing stock in DTC drug store including TU & PHI drug stores at end of the quarter)
SDS	0 months	3 months	(Quarterly consumption / 3) x 8 – (existing stock in SDS including stocks at all districts at end of the quarter)

**All PHIs may not have a reserve stock. Only PHIs where patient/s are initiated or on treatment will have reserve stock of second line drugs.*

With regard to substitution of Tab Levofloxacin (Type-A Box) with Tab Moxifloxacin for Levofloxacin resistant MDR patients and substitution of Inj. Kanamycin (Type-B Box) with Inj Capreomycin for Kanamycin resistant MDR patients, the same needs to be addressed and done at State Drug Stores only.

Anti TB Drugs for adult patients in Daily Regimen

The daily regimen is being initiated in five states and to be scaled up in other states in a phased manner.

Medicines for daily regimen are being supplied in Patient-wise Boxes (PWBs) in following weight bands :-

Weight category	New TB Case	Previously Treated Case
25-39 kg	PC-1 DI	PC-2 DI
40-54 kg	PC-1 DII	PC-2 DII
55-69 kg	PC-1 DIII	PC-2 DIII
=70	PC-1 DIV	PC-2 DIV

Further, procurement of loose drugs for 5% of expected TB patients who may have side effects from fixed dose combinations (FDCs) and may require loose drugs instead of FDCs is also done through same mechanism and as per the procurement standards of GOI.

Dosages:-

Type of TB Case	Doses in IP		Doses in CP
New	56 doses (7 days * 8 weeks)		112 doses (7 days * 16 weeks)
Previously treated	84 doses (7 days * 12 weeks)		140 doses (7 days * 20 weeks)

Supply Chain Management

- **Distribution and monitoring**: Drugs to be distributed in the same manner as it is being distributed under Intermittent Regimen.
- **Reconstitution of medicine boxes** The reconstitution shall be done as per the existing RNTCP guidelines.
- **Treatment to Hospitalised patients –** preferably from the balance strips of PWBs from default / death patients. If same is not available, fresh boxes may be used.
- **Quality Assurance** of Anti-TB Medicines under daily regimen is same as it being done for Intermittent Regimen.
- **Storage**: Anti TB Drugs should be adequately maintained in quality condition; at room temperature, dry, pest / termite free area and secured under lock and key.
- **MIS for Medicines stock management** have been annexed at Annexures I-IV.

Stocking Norms for adult drug boxes:

For First three weight bands: 25-39 kg ,40-54 kg and 55-69 kg

Flow of Drugs: At the beginning, the PHIs are supplied with a stock of two months (ie. stock for utilization in the first month along with a reserve stock of one month). Then every month, as per the monthly PHI report, they are supplied with stock from the TU which helps to maintain the reserve stock for a month at the PHI.

For the TU level to ensure that the PHIs have a month's utilization stock plus a reserve stock for one month, it needs to have a reserve stock of two months at the beginning of the quarter.

The district drug store should have at least a utilization stock of 1 month at the beginning of the quarter. Similarly the State Drug Stores should have at least a reserve stock of 3 months of consumption of the state.

It is expected that buffer stocks shall also be ensured at each level as per the stocking norms given in the table below :

Level	Stock for utilization	Reserve stock		Drug requirements
PHI	1 month	1 month		(Monthly consumption x 2) – (existing stock in PHI at end of the month)
TU drugstore	0 months	2 months		(Quarterly consumption / 3) x 4 – (existing stock in TU including PHI drug stores at end of the quarter)
DTC drugstore	0 month	1 months		(Quarterly consumption / 3) x 5 – (existing stock in DTC drug store including TU & PHI drug stores at end of the quarter)
SDS	0 months	3 months		(Quarterly consumption / 3) x 8 – (existing stock in SDS including stocks at all districts at end of the quarter)

*The stocking norms are different under daily regimen as the shelf life may be varied from 2-3 years.

For fourth weight band: >70 Kg

Flow of Drugs: whenever a patient is diagnosed and to be put on treatment at PHI, the TU will send the drug box to the PHI immediately. At the end of each quarter, the shelf life would be reviewed and if required, inter TU or inter district transfers of the PWBs will be done to manage shelf life of drugs so that drug do not expired at any point of time. Accordingly, the stocking norms for the flow of drugs for weight band >70 are briefed in the table in next page:

Level	Stock for utilization	Reserve stock	Drug requirements
PHI	0 months *	0 months	Upon diagnosis of a patient under this category, respective TU will send the drug box to PHI immediately
TU drugstore	0 months	2 months	(Quarterly consumption / 3) x 2 – (existing stock in TU including PHI drug stores at end of the quarter)
DTC drugstore	0 month	1 months	(Quarterly consumption / 3) x 3 – (existing stock in DTC drug store including TU & PHI drug stores at end of the quarter)
SDS	0 months	3 months	(Quarterly consumption / 3) x 6 – (existing stock in SDS including stocks at all districts at end of the quarter)

Criteria for identification of short expiry Patient Wise Boxes (PWBs) . The table below explains how to identify short-expiry drugs in the stores.

Item	Months			
	Duration of treatment	**Possible Interruption**	**Max transit time for shifting of box**	**At risk of expiry, if less than ***
PC-1 D	6	2	1	9
PC-2 D	8	2	1	11

TB HIV: State Drug Stores will issue anti-TB drugs to the respective ART Centres as per the requirement quarterly. These ART centre shall submit the monthly report to the State Drugs Stores and the SDS to indicate the issues / dispatches to ART centres in their monthly report; submitted to the Central TB Division.

Recording & Reporting

Maintenance of accurate records and registers of patients and programme activities; and reporting data to the state/central unit, 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 are used in the RNTCP

Forms	Registers
Referral Slip	Tuberculosis Laboratory Register
Laboratory request Form for Specimen Examination	Culture and DST Laboratory Register
Tuberculosis Treatment Card	Tuberculosis Notification Register
DR-TB Treatment Card	Second line TB treatment register
Patient's TB Identity Card	Stock Register
DR-TB patient identity card	Reconstitution Register
Referral form for treatment	
Referral form for treatment of DR-TB	
Transfer Form	

RNTCP request form for examination of biological specimen for TB (Annexure 15A)

The request form is kept at all the PHIs. It is filled generally by the MO of the referring health facility. This form is used for microscopy or CBNAAT or culture DST or Chest X-Ray or TST. Only one form is filled for each patient. Patient will report to the diagnostic health facility along with the request form. In case PHI is a sputum collection centre, sputum samples are sent to the diagnostic facility along with the request form. It is essential to record patient details, reason for testing and type of test requested. The same form is sent back to the treating unit with the results. When this format is used for C&DST, a copy of this form will be sent electronically to lab and DTC. In turn, the laboratory will send the result in electronic copy back to district with copy to DR-TB centre.

RNTCP referral slip (Annexure 15B)

The referral slips are used by peripheral health workers like ASHA, AWW, Link Workers etc. to refer patients to health facilities where specimen is collected either for examination or for transportation. This referral slip has contact details and symptoms of patient. At these health facilities, RNTCP request form for examination of biological specimen for TB is filled up by Medical Officer. (While printing Referral Slips, printing of Serial Number may be considered)

Tuberculosis Treatment Card (Annexure 15C)

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 anti-TBtreatment; Regimen prescribed; Duration of treatment; Amount of drugs to be given; Results of investigation before and during treatment; Drugs administered during the intensive and continuation phases of treatment; Treatment outcome of the patient; Retrieval actions for missing doses; Adverse event, Preventive treatment for children; details of X-ray or other tests for diagnosis of EP TB; information on TB comorbidity and Remarks. It also has information on the treatment supporter, person conducting the initial home visit and the signature of the MO. An additional treatment card should be kept, if treatment supporter is not at health facility. In such cases, treatment supporter should be trained on recording treatment card.

Patient's TB Identity Card (Annexure 15D)

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, weight bands, smear results, category and information on the date of starting treatment. The back portion of the ID card has the results of follow-up smear 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.

RNTCP PMDT Treatment Card (Annexure 15E)

This card is a key instrument for the treatment supporter administrating drugs daily to the patient. The card will be initiated at the DR-TB Centre when the patient is admitted for staring treatment. However for those patients who are not willing for admission the card will be initiated by the DTO. The card should be updated daily, ticking off the administration of drugs by the treatment supporter. The card is the source to complete and periodically update the PMDT register. The original treatment card will be maintained at the DR-TB Centre and a copy will be kept at treatment supporter. Accountable systems have to be developed locally for updating cards at all levels. When or if the patient moves from the DR-TB Centre to his/her district of residence a copy of the card, must follow the patient. A copy of this card may be used as a notification form and to inform about final outcome of treatment.

RNTCP PMDT Patient Identity Card (Annexure 15F)

When a patient is diagnosed as having DR-TB and is placed on a Regimen for DR TB, RNTCP PMDT patient identity card should be filled out by the health care provider at the same time that the treatment card is filled out. The card should be kept by the patient. The card, which is wallet-sized, contains the name, age, sex, PMDT TB number, essential information about the treatment (start date, regimen, and severe adverse reactions to drugs), and the details of the health centre and treatment supporter where the patient will receive treatment. Mention date of missed doses and date and result of all follow up cultures in the space under Intensive and Continuation Phase. It also has a place to write the date of the next appointment for follow up at DTC and the DR-TB Centre.

Referral/Transfer form for treatment (Annexure 15G)

Referral / Transfer form for treatment is kept at all health facilities. Medical officer of the diagnostic health facility which refers patients for treatment to other peripheral health facilities 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 TB notification register.

Referral / Transfer 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 Referral / 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. The first part of the form contains information about the patient, her/hisdisease, 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 re-registered as a “transfer in” case in the receiving unit. When the patient has reported to the receiving unit, the bottom part of the form is completed by the receiving unit and returned to the transferring unit. It is to communicate patients' follow up examination results at the end of intensive phase and treatment outcome to the transferring unit.

RNTCP PMDT Referral for Treatment Form(Annexure 15H)

This form has to be filled for all confirmed MDR or XDR TB cases that are referred from one centre to another centre. The form has to be filled by the doctor of the referring centre in duplicate and one copy sent along with the copy of the current treatment card to the referred centre. This form can be used for referring the patient at various points in time during the management of the patient between the PHI, DTC and DR-TB Centre for reasons like initiation of treatment, adverse drug reaction, transfer out, ambulatory treatment or any other reason. Incases that are transferred out, a copy of the updated PMDT treatment card must also be sent along with the referral for treatment form.

TB Notification register(Annexure 15I)

A TB notification register is maintained at each peripheral health facility. This register contains records of all patients diagnosed with TB and eligible for TB treatment, regardless of initiation of treatment. It will also incorporate those cases initiated on first line treatment and offered drug susceptibility testing and results are awaited. The registration data is based on the date on which a TB patient is diagnosed.

If patient is put on treatment in area of facility where s/he is diagnosed then information on treatment and follow up is recorded in the same TB notification register. If patient is treated in area other than where h/she is diagnosed then information on treatment and follow up is recorded in TB notification register of health facility where patients is residing.

In each health facility, TB notification register is maintained by its staff. STS of the respective TB units will support updation and coordination for completing the information.

For every patient, status of treatment should be recorded. The status of treatment for any patient would one of the following:

1. Initiated on First line treatment in the same Health Facility
2. Initiated on second line treatment in the same Health Facility
3. Initiated on treatment outside Health Facility
4. Treatment initiated outside RNTCP
5. Incomplete/ incorrect address
6. Died
7. Migrated & untraceable
8. Repeat diagnosis
9. Patient already on treatment/ Follow up patient
10. Wrong diagnosis
11. Referred for treatment with pending feedback
12. Other

RNTCP PMDT Treatment Register(Annexure 15J)

This register is maintained at DR-TB centre and at the district TB centre. In contrast to the TB notification register, it is restricted to patients who have actually started on a second-line TB treatment regimen. Date of registration will be date on which a patient is initiated on second-line treatment. The patients should be entered consecutively by their date of registration.

At DR-TB Centre, Medical Officer DR-TB centre will be responsible for maintaining the register. Statistical assistant will assist in updating it in consultation with districts and CDST laboratory. For patients who are unwilling for admission at the DR-TB Centre and are initiated on treatment at the DTC, the DTO will send the requisite information to the DR-TB Centre along with a copyof the treatment card. The DR-TB Centre will register the patient and communicate the PMDTTB number to the DTO electronically.

At district level, DR-TB supervisor will be responsible for maintaining and updating the register. In district level DR-TB register, every patient residing from the respective district and registered on treatment at DR-TB Centre will be registered using the PMDT TB number given from the concerned DR-TB Centre.

Tuberculosis Laboratory Register(Annexure 15K)

It is kept at all designated microscopy centres. The Tuberculosis Laboratory Register is used to record the results of smear examinations. The LT assigns a Laboratory Serial Number for each patient who has been referred to the Laboratory for microscopy. The TB laboratory register is used to record date of specimen collection, patient information including contact details, Name of the health facility that requested the examination (e.g. primary health centre, medical college, private practitioner, NGO, etc.); Reason for examination (diagnosis and follow-up); Results of smear examinations; information on testing for comorbidity and drug sensitivity and treatment initiation status and notification number. 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 can 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. Patients from the following month should be started from the next new page.

Culture and DST Register (Annexure 15L)

The RNTCP laboratory register for Culture and DST is used to record CBNAAT, LPA and culture and DST examination results. This register should be compared regularly with the RNTCP PMDT register to ensure that all DR-TB cases to be started on RNTCP Regimen for DR TB are entered in the PMDT register to ensure each case diagnosed is accounted for monitoring indicators and report generation. The lab NIKSHAY ID number is a unique number, given to a patient first time his/her specimen comes the lab. On all subsequent specimen sent to the lab, the same NIKSHAY ID number is retained for the patient, but the new specimen is provided with a new lab number. This gives an opportunity to easily extract the test results of all the specimen provided by the patient and there by track his/her response to the treatment.

Stock Register

This register is maintained at state/ district/ TU drug store. It is used for recording 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 ofdrugs 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

It 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

Supervision, Monitoring & Evaluation

RNTCP has a robust recording and reporting system in place along with multiple internal/external checks to ensure good quality data generation which forms the basis for existing RNTCP supervision and monitoring strategy.

However, in view of the expansion in program activities this strategy needs to be more comprehensive with transition from target-focused monitoring of performance to analysis of key process and outcome indicators. Establishing a reliable monitoring and evaluation system with regular communication between the central and peripheral levels of the health system is vital. This requires standardized recording of individual patient data, including information on treatment outcomes, which are then used to programme monitoring indicators in cohorts of patients.

The strong supervision, monitoring and evaluation ensure that activities are implemented as planned, and that the data recorded and reported is accurate and valid; incorporate a system which leads to remedial action to improve performance; serve as a tool to facilitate commitment of higher authorities at different levels, ensure equitable provision of services to all sections of the community, including vulnerable areas and populations such as urban slums, SC/tribal/minority pockets etc.; and above all, bring the transparency and accountability.

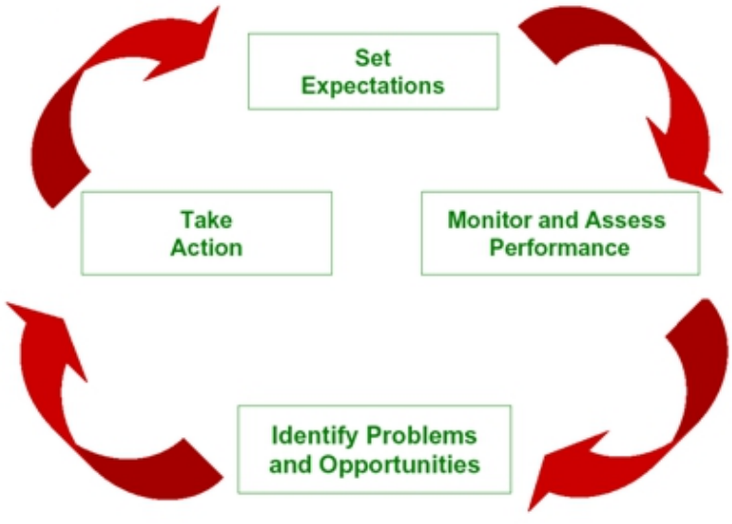
Program Supervision

Supervision is a systematic process for increasing efficiency of the health personnel by developing their knowledge, perfecting their skills, improving their attitudes towards their work and increasing their motivation. It is thus an extension of training.

Supervision is carried out in direct contact with the health personnel. It is a two-way communication between supervisors and those being supervised. It should not be a fault finding exercise but a collaborative effort to identify problems and find solutions.

It must also be realized that health personnel at all levels need on going support for solving problems and to overcome difficulties. They also need constructive feedback on their performance and continuous encouragement in their work. Such a supportive supervision ensures smooth implementation and continuous program improvement.

Process of Supervision



Guiding Principles for supportive supervision:

- Focus on processes and systems
- Nurture effective communication with staff
- Resolving conflicts
- Involvement and ownership-of supervisor and those supervised.
- Efficiency and delivery should be the target oriented
- Continuous learning, development, and capacity building of those supervised
- *Reinforcement on quality health outcomes at all levels*

Preparation for supervisory visit

1. Review of previous reports

Prior to undertaking the supervisory visit, monthly & quarterly reports and findings and recommendations of previous supervisory visit(s) are to be reviewed.

2. Prioritization of sites

Based on the data from above mentioned sources, it is important to prioritize on the sites to be visited and the key items to focus on during the supervisory visit.

There is a need to visit different types of health facilities at required intervals; some sites need more supervisory support than others. However a decision on this is based on certain performance indicators derived from various records and reports.

3. Preparation of Tour Programme

The visiting team has to prepare the travel plan well in advance to ensure availability of all concerned members of the supervisory team.

4. Intimation of tour programme to the Health Centre

It is always advisable to notify the in-charge of the health facility about the proposed visit so that the presence of the field staff can be ensured during the visit.

Occasionally, supervision can also be undertaken on a surprise visit to find out the factual situation.

5. Prepare objectives of supervisory visit

Objective of supervisory visit should be prepared in advance and should be shared with the supervisory team. The output of the supervisory visit will be to achieve those objectives in form of identification of reasons of the issues and solutions to address those issues and not merely fault finding. Since it may not be possible to evaluate all the activities on a single visit, it is important for the supervisory team to prepare their own objectives in continuation with observations made during earlier visits. Review of previous reports is useful for identifying the priority areas to be focused during the supervision.

6. *Supervisory Team:*

Supervisory team should possess a mix of skills and competencies keeping in mind the key areas and the sites to be visited.

CONDUCTING SUPERVISION

The supportive supervision approach should emphasize on constructive feedback, joint problem solving, and two-way communication between supervisors and those being supervised.

There are several ways in which the information could be obtained during the visit. Identified priority areas will require a mix of approaches, some of which are mentioned below:-

1. Discussion with Medical Officers and health workers

The knowledge and practices of the medical officers and health staff regarding their tasks is to be assessed during the discussion. Inadequacies observed during such interactions may be resolved by mutual consultation. Good work done by the health staff should always be acknowledged .

2. Review of records

Efficiency of the performance can also be assessed through review of important documents. Records that should be reviewed include:

- Lab register
- Treatment cards
- Register for drugs and consumables
- TB notification register

The information entered in more than one record is compared and checked for consistency. For example, the results of sputum examination are entered in lab register, treatment card and TB notification register. Random checking of such information in various records should be done to ensure consistency. Any inconsistencies that are observed should be discussed with the concerned personnel. Good record keeping practices should be appreciated.

The following records and reports are cross-checked for consistency:

- TB notification register, lab register and treatment cards
- monthly PHI-level report and lab register
- monthly PHI report and register for drugs and consumables
- monitoring indicators and TB notification registers

1. OBSERVATION

a) Observation of activities

On-site observation of various programme activities during their actual performance is one of the most effective tools for supervision. The activities at DMCs and DOT centers may be observed closely to assess the adherence to the programme guidelines. Immediate feedback should be provided on the work performed. While the correct practices should be acknowledged, any deviations observed should be communicated with the intention of improving systems and processes rather than targeting the individual.

b) Observation of Interaction between health staff and patients

Observing interactions between MO/Health staff and patients is crucial for understanding how the programme is functioning and the areas that require improvement.

At Health Centre:

Observing the interactions during various activities like sputum collection, DOT, health education, etc. will help the supervisor to understand the information provided to the patients and the manner in which it is provided.

The supervisory team should take note of the following:

- Health staff behaves politely with the patients.
- The health education messages conveyed should be simple and clear.
- Instructions to the patients are communicated clearly to the patients for example, correct way of bringing out sputum, adherence to treatment regularity, cough hygiene, etc..

Home visit: Interaction with the patients and their families is crucial to gauge patient's understanding of the disease he/she is suffering from and the course of treatment to be followed. This also provides an indication of the quality of health service delivery. Selection of patients to be visited at their home will be at the discretion of the supervisory team. However, smear positive patients and patients who have interrupted the treatment should be given preference.. It would be preferable if the In-charge of the health facility accompany the team during home visit. Feedback on the observations made during the supervisory visit should be provided to the concerned health staff. Information obtained during the patient interview should be cross-checked with the available records.

2. Examination of supplies

The following items are to be checked to assess the adequacy:

Drugs	Laboratory forms for sputum examination
Needles and needle cutters	Tuberculosis Treatment Cards
Syringes	Tuberculosis Identity Cards
Ampoules of water for injections	Tuberculosis Transfer Forms
Sputum containers	Referral for Treatment forms
Laboratory consumables	Supervisory Register

Equipments are checked for their functional status. Reagents are checked for date of preparation and expiry. Patient-wise boxes are also checked. It is to be ensured that drugs and reagents with earlier expiry date are used before the stock with later expiry date. Drugs or consumables should not be kept beyond their date of expiry. During supervisory visits, unused portions of patient-wise boxes of patients who have defaulted, died or transferred out are to be taken back to DTC. The partially consumed boxes are not to be re-used for any other patient, as this may result in incomplete treatment. However the unused blister packs will be used for reconstitution at DTC.

The stock of drugs and lab consumable is cross-checked with monthly PHI- reports and registers, followed by physical verification of the existing stock.

Recording feedback on supervision

Observations and recommendations arrived at during the supervision should be entered in the register meant for supervision. Besides, a report on feedback of supervision should be sent promptly to the health centre visited for corrective actions. Higher authorities may be furnished with a brief report for any administrative intervention if needed. Feedback and problem solving are key to effective supervisory activity.

Problem solving

Problem solving is one of the important objectives of supervision. The process begins with description of the problem identified and then, possible causes are identified. Subsequently, solutions are identified and implemented. The problems identified and the possible solutions could be discussed as a team. The steps mentioned above may be followed during the discussion.

Supervisory Protocols

1. RNTCP Supervisory staff protocol for district level category of Staff

Supervisor	Methodology	Frequency
DTO/MO – DTC	• Conduct interview with health staff and RNTCP key staff and other sectors • Conduct interview with health staff of Private/NGO hospitals • Interact with community and local opinion leaders • Randomly interview patients and community leaders. • Inspect records of the TU, PHC and CHC, and stock of anti-TB drugs and laboratory consumables. • Randomly check the microscopy centre and DOT Centers	Visit all TUs every month and all DMCs every quarter. Visit all CHCs and Block PHCs in the district every quarter, one sub-centre from each Block PHC area and a proportion of treatment observation centres every quarter. Conduct supervisory visit at least 3-5 days a week. Visit at least three patients at their homes per visit Visit prioritized private/NGO and other sector health care centres.
District PMDT TB-HIV coordinator	• Interview MPHS and MPWs at the PHC sub-centre. • Inspect records, PMDT Treatment Cards and PMDT Treatment Register. • Visit PMDT treatment observation centres and interview the treatment supporters • Randomly interview DR-TB patients and PLHIV with TB. • Inspect records, line list of presumptive TB referral at ICTC and ART centres, and HIV-TB register at ART centres • Interview health staff of identified Private/NGO/other sector health care centres	Visit DR-TB centres at every month and attend every coordination meeting at DR-TB centres Visit all TB Units once every quarter. Visit all sputum collection centres at least once a quarter. Visit all CBNAAT laboratories once in a month. Visit all DR-TB patients at their home within one month of treatment initiation. Visit all ART/Linked ART centres in a month Visit all ICTCs in a quarter Visit 3 HIV-TB patients during each visit Visit prioritized private/NGO and other sector health care centres.
District PPM Coordinator	• Interview health staff of identified Private/NGO/other sector health care centres • Inspect records, notification registers at private health facility, other records as prescribed for relevant services. • Randomly interview patients treated in private.	Visit prioritized private practitioners in a month Visit prioritized private hospitals in a month Visit prioritized laboratories in a month Visit prioritized chemists in a month Visit prioritized NGOs in a month Visit prioritized coroporate sectors in a month

Supervisor	Methodology	Frequency
		Visit Public Sector Units Visit at patients treated in private at their homes during visit Visit patient provider meeting, community meeting, school activity, sensitization of PRI/ASHA, outdoor publicity.
MO-TC	• Interview the MO I/C Block PHC/CHC/PHC./Private/NGO hospitals • Randomly interview patients and community leaders. • Interact with community and local opinion leaders • Randomly check the microscopy centre and DOT Center • Stock of anti-tuberculosis drugs and laboratory consumables.	Visit all DMCs every month. Visit all CHCs/BPHCs/ PHCs and a proportion of treatment observation centres at least once every quarter. Conduct supervisory visits 7days a month. Visit at least three patients at their homes per visit. Visit prioritized private/NGO and other sector health care centres.
STS	• Interview MPHS and MPWs at the PHC sub-centre. • Inspect records, Tuberculosis Treatment Cards and Tuberculosis Notification Register. • Randomly interview patients. • Interview health staff of identified Private/NGO/other sector health care centres	Visit all PHIs at least once every month and all DOT centers once every quarter. Visit all TB patients at their home within one month of notification from both public sector and private sector. Conduct supervisory visits at least 5 days a week. Visit prioritized private/NGO and other sector health care centres.
STLS	• Inspect all microscopy centres, review laboratory records, check stocks, inspect sputum collection centres and PHIs including that of private/NGO and other sectors	Visit all microscopy centres and CBNAAT laboratories in the jurisdiction at least once a month. Visit all specimen collection centres at least once a month. Visit prioritized private/NGO and other sector health care centres.

PROGRAM MONITORING

Monitoring is the process of observing whether an activity or service is occurring as planned. It implies systematic and purposeful observation, aiming to identify any diversion from the planned course of action. It is a routine tracking of program using input, process, output and outcome data collected on a regular and ongoing basis.

This helps identify the need for more formal evaluation of activities and find timely solutions to the problems.

Monitoring in TB programs is of paramount importance for ongoing program planning and implementation. A good monitoring strategy moves beyond the widely used case detection and treatment outcome indicators and applies the concept of input, process, output, outcome and impact indicators for measurement of key program activities.

A. Monitoring Indicators:
Various components of programme service delivery are feed in NIKSHAY from where various input, process, and outcome indicators drawn for different levels of health facilities. Analysis of these indicators will help in monitoring improvement in program performance. List of monitoring indicators is placed at Annexure 16.

B. Review meeting Protocol
Review meetings are useful monitoring tools and effective use of the same helps ensure standard practices in the program and help improve performance. The table is placed in annexure17 for the different types of review meeting conducted under RNTCP. More focussed reviews of specific activities may be planned by the program managers.

Following aspects are crucial for effective review meetings:
- Organization at convenient place and time
- Timely communication of the schedule, to allow preparation by the participants
- Advance planning of agenda items and thorough preparation by the organizers
- Two-way communication between the chair and participants
- Encouragement for experience sharing on important discussion points
- Review must be based on objective indicators and not opinion
- Prompt decision making and initiation of action
- Systematic recording and dissemination of minutes of the meeting including time bound action points
- Tracking of actions taken on decisions made in the meeting at the level of Managers

C. Monitoring tools:
Monitoring tools should never be used in Isolation; together with Good Monitoring Indicators they form the basis for effective Program Monitoring. Refer to document on supervision and monitoring strategy under RNTCP.

Program Internal Evaluation

Internal Evaluation forms an integral component of RNTCP supervision and monitoring strategy. It acts as a tool to evaluate if good program practices are adopted and quality services are provided to the community. The evaluations also offer an opportunity for program managers to look into all aspects of program critically and swiftly. These activities help program managers in understanding determinants of good as well as poor performance for replication of good practices in other states /districts andtake appropriate measures for improvement.

Objectives of IE

1. To provide a systematic framework for **assessment** of program performance, financial & logistics management, recording and reporting, and quality of care received by patients
2. To give **recommendations** for improving the quality of program implementation and performance with a realistic action plan and time line.
3. To **monitor** efforts to improve and maintain program quality and performance over time

Centrally driven internal evaluation (CIE): Central TB division selects 1state per month for evaluation based on the performance so that all big states are visited once in every 2 years. In the selected state at least 2districts are evaluated. CIE provides an opportunity to review performance in select district and to review overall performance of the state, programmatic challenges. It facilitates the centre to understand, address and support actions for improving quality of RNTCP implementation in the state.

The CIE team consists of representatives from CTD, NACO, WHO, STO's from other state, partners and consultants etc.

State Internal Evaluation team consists of State TB Officer or Deputy STO, STDC Director / representative (where STDC exists), One DTO of a district other than the one being evaluated, WHO RNTCP consultants, Medical college representative, Consultant from other programme partners (IMA, CBCI etc.), State Accountant and State IEC Officer

IE Methodology

Selection of districts: Upto 30 million – 2 districts per quarter; 30-100million – 3 districts per quarter; >100 million – 3-4 districts per quarter.

Aim is to cover all districts at least once in 3-4 years. In States/UTs with 4 or lessdistricts, 1 district or TU per quarter may be evaluated alternating selectionbetween a well performing district and an under performing district.

Selection ofTB Units/ DMCs:

DMC are listed based on presumptive TB cases examined in previous quarter. Five DMCs are selected out of these as follows:

1. DMC at DTC
2. Two DMC that are examining higher number of presumptive TB case (preferably from different TU)
3. Fourth and fifth DMCs is selected randomly from remaining DMCs (preferably from different TU)

Selection of DOT Centres /Treatment support centres:

- The team should visit the DOT Centres attached to each of the 5 selected DMCs (and Medical College conveniently selected).

- Also identify and visit 5 more Treatment Support Centres in the district with unique characteristics such as those attached to a medical college (other than the one conveniently selected for visit), other sectors like ESI, Railways, NGOs, private sector, anganwadi worker, ASHA, community volunteer)

Selection of patients:

- In each of the **2 DMCs with low case load** 4 NSP patients are selected randomly and one previously treated case conveniently (5 X 2= 10 patients)
- In each of the **DMCs at DTC & 2 TU level DMC**, 4 NSP patients are selected randomly and 1 patient each of the types Relapse, TAD and Failure are conveniently selected. Also select 1 TB/HIV patient and 1 DR-TB patient (7 X 3 =21 + 3 +3= 27)
- Visit at least 2 pediatric TB patients undergoing treatment within the district. Thus a total of 36 to 39 patients should be interviewed in the district.

Activities performed in IE:

- Triangulation of data, for all the TB Units in the district
- Visits to DMC, Treatment Support Centre, ICTC, ART centre, Medical College etc. Patient home visit for interview
- Compilation of the report
- Communication of Key observations to district authorities
- De-briefing of the findings to RNTCP staff
- Submission of IE report to STC and CTD - soft copies are sent to CTD as soon as possible and the hard copies, with cover page signed by all members, by courier not later than a week.

RNTCP has made incredible progress with regards to ensuring quality diagnostic and treatment services, but therein lies the risk of complacency creeping into the program. Further the program has expanded to involve all health care providers thorough PPM strategy, TB HIV collaborative activities, provision of PMDT services etc. which may compromise the quality of basic DOT services. Therefore it is important to ensure that basic components of DOTS are in place and Internal Evaluations are useful tool for the same.

Internal Evaluation Formats and Internal Evaluation Field Visit Report – Refer to the strategy document on supervision and monitoring available at www.tbcindia.gov.in

Surveillance

Complete surveillance is an important public health function in the prevention and control of any disease. Prompt notification to the public health system is an important component of the surveillance process and achieves the following public health objectives:

- It provides helps to measure disease burden, monitor epidemiological trends, detect outbreaks, and plan and target preventative and treatment services.
- It identifies people needing follow-up to ensure that treatment is completed, and enables contact tracing and screening of close contacts.

Notification of TB patients

In order to undertake comprehensive surveillance of Tuberculosis, ensure quality of care, reduce TB transmission and address the problem of emergence of spread of drug resistant TB, it is essential to have complete information of all TB cases. Government of India has declared Tuberculosis a notifiable disease in May 2012. Henceforth, all health care providers in public and private sectors have the public health responsibility to notify TB cases diagnosed and/or treated by them.

All TB cases irrespective of method of diagnosis (microbiologically confirmed or clinical), initiation of treatment (whether on treatment or not), source of treatment (Government or non-government), type of patients (TB or DR-TB), type of regimen used for treatment (daily or intermittent) should be notified to public health system.

Once private practitioner notifies TB patient information following action will be taken by local public health staff of general health system of Government or local bodies and entered in Niksahy:

- Patient home visit as per convenience of patient,
- Counselling of TB patient and family members,
- Treatment adherence and follow up support ensure treatment completion,
- Contact tracing, symptoms screening, evaluation of TB symptomatic and offering INH chemoprophylaxis to eligible contacts,
- Offering HIV testing, Drug Susceptibility Testing (DST), if eligible.

All laboratories shall notify TB cases with information as per Annexure 18 A and medical practitioners, Clinics, Hospitals, Nursing homes shall notify TB cases with information as per Annexure 18 B.

Strengthening Surveillance System will ensure that appropriate measures can be taken by the program to implement quality TB diagnosis and treatment as per STCI.

TB notification system

To make a complete surveillance system and to bring missing TB patients under surveillance system, all TB patients diagnosed under the programme (either microbiologically confirmed or clinical) need to be notified. All TB patients who are put on standardized treatment regimen under the programme or other regimen due to clinical indication (as initiated in tertiary care institute) within programme are to be notified. Over and above, all TB patients treated outside government health system need to be notified under one uniform surveillance system and to be accounted for total cases notified.

Once a TB patient is diagnosed, s/he will be notified in a **peripheral health facility TB notification register** (Annexure-attached TB notification register). The notification is to be done on the same day of diagnosis. If his/her treatment is initiated in the same health facility, patient's treatment information, follow up and treatment outcomes are updated in the same TB notification register. Else, the patient will be referred to the health facility catering area of patient's residence.

There s/he will be registered as referred-in patient, and treatment related information will be updated. There will be two cohorts – notification (diagnosed) and treatment cohorts. For final notification report for any health facility all cases notified will be included. For Treatment cohort reporting all cases initiated on treatment at the respective health facility will be included (including the transferred in patients)
To account for notification, TB notification register of health facility where patient is diagnosed will be source of information. And to account for treatment cohort, TB notification register of health facility where treatment is initiated will be source of information as well as transferred in and referred in patients.
Notification number will be generated at time of first notification either at diagnosis or at initiation of treatment whichever comes first.

Illustration of how the system will function in different situation

Situation 1: A patient is diagnosed in a health facility by any method and put on treatment in the same health facility.

Laboratory technician or MO will notify a patient and close the loop by initiating treatment and reporting information in the same notification register.

Situation 2: A patient is diagnosed in one health facility and referred to other health facility for treatment.

A patient will be notified by LT or MO and refer the patient for treatment with intimation to treating health facility. MO of treating health facility will initiate treatment and give feedback to diagnostic health facility to account for treatment which will be entered in the same register in which notification occurred at time of diagnosis.

Situation 3: A patient diagnosed as clinically (based on CXR, histopathology, cytology, USG, CT Scan, MRI, other), MO diagnosed the patient will notify the patient.

Situation 4: A patient is initiated on treatment without being notified earlier; MO of treating health facility will notify the patient.

Notification number will be generated at time of first notification either at diagnosis or at initiation of treatment whichever comes first.

For the purpose of monitoring and to ensure accountability for each notified TB patient following mechanism will be adopted.

Each health facility will be monitored for both indictors; fate of all notified patients as well treatment outcomes of all patients initiated on treatment including transferred in cases.

Since each health facility will have both patients diagnosed in their facility as well cases referred in and transferred in; reconciliation of treatment outcomes will be done at all levels starting from TB Unit and above.

Level of monitoring	Fate of notification for treatment initiation	Treatment outcomes of all those initiated on treatment
TB Unit	Compilation of information on each fate of notification for all health facilities within TU and those referred outside TU should be segregated and further monitored for those whose feedback is received and not received. While doing so, compilation on extend of all referred in patients and transferred in patients by all health facilities within TU should be done and monitored for extent to which the feedback is given to referring health facilities within TU and outside TU	Compilation of treatment outcomes at TU level should include all patients initiated on treatment at all health facilities within TU including referred in and transferred in patients The gap between all patients notified and whose treatment outcome is known should be monitored and should decrease over a period of time with increasing feedback to all health facilities for referred and transferred out patients within TU
District level	Compilation of information on each fate of notification for all health facilities within district and those referred outside district should be segregated and further monitored for those whose feedback is received and not received While doing so, compilation on extend of all referred in patients and transferred in patients by all health facilities within TU should be done and monitored for extent to which the feedback is given to referring health facilities within district and outside district	Compilation of treatment outcomes at district level should include all patients initiated on treatment at all health facilities within district including referred in and transferred in patients The gap between all patients notified and whose treatment outcome is known should be monitored and should decrease over a period of time with increasing feedback to all health facilities for referred and transferred out patients within district

Level of monitoring	Fate of notification for treatment initiation	Treatment outcomes of all those initiated on treatment
State level	Compilation of information on each fate of notification for all health facilities within state/UT and those referred outside state/UT should be segregated and further monitored for those whose feedback is received and not received While doing so, compilation on extend of all referred in patients and transferred in patients by all health facilities within TU should be done and monitored for extent to which the feedback is given to referring health facilities within state and outside state	Compilation of treatment outcomes at state level should include all patients initiated on treatment at all health facilities within state including referred in and transferred in patients The gap between all patients notified and whose treatment outcome is known should be monitored and should decrease over a period of time with increasing feedback to all health facilities for referred and transferred out patients within state
National level	At national level Compilation of information on each fate of notification for all should be monitored for the extent of feedback received against the sent by all health facilities. The gap should reduce over a period	At national level Compilation of treatment outcomes at district level should include all patients initiated on treatment at all health facilities in the country The gap between all patients notified and whose treatment outcome is known should be monitored and should decrease over a period of time with increasing feedback to all health facilities for referred and transferred out patients.

National level At national level Compilation of information on each fate of notification for all should be monitored for the extent of feedback received against the sent by all health facilities.

The gap should reduce over a period At national level Compilation of treatment outcomes at district level should include all patients initiated on treatment at all health facilities in the country.

The gap between all patients notified and whose treatment outcome is known should be monitored and should decrease over a period of time with increasing feedback to all health facilities for referred and transferred out patients. Such compilation and monitoring should be facilitated with use of Nikshay and review of the feedback mechanism in real-time using ICT coupled with exchange of information between health facilities, TB Units, district and states periodically; at least fortnightly at TU level, monthly at district level quarterly at state level and bi-annually at national level.

NIKSHAY

Nikshay is the platform for the National Tuberculosis Programme Surveillance System.Nikshay envisages to establish ICT enabled state-of-art surveillance system with system utilization by 100% stakeholders and ensuring 100% notification of TB cases at diagnosis (microbiologically confirmed &clinical). The programme also envisions continuous monitoring and treatment adherence for all TB patients registered with eNikshay, enable tracking of all registered TB patients across TB control lifecycle, geographies, transfers and referrals.

The first step is to ensure registration of all healthcare establishments across public and private sector in Nikshayand to ensure participation of all providers over time in e-Nikshay.Details of every TB patient diagnosed and / or initiated on treatment must be updated in NIKSHAY. If the patient has not been registered in NIKSHAY at the time of examination at the diagnostic centre, s/he may be registered/ notified afresh. Look for a NIKSHAY ID for the patient who has already been registered. If not available, registering/notifying afresh will generate a new ID. This ID is unique and is important for further follow up and linkages with treatment support programs. All health establishments must report all TB cases and their treatment outcomes to public health authorities (District Nodal Officer for Notification).

Detailed guidance on usage of Nikshay will be updated from time to time on the programme website and strategy document for Supervision, monitoring and evaluation.

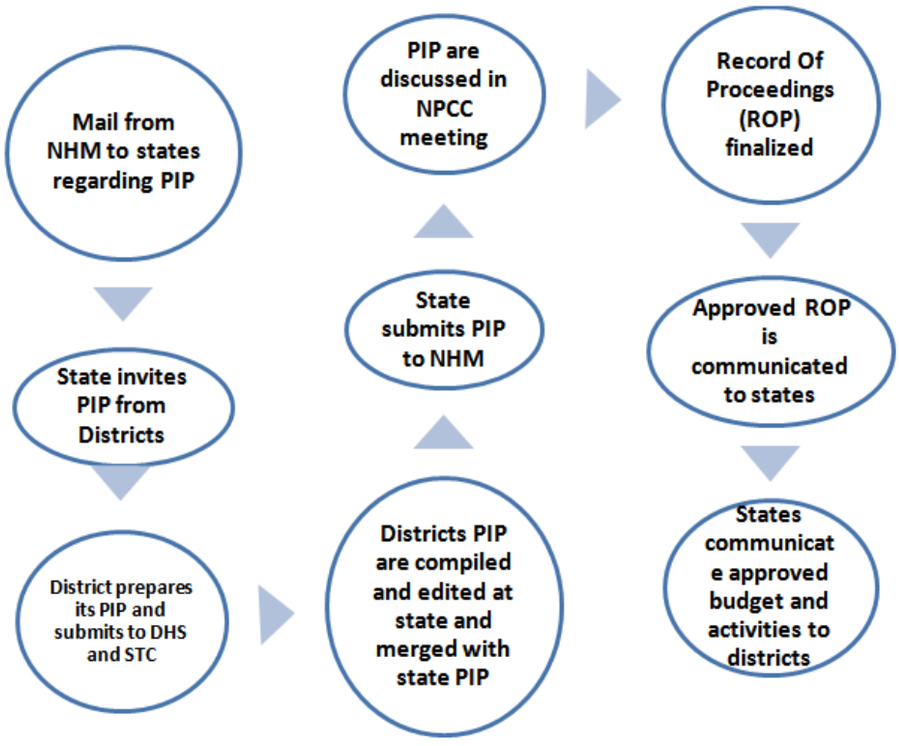
Project Implementation Plan & Planning process

RNTCP is one of the components under the National Health Mission (NHM) which is a flagship scheme under Government of India. Financial support to RNTCP is provided through NHM. The MoHFW follows equity-based approach to allocate funds under RNTCP to various States. The overall allocation is made on the basis of population and burden of disease in the states.

As a part of NHM; RNTCP also follows a Bottom Up approach for planning and budgeting. The process begins at the districts level, which prepares the "District Health Action Plan(DHAP)" based on inputs from all stakeholders in the districts. The RNTCP district PIP at district level will be formed by District TB Centre (DTC). These Districts Health Action Plans are then aggregated to form an "Integrated District Health Action Plan (IDHAP)" which is further sent to the State Level. The DHAPs of all districts are compiled and aggregated at the state level for framing the "State Program Implementation Plan (SPIP). All SPIPs are reviewed and compiled to estimate the next year's fund requirements for programme implementation activities under NHM/RNTCP. Under RNTCP State TB Cell is having a mandate to prepare a plan of action. The PIP should indicate the physical targets and budgetary estimates in accordance with the approved pattern of assistance under the NHM. These should cover all aspects of the programme activities for the period from April to March each year, and are sent by each State/ UT to the Ministry of Health & Family Welfare, GoI for approval well before the start of the year. The State TB Cell is expected to submit its PIP through State NHM to MoHFW, GoI. It is important that the action plan is realistic, practically implementable and correlates the physical outputs with the cost estimates.

The State PIP is approved by the Union Secretary of Health & Family Welfare as Chairman of the EPC, based on appraisal by the National Programme Coordination Committee (NPCC), which is chaired by the Mission Director and includes representatives of the state, Technical and Programme divisions of the MoHFW, National Technical Assistance agencies providing support to the respective states, other departments of the MoHFW and other Ministries as appropriate

Process of PIP



The salient features of RNTCP PIP process are following

1. The PIP under RNTCP is part of National Health Mission PIP under the Disease control program Flexi-pool.
2. The PIP process for the FY will be initiated by mail sent by National Health Mission , MoHFW, GoI
3. The unit for district PIP under RNTCP will be District TB Centre (DTC). The PIP of DTC should include activities and budgetary requirements of DTC, TB Units, Laboratories, DRTB centre, Partnerships (NGO, PP, Corporate sector etc.), Medical colleges.
4. The district PIP of RNTCP needs to be submitted at two place a) State TB cell and b) Districts Health Society/ DPMU. The RNTCP districts PIP must be included in District Health Action Plan (DHAP) of NHM.
5. The State PIP must include PIP of all districts and activities and budgetary requirements of all state level RNTCP institutions.
6. PIP must include the physical targets for state to be achieved in that FY.
7. Any innovation that has been proposed in PIP should come with detailed proposal.
8. PIP must include detailed proposal of the Human resources including the existing HR and new HR required under program.
9. The approved ROP will include central and state share.It includes approved cash as well as commodity component.
10. The state share may change from time to time as per guidelines issued by NHM, MoHFW, GoI
11. From 2016-17, PIP preparation and submission is software based. The process of submission will remain same. The URL of software is http://pip.nhm.gov.in. The user manual can be downloaded from this.

RNTCP TEMPLATES FOR PIP

Program division has detailed PIP template for both state and districts. The PIP templates are available on the programme website (www.tbcindia.gov.in). However states are expected to provide the detailed justification of the each budget lined requested under PIP.

Financial management

Under NHM, annual resource envelope of a State is decided based on its population, health lag and socio economic backwardness. Financing of RNTCP is managed through Central Domestic Support, State Government/UTs Share, Grants from The Global Fund, Credit from The World Bank and direct implementation through technical support from WHO, USAID, UNITAID, CF etc.

The States are required to adhere to NHM Operational Financial Management Guidelines strictly. The Financial Management Guidelines are applicable to all RNTCP entities (States, Districts, etc.) irrespective of the source of funds.

Key accounting policies and disclosures

a) Basis of Accounting – Cash Basis, to facilitate claim filing on paid expenditure basis.
b) Period of Accounting – On Financial year basis of GOI - i.e. 1st April to 31st March.
c) Method of Accounting: On double entry book keeping principles

Accounting Centers under RNTCP

The accounting centers are the offices where the basic accounting in respect of expenditure is carried out. These centers are responsible for maintaining the books of accounts, opening and operating bank accounts etc. The accounting centers for the project shall be Central TB Division (CTD), The State TB Cell (STC) and District TB Centres (DTC).

State Training cum Demonstration Centre (STDC), National Task Force (NTF), Zonal Task Force (ZTF), State Task Force (STF), TB Units (TUs), DMC, DR TB Centers etc. are not accounting centers

Responsibility of Controlling Officer in respect of Budget allocation is to ensure that
a) Expenditure does not exceed the budget allocation.
b) Expenditure is incurred for the purpose for which funds have been provided.
c) Expenditure is incurred in public interest.
d) Adequate control mechanism is functioning in department for prevention, detection of errors and irregularities, and
e) Mechanism or checks contemplated at (d) above are effectively applied.

GIA release

Amount of GIA release by Center to States/UTs depends on following:
a) Approved Annual Action Plan and Budget;
b) Unspent balance available with the States/UTs;
c) Projected requirement;
d) Release of state share of preceding year; and
e) Pace of utilization of funds released earlier.

The Government of India (GoI) will release funds to the State Treasury on the basis of plan of action/ budget of the SHS and DHS. From the State Treasury, the funds are released to SHS. Based on the submission of SOEs (DHS and SHS), Utilization Certificates, audit reports by the SHS(RNTCP sub committee) and state share, funds are released in two to three installments by the GoI.

Payment Procedure

a) All payments exceeding Rs. 2500/- shall be made by way of a cheque/demand draft/bank transfer only.
b) Cheque books and counterfoils shall be kept under custody of the STO/DTO.
c) All personal claims including TA should be submitted by the concerned individual within one month of completion of activity.
d) All bills/claims which are duly complete in all respects shall be cleared within 15 days from the date these are received at the DTCS/STCS.
e) Compensation package for the contractual staff will be decided by the respective State based on State specific situation, job contents, job responsibilities, compensation of similar positions in other programme under NHM. These compensation packages will be proposed by the respective State in the State PIP and got finalized through PIP appraisal mechanism in consultation with NRHM, Ministry of Health & Family Welfare.
f) The States are authorized for appropriation of expenditure in the subheads within overall ceding of budget approved. The DHS can appropriate the expenditure up to 15 % in the subhead at their own, however, re-appropriation beyond 15% shall be done with the approval of SHS.
g) To ensure that tax is deducted at source, wherever applicable, before making the payment.

No works shall be commenced or liability incurred until: -
a) administrative approval has been obtained;
b) sanction to incur expenditure has been obtained;
c) detailed design has been sanctioned;
d) estimates containing the detailed specifications and quantities of various items have been prepared and sanctioned;
e) funds are available;
f) tenders invited and processed;
g) a Work Order issued.

Books of Accounts

The following Books of Accounts are to be maintained at State/District level:

a) Cash Book: For recording transactions relating to the receipt and payment of cash and or from the banks as per specimen at Annexure VII of the Financial Management Guidelines (page 132)
b) General Ledger (Account head wise summary of the transactions): as per specimen in Annexure X of the Financial Management Guidelines (page 134)
c) Journal: for recording transactions/adjustment entries which do not involve the movement of funds, as per specimen at Annexure XI of the Financial Management Guidelines (page 134)
d) Format/Register for Bank Reconciliation: as per Annexure XVI of the Financial Management Guidelines (page 137)
e) Petty Cash Book : for record of receipt and payment from petty cash withdrawn from bank for meeting out the day to day and small expenses of the society, as per Annexure VIII of the Financial Management Guidelines (page 133)
f) Stock Registers: for consumable, printed material and for grant of drugs (Commodity grant)
g) Fixed Assets Register: as per format given at XV of Financial Management Guidelines (page 136)
h) Advances Register: as per format given at XII of Financial Management Guidelines (page 134)
i) Expenditure Control Register: containing approved Budget Estimates as per the Annual Plan and expenditure incurred under each head of account.
j) Record of Audit and Register of Settlement of Audit Objects,
k) Record of Utilization Certificates received from NGOs (pertaining to the Grant-in-aid given to any NGOs by the District or State Society

Financial Statements

Following financial statements are required to be submitted:

A. Statement of Expenditure on Quarterly basis,
B. Audited Statement of Accounts comprising:
    - I. Audited Receipt & Payment Account ,
    - II. Audited Income & Expenditure Account
    - III. Audited Balance Sheet.
    - IV. Audited Utilization Certificate
    - V. Audited Bank Reconciliation Statement
    - VI. Accounting Policy (as per the Financial Management Manual)
    - VII. Schedule of fixed assets
    - VIII. Schedule of outstanding advances recoverable/adjustable
    - IX. Schedule of Sundry debtors/creditors (if applicable)
    - X. Auditor's Report in the prescribed format
    - XI. Management Letter from the Auditors consisting of :-
        a. Comments/observations on accounting records/ systems/ controls.
        b. Deficiencies and areas of weakness in the system with recommendations for their improvement.
        c. Report on the degree of compliance with the financial/internal control procedures.
        d. Report on degree of compliance and deviation from the laid down procurement policies/procedures.
        e. Report on matters that have come to notice during audit which have a significant impact on the implementation of the project and also on any other matter which the auditor considers pertinent.
        f. Report on compliance with statutory requirements such as deduction of tax at source on contractual payments including remuneration paid to the contractual staff.

The Financial reporting requirements under RNTCP at various levels with time lines are placed at Annexure 19. The States are required to enter the transactions in Public Financial Management System (PFMS) and generate all reports from PFMS. The NHM in consultation with AG is likely to roll out all the modules of PFMS with effect from 1st April 2016.

Shortcomings/flaws noticed in general in the Utilization Certificate (UCs) which needs to be looked into by STOs/DTOs:

a) UC not furnished in the prescribed format as per the Guidelines
b) Bank interest, misc. receipts etc. not included in the receipt side of the UC.
c) No correlation between the expenditure indicated in Income & Expenditure Account plus increase or decrease in assets during the year and utilization indicated in UC.
d) Amount of sanction issued/released by Centre / State at the end of financial year but received in succeeding financial year not indicated in that year's UC
e) Sanction Nos. and dates through which the grant-in-aid is/was received during the year are not indicated in the UC.
f) UC not signed by the authorized signatories.

Shortcomings/flaws noticed in general in the Audited Statement of Accounts which needs to be looked into by STOs / DTOs:

a) Accounting method of "Accrual Basis" being adopted by many of the STCs/DTCs instead of the "Cash Basis" method laid down in the FM Guidelines.
b) Depreciation being charged on fixed assets by many Societies in spite of clear guidelines not to charge.
c) Auditors' Report in the prescribed format not attached to the AR.
d) Assets are being charged off by some Societies while being capitalized by others.
e) Reconciliation of expenditure figures as reported in the SOEs not done with the final A/R figures and reported to CTD.
f) One or more Part(s) of the Annual Statement of Accounts (Receipt & Payment A/c or Income & Expenditure A/c. or Balance Sheet) not included in the Audit Report.
g) Utilization Certificate not furnished along with the Audit Report.
h) Management letter from the Auditors on the internal control weakness and areas for improvement of the Societies not obtained from the Auditors and attached to the AR.
i) Wherever Management letters are attached, the replies/explanation/action taken on the points raised by the audit report not attached, duly vetted by the Auditors.
j) Financial Management Check-list in the prescribed format filled in and certified by the Auditors not attached to the Audit Report.
k) Monthly reconciliation of Bank Account not done.
l) Fixed Assets Register not maintained properly and physical verification done periodically.
m) Reasons for large cash balance at year end not explained.
n) The Note disclosing the basis of preparation of Financial Reports and significant accounting policies related to material items not added to the Audit Report.
o) Funds disbursed to DTCs shown as expenditure instead of showing separately as disbursements in the AR of STC
p) Funds spent by STC on behalf of DTCs not separately and distinctly shown in the Payment side of the R&P A/c. of STC.
q) Funds disbursed to DTCs shown on the payment side of Consolidated R&P A/c, whereas the same is not to be reflected in Consolidated R&P A/c.
r) Similarly funds received by DTCs shown wrongly on the receipt side of CR&P A/c.
s) Consolidated Schedule of Fixed Assets covering all DTCs and STC not attached to the Consolidated A/R.
t) Auditors' Report in the prescribed format not attached to the AR
u) The Note disclosing the basis of preparation of Financial Reports and significant accounting policies related to material items not added to the Audit Report.

The STOs/DTOs in the capacity of DDOs to conduct following essential checks:-

a) All monetary transactions should be entered in the cash book in the prescribed form as soon as they occur duly attested.
b) The cash book should be closed regularly and checked. At the end of each month the cash balance verified physically.
c) In respect of Government moneys paid into the bank, the relevant entry in the cash book should not be attested unless the bank's receipt on the challans is verified.
d) No money should be disbursed unless a legal aquittance from the person(s) entitled to receive the amount drawn on a bill is obtained.
e) An account of undisbursed Pay & Allowances should be kept in a register and the amounts remaining undisbursed for 3 months should be refunded.
f) For all moneys received, receipts in the prescribed form should be issued and it should be ensured that such receipts have duly been entered in the cash book.
g) All moneys received in cash or by cheques/Demand Drafts should be promptly paid into the bank or sent to the PAO, as the case may be.

h) Except where otherwise specifically provided, any loss or shortage of public money, stamps, stores or other properties caused by defalcation or otherwise should be immediately reported to the next higher authority as well as to the concerned Audit Officer.
i) No expenditure should be incurred without the sanction of the competent authority.
j) All charges actually incurred must be drawn and paid at once and under no circumstances be allowed to stand over to be paid from the next years' grant.
k) No money should be drawn in anticipation of demand or to prevent lapse of budget grant.
l) Expenditure relating to two or more major heads should not be included in one bill and full account classification must be recorded on each bill.
m) Expenditure control register should be maintained to exercise an effective check over expenditure against the budget allotment.
n) T.A. claim not preferred within one year from the date on which it became due should be dealt with in accordance with the provisions of SR 194-A and the GoI Orders thereunder.
o) DDOs should pay by bank transfer/cheques only such claims (e.g. pay and allowances, office contingencies etc.) as they have been authorized to entertain.
p) The bills should be subjected to the prescribed checks enumerated in CGA (R&P) Rules/CAM before they are passed for payment.
q) All cheques should be drawn on forms in cheque books supplied by the Bank, and the instructions contained in the Central Government Account (Receipts & Payments) Rules.

Advocacy Communication and Social Mobilization

Advocacy, Communication and Social Mobilization (ACSM) are three distinct concepts that are most effective when used together. ACSM is an important component of the TB control strategy and is necessary to ensure long-term and sustained impact.

To achieve universal access to TB care, it is critical to design and implement issue-based, region and audience specific ACSM initiatives. These will in turn create demand for RNTCP services facilitating early diagnosis and treatment as well as treatment completion. Engagement and forging partnerships with multiple stakeholders including healthcare providers, corporates, NGOs, CBOs, other vibrant community groups, local self-governments etc. will result in improved provision of care for TB patients. Major components of the ACSM strategy are:

1. Advocacy for administrative and political commitment will keep TB control high on the health and development agenda. Policy advocacy informs politicians and administrators about how an issue affects the country, outlining actions to improve laws and policies. Programme advocacy targets opinion leaders at the community level on the need for local action. Media advocacy validates the relevance of the subject and will help keep TB high on political, administrative and the public agenda.

2. Communication aims to favourably change knowledge, attitudes and practices among various groups of people. Audience segmentation and targeted behaviour change interventions will be the key to success.

3. Social mobilization brings together community members and other stakeholders to strengthen community participation. Empowering community structures helps facilitates referrals, strengthens patient support, promotes treatment completion and reduces stigma. Increasingly, the term '**community engagement**' is being preferred over social mobilisation.

ACSM initiatives help -

- Increase demand for early diagnosis and treatment
- Improve referral for case detection and community support for case holding
- Combat stigma and discrimination, and empower people affected by TB
- Increase capacity of health providers and front line workers to deliver ACSM messages
- Mobilize political and administrative commitment, and enhanced resources for TB
- Increase ownership by the community
- Increase capacity for prioritizing TB in health planning at the grass root level of Panchayati Raj

ACSM Advisory Committee: To benefit from external expertise and to streamline the process in all aspects of ACSM activities for RNTCP, the programme has established a system of drawing support and guidance from experts from the centersof the excellence in the field of health communication, communication research, mass media, academia, capacity building, monitoring and supervision, field personnel and civil societies for infusion of new ideas. National ACSM Advisory Committee has been constituted at Central TB Division to support RNTCPs ACSM programme for providing technical support in implementation of ACSM activities.

Similarly, a State ACSM Quality Support Group (SAQSG) is formed at the State level with a Goal to ensure quality support to the entire ACSM effort as an ongoing mechanism for continued quality assurance for TB Control program.

Peer Level Support Group is to be formed for DTOs to seek clarifications with a comfort level and higher participation. Members of SAQSG should include DTOs, IECOs, CFs, Consultants and Partners. There should be 5-7Quality Coach (QC) per state.One QC to be designated as State Coordinator SAQSG. Each DTO will be attached to one QC. DTOs can be given a choice to opt for one of the QCs. However, no QC should have more than 8-10 districts. QCs will help their selected DTOs in improving quality of ACSM plans and activities in their area. Support is given by giving advice and suggestions, sharing good work and best practices from other districts/states, suggesting exposure for CFs (inter district or interstate) for actual field activity that ensures faster learning, sharing communication materials – specially the local performing arts communication.

Coordinator SAQSG to inform all DTOs/STO of specific best practices, success stories, special events and activities by the 5th of the next month. Coordinator SAQSG will also share this information with all neighboring states' Coordinators so that some innovative work gets used by others. Through STO this information will be shared with CTD on a monthly basis (by 7th of the next month).

ACSM Planning

- Under RNTCP, planning is decentralised to States and Districts for greater efficacy and ensuring that need-based initiatives are undertaken. Given India's vast geography, population size and socio-cultural milieu, it is critical to design and implement issue-based and audience specific interventions / activities. A language and a medium that works in one district may not be the best suited for another. Similarly, pamphlets, posters or wall painting may be read by a literate audience, but for others audio-visual media may work better. Each medium has its advantage and disadvantages and these may be selected based on the target group the initiative is being planned for. No single media reaches all and a combination of media will ensure wider outreach.
- The DTO with support from the District PPM Coordinator in consultation with all relevant cadres at the district level is responsible for the planning, development and implementation of the Annual ACSM Action Plan based on the needs and priorities of the district. The STO with support from State IEC/ACSM officer develops the State Annual Action Plan (SAAP).
- District teams must brainstorm and analyse district specific data from quarterly reports to identify issues and list priorities for a particular planning period.
- RNTCP seeks to generate awareness through a mass media campaign based on audience segmentation and an appropriate media mix to tackle a host of issues related to case detection, demand generation for TB services, treatment adherence as well as address concerns related to Drug Resistance, TB notification, private sector involvement, ban on commercial use of serological diagnostic tests, TB co-infections etc., as well as developing appropriate job aids to enable field staff in delivering their responsibilities more effectively. RNTCP surveillance data collated through Epicentre and Nikshayis used to guide the media planning exercise.

- **Resource mobilisation:** To supplement ACSM resources explore partnership options with NGOs, Community based organisations, Corporates available in the region etc. Integration with NHM, the General Health System, Government institutions, programmes etc. must be explored.

Strategic Approach

The most crucial aspect of planning would be to define the objective. ACSM strategies should be formulated to achieve these objectives.The communication plan should be based on the identified target groups.

Implementation of annual action plan

1. Annual action plan should have a calendar of activities - who will do what and when
2. Split activities – quarter/ month/ weekly
3. Assign work to staff
4. Utilize existing or develop new communication material as per need
5. Implement activities
6. Provide supervision and support to staff for implementation
7. Document / Report writing
8. Quarterly reporting of activities

Communication Materials

- Given the socio-cultural diversity of India, it is important to communicate to people in a language that they understand well. Hence, materials can be developed locally in appropriate regional languages and cultural context.
- Communication materials developed at the National-level have been shared with all States. State ACSM/IEC Officers can be contacted to facilitate access to existing communication materials.

Target Audience	Objective	Methodology	Tools/Materials
Advocacy			
Policymakers Administrators and program managers Elected representatives Media professionals Other influencers in society	Seek support in terms of supportive policies, greater resources	Meetings, discussions, sensitization workshops	Relevant fact sheet & data; background reading material; case studies; printed documents or PPTs with necessary information
Communication			
Public at large Cured patients Healthcare providers	Create awareness for improved case detection (this is just one communication objectives, these can vary based on target audience and what is expected from the interaction with them)	Mass media & Mid-media channels; Inter-personal Communication and face to face interactions	TV, Radio and Print advertisements; Posters, leaflets, booklets, pamphlets; wall writings & hoardings; Folk performances, street plays etc.; Flip charts and other Audio & Visual aids
SocialMobilization / Community Engagement			
Community Vulnerable populations such as slum dwellers, prisoners, mine workers etc. Youth	Awareness and motivate them to support specific action	Group meetings with more specific targeted information and interaction to address participants' concerns	Audio-visual aids, posters, banners, charts etc.

Guidelines to conduct Community meeting, patient provider meeting, school health activities, sensitization of PRI/AHSA and Outdoor publicity (including World TB Day observation) are placed at annexure 20. For detailed guidelines and further clarification may refer to Operational Handbook on ACSM available at www.tbcindia.gov.in

Partnerships

Synergistic efforts of all stakeholders involved in TB control in India are the key towards realising the goal of "Universal access to TB care and treatment for all". Revised National TB Control Programme is working towards this goal with the basic philosophy that government is not the sole provider of services for TB and optimum efforts should be made to utilise the resources in the private sector. In this context an enabling environment should be created through regular interaction with partners involved in TB control and promoting innovative TB control initiatives at district, state and national level.

Definition

Partnership means an arrangement between any two or more entities; most often, government owned entity on one side and a private sector entity on the other, for the provision of public assets and/or public services, through investments being made and/or management being undertaken by the private sector entity, for a specified period of time.

Such arrangements may have options of receiving performance linked incentives that conform (or are benchmarked) to specified and pre-determined performance standards, measurable by the public entity or its representative.

This concept of partnership is much broader as compared to previous approaches of Public Private Mix (PPM) under RNTCP which entailed strategies that link all entities within the private and public sectors (including health providers in other governmental ministries) to the national TB programme for DOTS expansion'.
Involvement of all health care providers is necessary to achieve Universal access to TB care.

Health care providers in India

Ministry of Health	Other Ministries	Non-Government
Directorate of Health (RNTCP, Primary health care) Directorate of Medical Education (Medical Colleges)	Railways Employees State Insurance (ESI) Mining Coal Steel Ports Prisons Armed Forces	NGO Private hospitals Corporate industries Private practitioners Traditional practitioners (AYUSH)

There are large number of health facilities run by public sector other than Ministry of Health & Family Welfare under different ministries of centre / state governments as mentioned above. There are corporate sector companies in the public sector like Coal India, SAIL etc. which run their own set ups. Usually these facilities cater to a "captive population" who receive subsidized or free services from said facilities. Additionally ministries like defence, railways, home ministry etc. have their own medical services set up and they have been involved at various levels under the RNTCP. The program had already involved ESI, NTPC, Railways, CGHS, Coal, Prisons, Armed Forces, Mines and Port. Further there are also health services offered by ITBP, BSF, CRPF, Assam Rifles, CISF and Ministry of Home, apart from some local initiatives to involve these institutions.

There is integration of service delivery and reporting at the TU and district level with most of the partners delivering health care through their own set up.

RNTCP has formed the National Technical Working Group on Public Private Mix to provide a forum for dialogue, to ensure sustained attention on the issue, and guide innovation and learning. The group provides guidance on technical aspects such as the inclusion of all internationally accepted regimens, guidance on the scope and geographic distribution of initial projects, and policy requirements for improved PPM.Institutional mechanisms to support the States for effective contract management, hiring interface agencies to manage activities of engaging private sector and other partnership-strengthening functions need to be developed.

RNTCP has proactively sought the involvement of NGOs in TB control activities.Using the experiences gained from collaborations with NGOs and the private sector, the Central TB Division has brought out the National Guideline for Partnership 2014 for engagement with all stakeholders. However, RNTCP does not restrict to these guidelines alone and rather promote innovation for reaching the goal of universal access to TB care. One example is flexibility as mentioned below.

Flexibility in budget for Partnership

Under this approach the states have been provided greater flexibility whereby they can utilize 30% of their PPM budget for piloting new projects and innovations as per requirements of the state. The states have been given the flexibility for utilization of 10% of their PPM projects for capacity building and promotion of NGO-PP activities.

Process of Partnership

Before going into detail of each partnership option we need to understand the processes involved in partnership formation which is crucial for the work of PPM Coordinators and Program Managers at district and state level. The processes involved in partnership are:

- The PPP strategy is for reaching the unreached and also to reach patients even if they are accessing private / other sector as **RNTCP in this case would act as an enabler and not provider of services**
- Undertake assessment of gaps in health service delivery in RNTCP in different districts of your state. Identify the geographical and functional gaps. The identified gaps would form the basis for formation of partnership and this information may be displayed on your state website and office of STOs/DTOs.
- NGOs and other partners must be involved for supplementing capacities in some key areas where the formal health delivery system is unable to provide optimal services
- NGOs and other partners would be encouraged to work in unserved and underserved areas which would be areas in hilly, tribal, desert regions or peri-urban areas and slums. The State and the District Health Societies would have the flexibility to categorize unserved and underserved areas for focused attention
- Private sector health care services are more concentrated in urban and peri-urban areas and National Sample Surveys has consistently shown that vast majority of not only rich, but also poor population do seek care from private sector. Attempts should be made to develop partnerships with private sector, so that the goal of universal access can be achieved.
- The process of renewal of MOU would be on the basis of performance as per the review and quarterly reports submitted
- The updated list of approvals and collaborations must be maintained at the district and state level for all partnership options. The updated list has to be updated in Nikshay. The presence of these healthcare setups in the States/ districts needs to be prioritised and effective communication channels and reporting mechanisms set up at the district and State levels.

Partnership Options

The National Guideline for Partnership was developed in 2014 on how different stakeholders can supplement the efforts of the government for TB control in India. The National Guideline for partnership consists of four thematic areas:

1. Advocacy Communication and Social Mobilisation (ACSM)
2. Diagnosis and treatment
3. TB & Co-morbidities
4. Programme Management

Engagement of Professional Associations

Professional associations have a key role to play in TB control activities In India and any their engagement and active involvement is important for stewardship in private sector engagement. Organisations like IMA, Indian Academy of Paediatrics (IAP), Indian Nursing Association, Indian association of medical microbiologists, Indian Public Health Association etc. are key resources for dissemination of knowledge on diagnosis and treatment guidelines in RNTCP and Standards for TB Care in India.

Pharmacist / Chemists involvement:

RNTCP has signed MOU with Indian Pharmaceutical Association (IPA), All India Organisation of Chemists & Druggists (AIOCD), Pharmacy Council of India (PCI) and SEARPharm Forum representing World Health Organization (WHO) – International Pharmaceutical Federation (FIP) Forum of National Associations in South East Asia for engaging pharmacists in RNTCP for TB Care & Control in India. Pharmacists should be involved for early identification and referral of presumptive TB cases for diagnosis, treatment supporter for TB patients, increasing community awareness about TB and MDR-TB, patient education and counselling, promoting rational use of Anti-TB drugs and contributing to preventing the emergence of drug resistance

Laboratory involvement:

To reach all TB patients in India need to include dominant private sector and private laboratory is not an exception. Laboratories are engaged through partnership options under National guidelines of partnerships. Additionally, to facilitate use and access to affordable and accurate tests endorsed by the World Health Organization (WHO) and the Revised National TB Control Programme (RNTCP). One of such mechanism is Initiative for Promoting Affordable, Quality TB Test (IPAQT). Under this initiative, several private laboratories in India have agreed for not exceeding negotiated, ceiling prices to patients, notifying the government of the cases diagnosed, promoting the use of these tests and participating in external quality assurance (EQA) and in exchange, they would get reagents at significantly reduced prices. In exchange for offering lower prices, the manufacturers and distributors would receive greater and more predictable volumes from the previously untapped private market.

Involvement of Medical colleges in RNTCP

To widen access and improving the quality of TB services, involvement of medical colleges and their hospitals is of paramount importance.

The medical colleges in India have been involved under RNTCP in a structured task force mechanism of National, Zonal and State level task forces in addition to the medical college core committee. The main role of the NTF is to guide, provide leadership and advocacy for the RNTCP, recommend policy suggestion regarding medical colleges' involvement in the RNTCP, coordinate with the Central TB Division, and monitor the activities of the ZTF. ZTF facilitates the establishment & functioning of State Task Forces (STF), coordinates between the national and STF, as well as between medical colleges and the State/District TB Centres, and monitors the activities of STF.

STF facilitates establishment of Designated Microscopy Centres (DMCs) & Treatment Support Centre, as well as other activities, in all the medical colleges in the respective States. Core Committees, at the level of medical colleges facilitate inter-departmental coordination for programme implementation. Core committee meet every month. DMC and Treatment Support Centre are established in all government and private medical colleges and these are equipped with suitably trained additional manpower in the form of Medical Officer (MO), laboratory technician (LT) and TB health visitor (TBHV).

STF Workshops are held once a quarter in each State to review the activities of the previous quarter and dissemination of the updates under RNTCP to all medical colleges. Annual ZTF CMEs cum Workshops are held every year. This is an opportunity for reviewing the performance of STF & medical colleges and advocating the guidelines of RNTCP. Operational research is one of the important activities of Medical Colleges. To encourage young physicians RNTCP support postgraduate thesis on tuberculosis

Research

The National TB Control Programme is based on global scientific and operational guidelines and evidence. As new evidence became available, RNTCP has made necessary changes in its policies and programme management practices. In addition, with the changing global scenario, RNTCP is incorporating newer and more comprehensive approaches to TB control. To generate the evidence needed to guide policy makers and programme managers, the programme implemented measures to encourage operational research (OR).

The program requires more knowledge and evidence of the effectiveness of interventions to optimize policies improve service quality and increase operational efficiency. This has led to the realization of the need for a more proactive approach to promoting OR for the benefit of the TB control efforts. Furthermore, the program seeks to better leverage the enormous technical expertise and resources existing within India both within the Program, and across the many medical colleges, institutions and agencies.

Operational research aims to improve the quality, effectiveness, efficiency and accessibility (coverage) of the control efforts.

To promote and support OR, a Research Cell has been constituted at CTD to Coordinate the National Standing Committee on Operational Research comprising of 14 individual and institutional members. This Committee mainly provides technical guidance to CTD on OR and expertise to identify OR priority areas for commissioned research. Apart from it there are Zonal and State Operational Research Committees which identify priority areas for research as relevant to their Zone/State, based on the national research agenda.

The scientific agenda, developed by the Central TB Division and partners, articulates opportunities to understand RNTCP weaknesses, develop solutions, and refine policies to better achieve the programme objectives. The RNTCP promotes and supports research on issues which are of key relevance to guide interventions and to monitor and evaluate the impact of the programme through collaboration with specialized institutions.

Studies on the RNTCP Operational Research agenda is prioritized for funding by the RNTCP. Proposals are to be submitted in the prescribed RNTCP OR proposal format as per prescribed mechanisms to the state and zonal OR committees. Proposals with a budget of Rs. 5 lakhs or less will be reviewed and forwarded by the State OR Committee to the respective zonal OR committee for approval or rejection and it will not require approval by CTD. Proposals of more than Rs. 5 lakhs will be reviewed and sent to CTD for consideration. PG students undertaking research on a topic listed on the RNTCP Operational Research agenda are eligible for a grant of Rs 30,000. Approved proposals would be funded by the respective state from the account head on “Medical College” if the proposal is from a Medical College and from the “research and studies” head if the proposal is from another type of institution or agency. Funds for OR proposals will be released in three instalments – 50 % at the beginning of the study, 30% at mid-point of the study when a particular milestone has been achieved and remaining 20% after the final report is made available. Thesis grants will be released at 80% in the beginning and remaining 20% after the final report is made available.

Projects that involve human subjects require documentation of ethical approval from an institutional ethical committee. Before submission, all studies should have agreement from the host (public or private) institution where they will take place, and the endorsement should accompany the proposal.

For detailed information on the research priority areas, processes for submission of the research proposals, funding mechanisms, levels of approval & details of researches done over a period of time under the programme, the information is available on the official web site of National TB Control programme tbcindia@gov.in

Disaster Management and TB

On many occasions, when a disaster strikes a primary health care service, it loses control over tuberculosis and the cases can migrate. Under those circumstances, the most important thing is to continue the treatment of those in temporary shelters and establish a monitoring system over those that have shown respiratory problems of the disease for over two weeks. Those who persist with respiratory symptoms should have a diagnostic evaluation done and the treatment should immediately started for diagnosed cases.

Keeping a stock of first line medicines is necessary. A nurse, nurse auxiliary or other health professional should manage this stock in the shelter.

In temporary shelters or camps which remain for a long periods following the emergency, it is necessary to take into account the following risk factors:

- Population displacements are common in disaster situations, and this can create problems in treating and monitoring patients with TB.
- Population migration in the aftermath of disasters makes it common for persons from areas where the prevalence of TB differs, to come into contact with each other.
- Overcrowding is common in shelters and temporary settlements. A patient that is sputum smear positive and that is not managed, becomes source of transmission.

Do's and Don'ts:

1. Avoid close contact with people who are having respiratory illness.
2. The sick person should stay at home, and avoid going into the community, school/office, public places for at least 24 hours after symptoms have resolved.
3. Sick persons at home should keep distance from others.
4. Respiratory Hygiene/Cough Etiquette:-
   a) Cover the nose/mouth with a handkerchief/ tissue paper when coughing or sneezing which should be disposed off in dustbins;
   b) Perform hand hygiene (e.g., frequent hand washing with soap and water, alcohol-based hand rub, or antiseptic hand wash) and thoroughly dried preferably using disposable tissue/ paper/ towel after contact after having contact with respiratory secretions and contaminated objects/materials.
      a. Triple layer surgical Mask of standard and certified make should be worn by Suspected/ probable/confirmed cases of TB or by the care provider in home care settings and close family contacts of such cases undergoing home care.
      b. Get plenty of sleep, be physically active, manage your stress, drink plenty of fluids, and eat nutritious food.
      c. Avoid smoking.
      d. Persons who have difficulty breathing or shortness of breath should seek immediate medical attention and report to the nearby hospital.
      e. If sick persons must go into the community (e.g., to seek medical care), then they should wear a face mask or use a handkerchief or tissues to cover any coughing and sneezing so as to reduce the risk of spreading the infection in the community.

Post disaster rapid assessment of TB programme:

Rapid assessment and response in disaster situation for TB should be integral part of rapid response team.

Infection Control measures

Airborne Infection Control

Acute respiratory infections (ARIs) are the leading cause of morbidity and mortality from infectious disease worldwide, particularly affecting the youngest and oldest people in low and middle-income nations. These infections, typically caused by viruses or mixed viral– bacterial infections, can be contagious and spread rapidly. Although knowledge of transmission modes is ever-evolving, current evidence indicates that the primary mode of transmission of most acute respiratory diseases is through droplets, but transmission through contact (including hand contamination followed by self-inoculation) or infectious respiratory aerosols at short range can also happen for some pathogens in particular circumstances.

In modern medicine, infection prevention and control (IPC) measures in health-care settings are of central importance to the safety of patients, health-care workers and the environment, and to the management of communicable disease threats to the global and local community. Application of basic IPC precautions, such as Standard Precautions, is a cornerstone for providing safe health care. In an era of emerging and re-emerging infectious diseases, IPC in health care is as important now as ever.

TB infection control is a combination of measures aimed at minimizing the risk of TB transmission within populations. The foundation of such infection control is early and rapid diagnosis, and proper management of TB patients. National guidelines on airborne infection control in all health settings including HIV care settings were developed that included a combination of simple managerial, administrative, environmental and personal protection measures. Operational feasibility and effectiveness of the guidelines have been conducted in the states of West Bengal, Gujarat and Andhra Pradesh.

The programme envisages integrating the airborne infection control guidelines of the programme with the general health system guidelines. Activities such as advocacy, guideline awareness and capacity building would be initiated at the state level and subsequently overseen by the general health system. NAIC guideline will be implemented at high risk centers at DR-TB Centers, ART Centers, C& DST Laboratory. The Implementation of National Airborne Infection Control policy includes following:

- Airborne infection control committee and plan
- Baseline assessment
- Resource planning and budgetary provisions
- Training of health care workers
- Implementation of administrative, environmental and personal protection measures.
- Prospective establishment health care centres should be in accordance with NAIC policy.

For detailed information on airborne infection control measures in health care settings, refer to Guidelines on Airborne infection control, 2010 at TBC India official web site tbcindia.gov.in

Healthcare worker surveillance

Successful AIC implementation is also important in preventing HCWs from becoming infected with drug-susceptible and drug-resistant TB, and thus preventing occupationally acquired TB disease. Screening HCWs at high risk of TB is likely to reduce transmission and with earlier diagnosis and treatment, prevent serious illness and disability. In an era of inadequate human resources for health, introducing the screening of HCWs for TB is crucial.

All HCW should be classified as Key populations due to their higher risk of acquiring TB and those who are symptomatic or/and with any signs of TB or Chest XRay abnormality will be offered a upfront CBNAAT testing upfront to rule in or rule out TB at the first instance and during periodic screening also.

For details, refer to Healthcare Worker (HCW) surveillance for tuberculosis (TB) in India- A handbook for health facilities.

Bio-Medical Waste Management

The Bio-medical waste generated from various sources has become a problem and much attention is being given worldwide to find out solution of this problem. The main concern lies with the hospital waste generated from large hospitals/nursing homes as it may pose deleterious effects due to its hazardous nature. Bio-medical wastes, if not handled in a proper way, is a potent source of infections, like HIV, Tuberculosis, Hepatitis, MRSA and other bacterial infections causing serious threats to human health. Owing to the discussed potential threats this waste needs prime attention for its safe and proper disposal.

The Government of India (GoI) 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.

According to these rules, Bio-medical wastes have been categorized under 10 categories and are required to be managed and handled as per prescribed procedures **(Annexure 21).** Bio-medical waste should not be mixed with other wastes but segregated into containers/bags at the point of generation in accordance with prescribed norms for its storage, transportation, treatment and disposal.

Bio-medical waste"means any waste, which is generated during the diagnosis, treatment or immunisation of human beings or animals or in research activities pertaining thereto or in the production or testing of biologicals, and including categories mentioned in Schedule I;

It is the duty of every hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank etc which generates biomedical waste to take all steps to ensure that such waste is handled without any adverse effect to human health and the environment.

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 cartridges);
- Laboratory and general waste such as liquid waste, broomsticks, and paper waste; and
- Construction waste (waste generated from civil work activities).

Waste Management for RNTCP

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 treatment supporter 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

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 foot operated plastic bucket/bin with 5% phenol or phenolic compound diluted to5%. The cups and lids should be fully immersed in the solution. Keep it overnight/ for about 12 hours.
Step 3: Next day/ at the end of the day, drain off the phenol solution in to the drain.
Step 4: Take out the sputum cup/lid/wooden sticks and put into a reusable metal or autoclave-able plastic container or red bag. The red bag should have abiohazard symbol and adequate strength so that it can withstand the load of waste and be made of non-PVC plastic material.
Step 5: Put this container/bag into the autoclave with other auto clavable BMW and the contents should be autoclaved at 121°C at 15 psi pressure for 15 – 20minutes. 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 7 litre 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.If a common waste treatment facility is not available in the area, the sputum cups/lids/wooden sticks after autoclaving, can be buried in a deep burial pit. LTs and support staff handling biological waste should wear gloves.

Disposal of stained slides

Step 1: The slides should be put into a puncture proof container and 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 2 : Dispose off the autoclaved/ pressure boiled slides into a pit for sharps
Under no circumstances should the slides should be broken.

For detailed information on the Biomedical waste management refer to the documents-

1. Ministry of Environment, forest and climate change – Gazette Notification
2. Revised draft Guidelines for Common Biomedical Waste Management Treatment Facilities, Central Pollution Control Board, Delhi, February, 2014 and as updated by Ministry of Environment Forest and Climate or Central Pollution Control change from time to time.

ANNEXURES
&
APPENDIX

Annexure -1

Ziehl-neelsen staining procedure

1. A new unscratched slide is selected and the slide is labelled 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 theslide 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 completelyabsorbed. Xylene is not to be used for cleaning the slides, as it may give falseresults at repeat examination after storage.
16. All positive and negative slides are stored serially in the same slide-box untilinstructed by the supervisor.
17. All contaminated materials are disinfected as per guidelines before discarding.

Grading of smears

The table below depicts information on grading and the number of fields to be examined in different situations:-

Examination finding	No. of fields examined	Grading	Result
No AFB in 100 oil immersion fields	100	0	Neg
1-9 AFB per 100 oil immersion fields	100	Scanty*	Pos
10-99 AFB per 100 oil immersion fields	100	1+	Pos
1-10 AFB per oil immersion field	50	2+	Pos
More than 10 AFB per oil immersionfield	20	3+	Pos

*Record actual number of bacilli seen in 100 fields – e.g. “Scanty 4”

Annexure -2

Fluorescence staining procedure

Smear Preparation-

- Mark a new, clean, grease free slide with laboratory number
- Pick the purulent portion of the sputum using the crushed end of the broom stick
- Prepare smear in an oval shape in the centre of the slide(3x2cm), for good spreading of sputum firmly press the stick perpendicular to the slide and move in small concentric circles
- Thorough spreading of sputum is very important; it should be neither too thick nor too thin. Prior to staining, hold the smear about 4-5 cm over a piece of printed paper, if letters cannot be read, it is too thick.
- Allow smear to air dry at room temperature
- Heat fix by passing the slide over flame 2-3 times for about 2-3 seconds each time. (Do not heat or keep the slide stationary over the flame or for too long or else it will be scorched)

Staining

Arrange slides in serial order on staining bridge, with smear side up, at a distance of at leastone cm between every slide

1. Flood the slide with filtered 0.1% Auramine solution
2. Do not heat
3. Keep the staining reagent for at least 20 min; make sure that the smear area iscontinuously covered with Auramine by adding more if needed
4. Rinse with water and drain
5. Apply decolourising solution, 0.5% acid alcohol for 3 minutes
6. Gently rinse with water until the macroscopically visible stain has been washed awayand drained
7. Flood smear with 0.5% potassium permanganate solution for 1 minute. Time iscritical because counter staining for longer time may quench the acid fast bacillifluorescence.
8. Gently rinse with water and drain
9. Air dry on a slide rack away from sunlight. If they are not read immediately placethem in slide box.

Reading

- Keep stained smears in the dark (box or folder), and read on the same day of staining as the fluorescence is prone to fading with time.
- To be able to focus with ease, better to read first a positive control smear stained by auramine O
- Use the objective 20x for focusing and read the slide using 40X objective (avoid using oil and immersion 100X objective, inexperienced readers should ask confirmation from a supervisor)
- Scan the stained smear systematically from one side to the other, for one length of the smear
- Acid-fast bacilli appear bright yellow against the dark background material.
- Store the slides in a slide box following the Laboratory Register Number as they will be needed for EQA. Do not write the result on the slide.

Grading of smears

The table below depicts information on grading and the number of fields to be examined in different situations:-

200-250x magnification: 1 length = 30 fields = 300 HPF	**400x magnification: 1 length = 40 fields = 400 HPF**	**Grading**	**Result**
No AFB per 1 length	No AFB per 1 length	0	Neg
1-29 AFB per 1 length	1-19 AFB per 1 length	Scanty*	Pos
30-299 AFB per 1 length	20-199 AFB per 1 length	1+	Pos
10-100 AFB per 1 field on average	5-50 AFB per 1 field on average	2+	Pos
More than 100 AFB per 1 field on average	More than 50 AFB per 1 field on average	3+	Pos

Annexure 3

Specimen collection and Transport of samples to C & DST laboratory (including CBNAAT laboratory)

Specimen Collection

An often-overlooked problem is that of obtaining adequate good quality specimens at theperipheral laboratories. Unless specimens are collected with care and promptly transported tothe laboratory under temperature control, diagnosis may be missed, and the patient couldmiss the chance to be detected and put on the correct treatment. A good sputum specimenmay literally make the difference between life and death, and allow containment of thedisease and prevent spread to others in the family and community.

The Laboratory technician needs to explain the process of collecting “a good quality sputumspecimen” and avoid using vernacular terminologies that convey the meaning as salivainstead of sputum. In addition though the general guideline for collection of sputa is one spotand one morning, this does not preclude from collecting 2 spot specimens that need to becollected with a gap of at least one hour (60 minutes) if the patient is coming from a longdistance or there is a likelihood that the patient may default to give a second specimen.

A good sputum specimen consists of recently discharged material from the bronchial tree,with minimum amounts of oral or nasopharyngeal material. Satisfactory quality implies thepresence of mucoid or mucopurulent material. Ideally, a sputum specimen should have avolume of 3-5ml. The patient must be advised to collect the specimen in a sterile container(falcon tube) after through rinsing of the oral cavity with clean water.

Specimens should be transported to the laboratory as soon as possible after collection. Ifdelay is unavoidable, the specimens should be refrigerated up to 1 week to inhibit the growthof unwanted micro-organisms.

Specimen transportation to culture-DST laboratories

Fresh sputum samples will need to be transported from the DMC to the RNTCP-certified CDSTlaboratory in cold chain within 72 hours. Ideally an agency (courier /

speed post) with apan district presence should be identified for this purpose. Two innovative models forspecimen collection and transport using fresh samples in falcon tubes to be transported incold chain using gel packs and their technical specifications have been developed by Gujarat(from peripheral DMCs) and Andhra Pradesh (from high burden DMCs at TUs/DTCs).

All states and districts should establish sample transport system in cold chain irrespective ofthe time taken for transport considering the hot climatic conditions in most of the statesduring most of the year. An appropriate courier / speed post service with pan district presenceshould be identified and contracted by the DTO of every district for prompt transport of thespecimen cold box on the same day from the DMC linked to the courier / speed post office inthe locality to the assigned RNTCP-certified C-DST laboratory.

The following points are critical for the collection of fresh sputum samples at DMCs:

- The falcon tubes and the 3 layer packing materials like thermocol box, ice gel pack (pre-freezed at -20 degree for 48 hours), request for C-DST forms, polythene bags, tissue paper roll as absorbent, para-film tapes, brown tape for packaging box, permanent marker pen,labels, bio-hazard sticker, scissors, spirit swab etc. should be supplied to the DMCs forcollection of sputum through the DTO.
- The falcon tubes should carry a label indicating the date of collection of the samples andthe patient’s details like name, date of sample collection, name of DMC/DTC, Lab. No:-XYZ, specimen A or B
- The Lab technicians at DMCs should be trained to carefully pack the sputum samples in thecold box to avoid spillage of the samples.
- The LT of DMC issuing the falcon tubes to the patients should also give clear instructionsto the patients on correct technique of collection of the sputum. Also the date of issue of thefalcon tubes to the patient should be recorded.
- The LT of the DMC should ensure that the request for C-DST form is packed in a separateplastic zip pouch and placed in the cold box before sealing the lid of the box. Also, the biohazardsymbol should be pasted on the external side of the cold box along with the labelindicating the postal address of the RNTCP-certified C-DST Lab assigned.

- The LT of the DMC should promptly inform the sample transport agency like a courier /speed post service, speed post or a human carrier to collect and transport the samples

As per the national guidelines for biomedical waste management the containers used fortransporting sputum samples to the RNTCP-certified laboratory should be labelled with a “BIO-HAZARD” sticker.

For every presumptive DR TB referred by the MO-DMC, the date of referral and transport ofsputa samples to the Culture & DST laboratory should be entered in the “Remarks” columnof the respective DMC Lab register and the TB notification register**.** Alternatively the presumptive DR-TB patients referred to nearby DMCselected for sample collection and transport for C-DST may be provided two falcon tubes bythe concerned DMC LT/MO and instructed on collecting two samples (one early morningand one supervised spot). These samples will be taken by the patient / relative to the DMCselected for sample collection for C-DST from where these will be packed in cold boxes andtransported to the RNTCP-certified laboratory for culture and DST. Once the sputum hasbeen transported to the RNTCP-certified laboratory, the p should return tocontinue their RNTCP DOTS treatment.

Standard Operative Procedure for collection, transport and processing and inoculation of Extra-pulmonary specimens

1. *Introduction:*

Mycobacteria may not be suspected as the causative agent of an extra pulmonary disease because the chest X-ray or the tuberculin test is negative or both. However, based on clinical symptoms and because mycobacteria can infect almost any organ in the body, the laboratory should expect to receive a variety of extra pulmonary specimens such as body fluids, surgically excised tissues, aspirates or draining pus and urine.

Extra pulmonary specimens are divided in to two groups based on the site and mode of collection and the extent of contamination.

- Aseptically collected specimens, usually free from other microorganisms (sterile) **–** fluids like spinal, pleural, pericardial, synovial, ascitic, blood, bone marrow, tissues (lymph node, tissue biopsies) and fine needle aspirates (FNAs)
- Specimens contaminated by normal flora or specimens not collected aseptically (not sterile) **–** gastric lavage, bronchial washings, urine , pus and stool (in case of disseminated TB in HIV infected patients and infants)

2. *Collection of extra pulmonary specimens*

Body fluids (spinal, pleural, pericardial, synovial, ascitic, bone-marrow) should be aseptically collected in a sterile container by the physician using aspiration techniques or surgical procedures. Specimens should be transported to the laboratory as quickly as possible.

2.1 Pleural fluid

Considered a suboptimal specimen as tubercle bacilli are mainly in the pleural wall and not within the fluid. The minimum volume for pleural fluid required for processing for culture is 20**–**50ml. The fluid is collected using pleural tap or thoracocentesis.

2.2 Pericardial fluid

Should be collected using ultra sonogram

2.3 Blood

Blood as a specimen for isolating *M. tuberculosis* should be generally discouraged for the low diagnostic yield and high possibility of contamination with respect to the technique required for its culture. However, if there are specific indications when a physician suspects disseminated TB in a HIV infected patient, blood can be collected provided, the culture systems for recovery of

mycobacteria is available in that laboratory (BacTAlert, MB Bact or MycolyticF medium on BACTEC 9050 systems)

2.4 Tissues

The aseptically collected tissues are placed by the physician in sterile containers preferably without fixatives or preservatives. If the specimen is to be shipped, it should be protected from drying by adding sterile saline or ideally in selective Kirchner's liquid medium and maintaining a temperature of 4- 15^{0}C. Specimens should be transported to the laboratory as quickly as possible.

2.5 Swabs

Swabs are always sub optimal specimens and not recommended because of risk of infection for specimen collector. They may be useful in children and patients who cannot produce sputum or may swallow it. A sterile absorbent cotton swab should be used for collection. The best time for the collection is early morning before food and drinks are taken. The swab should be placed in a screw capped container containing normal (0.9%) saline to prevent drying. Swabs except for laryngeal swabs or from discharging sinus should be avoided.

2.6 Urine

Among specimens expected to be contaminated, urine is the most common. To minimize excessive contamination of urine specimens, special instructions for collecting urine with adequate cleansing of external genitalia to prevent contamination by commensals should be given. Early morning sample should be collected in 500 ml screw capped sterile containers. Once received in the laboratory, urine must be immediately processed or centrifuged and the pellet refrigerated for further processing. As excretion of tubercle bacilli in urine is intermittent, three early morning specimens must be collected on different days.

2.7 Bronchial secretions

Other respiratory specimens that can be submitted to the laboratory for mycobacteria culture are bronchial secretions (minimum volume: 2- 5ml) and bronchial alveolar lavage (BAL) (minimum volume of 20 – 50 ml). Trans-bronchial and other biopsies should be collected under sterile conditions and placed in 0.5-1.0 ml of sterile normal (0.9%) saline to prevent drying during transportation to the laboratory.

2.8 Gastric Lavage

In children, who rarely produce sputum, the aspiration of the early morning (gastric content) may be used for TB diagnosis. This is done as an inpatient procedure. This should be transported immediately to the lab and processed (nor more than 4 hours) to prevent the killing action of the acid content in the gastric lavage on the tubercle bacilli. In the event of delay, the sample can be neutralised using 1-2 ml of sterile 10 % sodium bicarbonate solution depending on the volume of gastric aspirate. Trisodium phosphate at a final concentration of

25% can be used but it may affect the viability of tubercle bacilli with prolonged storage.

NOTE:

- Samples for culture should **never be** collected in formalin.
- If histo pathological examination is required, two samples should be collected
- No preservative should be used for any extra-pulmonary specimen for culture. Necessary instructions are to be given to the concerned staff for sending the biopsy specimen in normal saline for culture and NOT IN FORMALIN as it will kill the bacilli.
- Extra pulmonary specimens should never be collected or transported in CPC.

3. TRANSPORTATION OF EXTRA PULMONARY SPECIMENS

As for pulmonary samples, extra pulmonary specimens will need to be transported in cool boxes which maintain temperatures below 20^0C for specimens to be compatible for solid, liquid culture systems as well as molecular methods. Triple packing system should be utilised for transportation. All precautions that are followed for transporting pulmonary samples should be followed. For sending material across international or state boundaries this container may have to be packed in the same way with an additional outer container; in such cases, special administrative arrangements with postal authorities and/or airlines may be necessary.
When sending out specimens or when receiving them, check that:

- Request forms are located separately from the specimen containers
- Containers are labelled not on the cap but on the wall of the container
- Each transport box has an accompanying list which identifies the specimens and the patients; the information on the specimen containers should correspond to that on the accompanying list.
- Accompanying list contains the necessary data for each patient
- Date of dispatch and particulars of the health centre are on the accompanying list.

3.1 Specimens and request forms

All specimen transported to the laboratory must be accompanied by the request form for C & DST in hard and soft copy formats (See C & DST request form). For quality control reasons, the tests must be performed only upon written request of authorized persons and oral requests without follow up written instructions should not be allowed. It is also important that specimen request forms are kept separate from the specimens themselves. Forms that have been contaminated by specimens should be sterilized by autoclaving. If mistakes in filling request forms and labelling of specimens are found, reject specimens and do not register them. Document the arrival of specimens in the laboratory and note any delays in

delivery in the remarks column of the specimen register and on the report form, particularly for negative/contaminated results. The packaging material should be autoclaved before discarding.

4. REGISTRATION OF SAMPLES

4.1 Receipt of incoming specimens

For safety and work-flow reasons, specimens should be received in the office area of the laboratory and delivery boxes should be opened using all the applicable biosafety procedures inside the lab.

To minimize risk of infection, the following procedures should be applied:

1. The specimen package received should be opened only in a biosafety cabinet which may be located in a small area within the reception or in the culture room, as they could potentially be MDR or XDR Tuberculosis. (DO NOT OPEN ON AN OPEN BENCH AT THE LAB RECEPTION)
2. Before opening the packet, inspect the delivery box for signs of leakage; if there is gross leakage evident, discard the box by autoclaving or burning; do not try to open and retrieve any specimen.
3. If on gross inspection there is no leakage, disinfect the outside of the delivery box using cotton wool or paper towels saturated with a suitable disinfectant (5% phenol)
4. Open carefully and check for cracked or broken specimen containers or leakage within the packaged container. If there is minimal leakage without any gross loss of specimen, they may be processed with an asterix that leakage was noted on receipt. (This will assist in identifying reasons for contamination used in lab performance indicators). In case of gross leakage, with only very little sample being available, accept the sample and process after carefully making a note of the same – as extrapulmonary specimens are precious and repeat collection may not be possible.
5. Check labelling of specimens with individual identification numbers and correspondence with numbers on the accompanying list or Clinical information forms (CIF) that are accompanying the specimens.
6. Disinfect the inside of the delivery box, wash hands after handling specimen containers
7. Autoclave the packaging material before discarding.
8. Assign unique lab serial number to each patient.
9. Evaluate the quality of specimens and make a note as to volume (in case of fluids), leakage, blood mixed etc. Always register the incoming specimen in the laboratory register; each specimen receives a serial number that should be used to label every test for the specimen. Other data that should be reported on the laboratory register are: the date of the receipt of the specimen, patients name, age, sex and address, the name of the referring health centre, the reason for DST. The signature (with the name in capitals) of the person requesting the examination should always be present.

4.2 Decontamination of extra pulmonary samples

Most of the extra pulmonary specimens are paucibacillary in nature. Hence, they require milder decontamination. When using solid culture for primary isolation of tubercle bacilli from these specimens, it is preferable to use multiple media including one liquid medium made selective by the use of specific antibiotics that inhibit the growth of other micro organisms. The media include, LJ, LJ with sodium pyruvate (LJ–P) and selective liquid Kirchner's medium (SK). Sodium pyruvate facilitates the growth of *M. bovis*. Antibiotics incorporated in the liquid medium include polymixinB, amphotericin B, carbenicillin and trimethoprim (PACT) and vancomycin.

Preparation of media

LJ MEDIUM WITH SODIUM PYRUVATE

LJ medium is enriched with 0.5% sodium pyruvate. In the preparation of the mineral salt solution, glycerol is omitted and 8.0g sodium pyruvate is added for every 600 ml. This is added to 1 litre of egg fluid, mixed well and distributed.

SELECTIVE KIRCHNER'S MEDIUM (For culture of extra-pulmonary specimens**)**

Disodium hydrogen phosphate, $Na_2HPO_4.12H_2O$, A.R.	19.0 g (7.5g of anhydrous salt)
Potassium dihydrogen phosphate, KH_2PO_4, A.R.	2.0 g
Magnesium sulphate, $MgSO_4.7H_2O$, A.R.	0.6 g
Sodium citrate	2.5 g
L-asparagine	5.0 g
Casein hydrolysate (Bactocasitone)	0.5 g
Glycerol	20.0ml
Phenol Red, 0.4% solution	3.0 ml
Distilled water, to	1 litre

Check pH to 6.9 – 7.2

Autoclave at 15 lbs/15 minutes

Then add aseptically the following:

Polymyxin B (20,000 units)	31 mg
Carbenicillin	100 mg
Trimethoprim	10 mg
Amphotericin B, solubilised	10 mg

Dissolve the above in 5 ml sterile distilled water before addition

Also, add sterile calf serum 100 ml

Mix the above carefully and distribute, under sterile conditions, in 10 ml amounts. Check sterility by overnight incubation at 37^{o}C and store in the cold.

5. CULTURE BY SOLID CULTURE METHODS

5.1 CSF and pericardial fluid

Smear:

1. Label a clean dry slide with the lab number and place the slide and the sample container inside the cabinet
2. Mix well and aseptically remove one loopful of the fluid and place in the centre of the slide; close the container and allow the drop to air-dry
3. Place one more drop of the CSF on the same spot and let dry.
4. Place the third drop after processing the sample as below:

Culture:

Culture of CSF is done in two steps:

1. Direct inoculation in media 2. Inoculation after decontamination

Direct

1. Place one loopful of CSF on to one slope each of LJ and LJ-P
2. Add 0.2 ml of CSF in to one bottle containing SK medium
3. Label the set as 'A'

Decontamination

1. Add 1ml of 5% H_2SO_4 to CSF
2. Mix well and let stand for 15 minutes
3. Fill the container with sterile distilled water and centrifuge at 3000 x g for 15 minutes
4. Aspirate the supernatant carefully without disturbing the deposit or discard carefully in to a disinfectant bin containing 5% phenol or any other mycobactericidal solution
5. Inoculate one slope each of LJ and LJ-P with one loopful of deposit for each slope
6. Transfer the remaining deposit in to one bottle of SK
7. Label the set as 'B'
8. Incubate both set A and B at 37^{o}C

5.2 BAL

1. Make a direct smear
2. Process using 5% H_2SO_4 as in CSF
3. Inoculate two slopes each of LJ and LJ-P with one loopful of deposit using 5mm twisted wireloop
4. Transfer the remaining deposit in to one bottle of SK
5. Incubate the slopes and SK medium at 37^{o}C

5.3 Gastric Lavage

1. Gastric Lavage should be processed immediately upon arrival in the lab to prevent the killing action of the gastric pH (due to HCl) on the tubercle bacilli
2. Make a direct smear and process by modified Petroff's method
3. Place one drop of the final pellet on the direct smear
4. Inoculate two slopes each of LJ and LJ-P with one loopful of deposit for each slope
5. Transfer the remaining deposit in to one bottle of SK
6. Incubate the slopes and SK medium at 37^{o}C

5.4 Tissue / Biopsy

1. Ideally, biopsy specimens should be collected and transported in SK medium
2. Carefully place the tissue inside a sterile petriplate inside the BSC
3. Using sterile scissors and forceps, cut the tissue in to tiny pieces
4. Transfer to a sterile tissue grinding tube – add a little water to the petriplate to facilitate transferring
5. Add sterile distilled water to the tube (not more than 5 ml)
6. Homogenise using a sterile Teflon grinding rod using a foot operated tissue grinder
7. Make a direct smear from the homogenate
8. Centrifuge the homogenate at 3000 x g for 15 minutes
9. Decant the supernatant carefully in to the disinfectant bath
10. To the deposit add 1 ml of sterile distilled water
11. Add one drop to the direct smear, air dry, fix and stain
12. To the remaining pellet, add 1ml of 5% H_2SO_4
13. Proceed as for CSF
14. Inoculate two slopes each of LJ and LJ-P with one loopful of deposit for each slope
15. Transfer the remaining deposit in to one bottle of SK
16. Incubate the slopes and SK medium at 37^{o}C, along with the SK medium used for transporting

5.5 Fine Needle Biopsy specimen

1. Fine needle specimens should be collected and transported only in SK medium or any other liquid medium
2. The medium is incubated as such at 37^{o}C, since only a very tiny piece of the tissue is obtained as sample

If the sample is received without SK

1. Add the contents of two SK medium bottles to the specimen
2. Shake vigorously and let stand for 10 minutes
3. Divide the medium in to two aliquots and incubate both at 37^{o}C

5.6 Pus

1. Make a direct smear, air dry, fix and stain

2. If the pus is thick or purulent, process by modified Petroff's method using 4% NaOH
3. Inoculate two slopes each of LJ and LJ-P with one loopful of deposit for each slope
4. Transfer the remaining deposit in to one bottle of SK
5. Incubate the slopes and SK medium at 37°C
6. If the pus is thin or dilute, proceed with decontamination using 5% H_2SO_4
7. Inoculate two slopes each of LJ and LJ-P with one loopful of deposit for each slope
8. Transfer the remaining deposit in to one bottle of SK

5.7 Urine / Ascitic fluid

1. Distribute the entire specimen in to 20 or 40 ml volumes in Universal containers / Falcon tubes inside a BSC
2. Centrifuge at 3000 x g for 15 minutes

Process the supernatant and deposit independently as follows:

Supernatant:

3. Aspirate carefully 1ml of the top layer from each tube and pool
4. Process by 5% H_2SO_4 as for CSF
5. Transfer 1ml of the final supernatant on to two bottles of SK each – Label the set as DSS (Decontaminated Supernatant Supernatant)
6. Decant the supernatant carefully in to the disinfectant bath
7. From the deposit transfer about 0.2 ml and the remaining in to 2 bottles of SK respectively – Label as DSD (Decontaminated Supernatant Deposit)

Deposit:

8. Pool all the deposit in to one tube
9. Process using 5% H_2SO_4 as for CSF
10. Inoculate two slopes each of LJ and LJ-P with one loopful of deposit for each slope
11. Transfer the remaining deposit in to one bottle of SK

5.8 Swabs:

If two swabs are available, use one for smear and one for culture; if only one is available do only culture

1. Immerse the swab in 5 ml of 4% H_2SO_4 for 1 minute
2. Transfer the swab to another tube containing 5 ml of 4% NaOH
3. Directly inoculate two slopes each of LJ, LJ-P
4. Transfer the swab finally to a tube containing SK medium
5. Incubate all tubes at 37°C

5.9 Culture Reading

1. Read all cultures used for isolating *M. tuberculosis* from extrapulmonary specimens every week for up to 8 weeks using the same methodology used for pulmonary samples
2. If the solid media show typical growth report immediately after confirmation

3. Read SK medium up to 6 weeks
4. MTB appears as whitish granular or flaky growth that settles down at the bottom
5. If the SK medium shows growth or contamination (in the form of turbidity) within 6 weeks, decontaminate as sputum by modified Petroff's method and inoculate deposit on LJ medium alone and read up to 8 weeks
6. Even if the SK medium shows no growth within 6 weeks, proceed with decontamination using modified Petroff's method and inoculate deposit on LJ medium alone and read up to 8 weeks
7. If LJ shows typical MTB growth within 8 weeks, report immediately after confirmation
8. Report as negative only after LJ completes 8 weeks (a total of 14 weeks)

6. Processing of extra pulmonary samples for MGIT960

Isolation of M. tuberculosis by MGIT system requires the final inoculum to be in an ideal condition that will not interfere with the fluorescence.

6.1 Pus and other muco-purulent specimens

1. Thick pus of volume >10 ml is decontaminated using the NALC – NaOH method as sputum
2. If the volume is < 10 ml, either aliquot and process only 10 ml by NALC – NaOH method or concentrate the initial volume by centrifugation for 15 – 20 minutes and resuspend the pellet in 5 ml of sterile distilled water. If the pus is too thick, add about 50-100 mg of NALC powder; mix well and decontaminate using NaOH. Resuspend the final pellet in buffer to reduce the pH
3. If the pus is not thick, decontaminate using 2-4% NaOH. The concentration of NaOH can be changed based on the expected level of contamination in the specimen which depends on the site of collection

6.2 Gastric aspirates

1. Distribute the volume in smaller aliquots and centrifuge the tubes at 3000 x g
2. Pool the deposits, add 5ml distilled water and decontaminate it using NALC-NaOH or 2-4% NaOH

6.3 Bronchial washings

1. Process using NALC-NaOH like sputum
2. If the specimen is >10 ml in volume, process the whole specimen.
3. If <10ml, concentrate the specimen by centrifugation (3000x g, 15-20 minutes)
4. Add 5 ml sterile water to the pellet and decontaminate as for sputum

6.4 Laryngeal swabs

1. Transfer the swab into a sterile centrifuge tube and add 2 ml sterile water.
2. Add 2 ml of NaOH-NALC solution and mix well in a vortex mixer.

3. Let stand for 15 minutes. Remove the swab with forceps, squeezing the liquid out of the swab and discarding it.
4. Fill the tube with phosphate buffer and mix
5. Centrifuge at 3000xg for 15-20 minutes.
6. Discard the supernatant fluid and resuspend the sediment in 1-2 ml sterile buffer. Use this suspension for smear and culture.

6.5 Tissue

1. Homogenize the tissue in a tissue grinder with a small quantity of sterile saline or water (2-4 ml).
2. Decontaminate the homogenized specimen using NALC-NaOH procedure as in sputum.
3. Resuspend the sediment with phosphate buffer
4. If the tissue grinder is not available, use a mortar and pestle.
5. Tissue may also be placed in a Petri dish with sterile water (2-4 ml) and be torn apart with the help of two sterile needles.

6.6 Urine

Isolation of mycobacteria from urine specimens using MGIT has not been validated.

1. Aliquot the entire volume in several centrifuge tubes
2. Concentrate the specimen by centrifugation for at least 20-25 minutes
3. Resuspend the pellet in each tube with 1-2 ml of sterile water and pool together
4. Decontaminate using 4% NaOH as for sputum

6.7 Other body fluids (CSF, synovial fluid and pleural fluid)

As these fluids are collected usually under aseptic conditions, they require only milder decontamination

1. If the specimen volume is more than 10 ml, concentrate by centrifugation at about 3000x g for 15-20 minutes
2. Liquefy thick or mucoid specimens prior to centrifugation by adding NALC powder (50-100 mg).
3. Resuspend the sediment in about 5 ml of saline
4. Mix and decontaminate as for sputum

6.8 Blood

Isolation of mycobacteria from blood specimens by MGIT 960 has not been evaluated thoroughly. A few published studies have used blood after lysis centrifugation. Ideally BACTEC Myco/F Lytic medium is recommended for isolation of mycobacteria from blood samples.

Institution **Laboratory name** Location Head/Responsible person	Standard Operating Procedure (SOP) Specimen processing of CSF, lymph nodes and other tissues for Xpert MTB/RIF	Code: Version: no. Date: of release Page: **1** of **7**

Content

	Compiled by	Examined by	Approved by	Replaced	New version
Name				Code:	Code:
Date					
Signature					
Laboratory area:		No of copies:	Reason for change:		

1. Scope

This SOP describes methods of specimen processing CSF, lymph nodes and tissues for testing in the Xpert MTB/RIF assay and for purposes of culturing *Mycobacterium tuberculosis* culture on solid and / or liquid media.

2. Definitions and abbreviations

BSC : biological safety cabinet
CSF: cerebrospinal fluid
ID: patient's specimen identification, usually laboratory number
LJ: Löwenstein–Jensen
NTP: national tuberculosis programme
PBS: Phosphate buffer 0.067 mol/ litre, pH 6.8
RCF: relative centrifugal force

3. Procedure

3.1 Principle

WHO has issued policy recommendations for the use of Xpert MTB/RIF in the diagnosis of extrapulmonary TB and rifampicin resistance detection

- Xpert MTB/RIF should be used in preference to conventional microscopy and culture as the initial diagnostic test in testing **cerebrospinal fluid specimens** from patients presumed to have TB meningitis (strong recommendation given the urgency of rapid diagnosis, very low quality of evidence);

- Xpert MTB/RIF may be used as a replacement test for usual practice (including conventional microscopy, culture, and/or histopathology) for testing of specific non-respiratory specimens (**lymph nodes and other tissues**) from patients presumed to have extrapulmonary TB (conditional recommendation, very low quality of evidence).

For CSF specimens, Xpert MTB/RIF should be preferentially used over culture if the sample volume is low or additional specimens cannot be obtained, in order to reach quick diagnosis. If sufficient volume of material is available, concentration methods should be used to increase yield;

Individuals presumed to have extrapulmonary TB but with a single Xpert MTB/RIF - negative resultshould undergo further diagnostic testing and hence processing of tissue samples (lymph nodes and other tissues) for Xpert MTB/RIF should include a decontamination step to enable samples to be concurrently cultures

Pleural fluid is a suboptimal sample for the bacterial confirmation of pleural TB, using any method. A pleural biopsy is the preferred sample.

These recommendations do not apply to stool, urine or blood, given the lack of data on the utility of Xpert MTB/RIF on these specimens.

3.2 General considerations

Important points about specimen processing procedures

- Process all specimens as soon as possible, for an optimal culture recovery of MTB. Longer transport should not affect Xpert positivity
- Ensure that the Xpert MTB/RIF cartridge and any culture media to be inoculated are labelled correctly and clearly.
- **Tissues must be processed within a BSC** given the risk of aerosol production while grinding and homogenizing samples.
- **CSF samples are paucibacillary** and can be processed using the same precautions as for sputum EXCEPT when concentrated by centrifugation
- It is important to use Safe Working Practices to avoid contamination by bacteria other than tubercle bacilli and especially cross-contamination by tubercle bacilli from other specimens.
- When sufficient sample is available, culture should be performed concurrently
- Samples requiring decontamination must have the exposure time to decontamination reagents strictly controlled.
- **Decontaminate samples** for culture using either 4% NaOH or NaOH-NALC **depending on usual practice** in the laboratory. The example below uses 4% NaOH.

3.3 Specimen processing

The Xpert MTB/RIF assay can be used directly for CSF specimens and homogenised extrapulmonary samples (lymph node biopsies and other tissues) or on decontaminated specimens if culture is performed concurrently.

Whenever possible, specimens should be transported and stored at 2 to 8°C prior to processing (a maximum of 7 days).

3.3.1 Lymph nodes and other tissues (for Xpert MTB/RIF only)

1. Cut the tissue sample into small pieces in a sterile mortar (or homogenizer / tissue grinder) using a clean, sterile pair of forceps and scissors
2. Add approximately 2ml of sterile phosphate buffer (PBS)
3. Grind tissue/PBS-solution with a mortar and pestle (or homogenizer / tissue grinder) until a homogeneous suspension is obtained
4. Transfer approximately 0.7 ml of homogenized tissue sample to a sterile conical, screw-capped tube using a transfer pipette

NOTE: Avoid transferring any clumps of tissue which have not been properly homogenized.

5. Add a double volume of Xpert MTB/RIF Sample Reagent (1.4 ml) to 0.7 ml of homogenized tissue using a transfer pipette
6. Vigorously shake 10 to 20 times or vortex for at least 10 seconds
7. Incubate for 10 minutes at room temperature, and again shake the specimen vigorously 10 to 20 times or vortex for at least 10 seconds
8. Incubate the sample at room temperature for an additional 5 minutes
9. Using a fresh transfer pipette, transfer 2ml of the processed sample to the Xpert MTB/RIF cartridge
10. Load the cartridge into the GeneXpert instrument as per manufacturer's instructions

3.3.2 Lymph nodes and other tissues (Non-sterile collections – Xpert MTB/RIF and culture)

1. Cut the tissue sample into small pieces in a sterile mortar (or homogenizer / tissue grinder) using a clean, sterile pair of forceps and scissors
2. Add approximately 2ml of sterile phosphate buffer (PBS)
3. Grind tissue/PBS-solution with a mortar and pestle (or homogenizer / tissue grinder) until a homogeneous suspension is obtained
4. Use a sterile transfer pipette to add the suspension into a 50ml conical tube
5. Add an equal volume of 4% NaOH and tighten the screw-cap
6. Vortex thoroughly to homogenise the suspension
7. Stand for 15 minutes at room temperature.
8. Fill the tube to within 2 cm of the top (e.g. to the 50-ml mark on the tube) with PBS
9. Centrifuge at 3000*g* for 15 minutes
10. Carefully pour off the supernatant through a funnel into a discard can containing 5% phenol or other mycobacterial disinfectant
11. Re-suspend the deposit in approximately 1-2 ml PBS
12. Use another sterile transfer pipette to inoculate deposit into liquid media and/or onto two slopes of egg-based medium labelled with the sample ID number.
13. Label a Xpert/MTB/RIF cartridge with the sample ID

14. Using a transfer pipette, transfer approximately 0.7 ml of homogenized tissue sample to a conical, screw-capped tube for the Xpert MTB/RIF.

NOTE: Avoid transferring any clumps of tissue which have not been properly homogenized.

15. Using another transfer pipette, add a double volume of Xpert MTB/RIF Sample Reagent (1.4 ml) to 0.7 ml of homogenized tissue.
16. Vigorously shake 10 to 20 times or vortex for at least 10 seconds
17. Incubate for 10 minutes at room temperature, and again shake the specimen vigorously 10 to 20 times or vortex for at least 10 seconds
18. Incubate the sample at room temperature for an additional 5 minutes
19. Using a fresh transfer pipette, transfer 2ml of the processed sample to the Xpert MTB/RIF cartridge
20. Load the cartridge into the GeneXpert instrument as per manufacturer's instructions

3.3.3 Lymph nodes and other tissues (Sterile collection – Xpert MTB/RIF and culture)

1. Cut the tissue sample into small pieces in a sterile mortar (or homogenizer / tissue grinder) using a clean, sterile pair of forceps and scissors.
2. Add approximately 2ml of sterile phosphate buffer (PBS)
3. Grind tissue/PBS-solution with a mortar and pestle (or homogenizer / tissue grinder) until a homogeneous suspension is obtained and adjust to a final volume of approximately 2ml with PBS
4. Transfer the suspension with a sterile transfer pipette to a 50ml conical tube
5. Use a another transfer pipette to inoculate suspension into liquid media and/or onto two slopes of egg-based medium labelled with the sample ID number
6. Label an Xpert/MTB/RIF cartridge with the sample ID
7. Transfer approximately 0.7 ml of homogenized tissue sample to a conical, screw-capped tube for the Xpert MTB/RIF using a transfer pipette

NOTE: Avoid transferring any clumps of tissue which have not been properly homogenized.

8. Transfer a double volume of Xpert MTB/RIF Sample Reagent (1.4 ml) to 0.7 ml of homogenized tissue using a transfer pipette

9. Vigorously shake 10 to 20 times or vortex for at least 10 seconds
10. Incubate for 10 minutes at room temperature, and again shake the specimen vigorously 10 to 20 times or vortex for at least 10 seconds
11. Incubate the sample at room temperature for an additional 5 minutes.
12. Using a fresh transfer pipette, transfer 2ml ml of the processed sample to the Xpert MTB/RIF cartridge
13. Load the cartridge into the GeneXpert instrument as per manufacturer's instructions

3.3.4 CSF

The preferred processing method for CSF in Xpert MTB/RIF depends on the volume of sample available for testing.

NOTE. Blood stained and xanthochromic CSF samples may cause false negative Xpert MTB/RIF results

More than 5 ml of CSF

1. Transfer all of the sample to a conical centrifuge tube and concentrate sample at 3000*g* for 15 minutes
2. Carefully pour off the supernatant through a funnel into a discard can containing 5% phenol or other mycobacterial disinfectant
   NOTE: Decanting concentrated CSF should be performed within a BSC
3. Re-suspend the deposit to a final volume of 2ml with Xpert MTB/RIF sample reagent.
4. Label an Xpert/MTB/RIF cartridge with the sample ID
5. Using a fresh transfer pipette, transfer 2ml ml of the concentrated CSF sample to the Xpert MTB/RIF cartridge
6. Load the cartridge into the GeneXpert instrument as per manufacturer's instructions

1-5 ml of CSF (including blood-stained or xanthochromic samples)

1. Add an equal volume of the CSF to the sample reagent
2. Add 2ml of the sample mixture directly to the Xpert MTB/RIF cartridge
3. Load the cartridge into the GeneXpert instrument as per manufacturer's instructions

0.1-1ml of CSF

1. Re-suspend the CSF to a final volume of 2 ml with Xpert MTB/RIF sample reagent.
2. Add 2ml of the sample mixture directly to the Xpert MTB/RIF cartridge
3. Load the cartridge into the GeneXpert instrument as per manufacturer's instructions

Less than 0.1ml

1. Insufficient sample for testing in the Xpert MTB/RIF assay

4. Related documents

1. Xpert MTB/RIF system for the diagnosis of pulmonary and extrapulmonaryTB and rifampicin resistance in adults and children. A pre-publication version of the policy guidance may be accessed at: http://www.stoptb.org/wg/gli/assets/documents/WHO Policy Statement on Xpert MTB-RIF 2013 pre publication 22102013.pdf

2. The full Expert Group meeting report is available at: http://www.stoptb.org/wg/gli/assets/documents/Xpert%20Meeting%20Report%2024102013%20%20Pre%20publication%20FINAL.pdf

Revised National TB Control Programme

Instructions for administering Purified Protein Derivative (PPD):

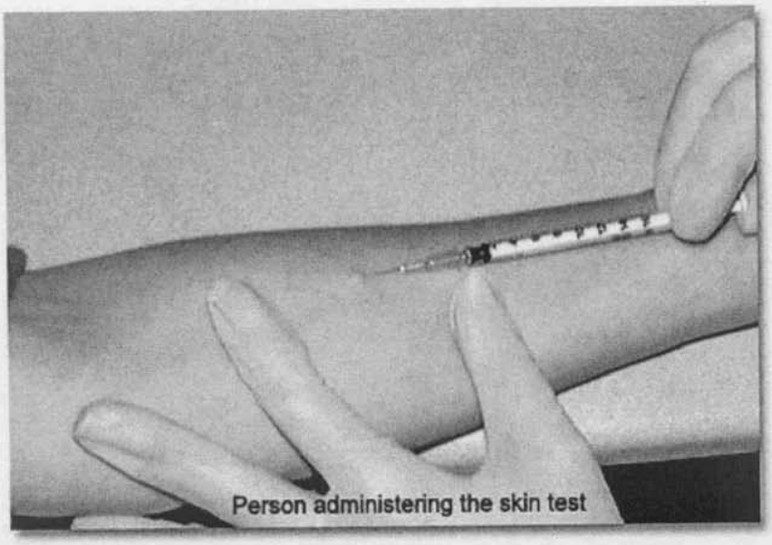
Supplies needed:

- Vial of tuberculin – 1tuberculin units (TU) purified protein derivative (PPD) 1.5 ml solution
- Single-dose disposable tuberculin syringe
- 2x2 gauze pads or cotton balls
- Alcohol swabs
- Puncture-resistant sharp disposal container
- Mantoux Tuberculin Skin Test Record Form
- Appointment cards
- Gloves

Preparation before administration:

- Purified protein derivative (PPD) solution must be kept refrigerated at 2-8°C (DO NOT FREEZE)
- To avoid fluctuations in temperature, do not store on the refrigerator door
- Read the vial label to ensure that the correct solution and tuberculin unit (TU) strength have been selected
- Check the expiration date and the date that the vial was opened. The vial should be discarded if it has been open for more than 30 days or the expiration date has passed. The vaccine vials comes in a pack of ten in a box which also has the vaccine vial monitor (VVM) indicator. All the vials should be taken from a single box, the vaccine vials should not be taken if the VVM on the box has changed its color or if it has crossed the expiry date.
- Select a well-lighted area for administering the test. Have all the equipment and supplies on hand
- Introduce yourself to the patient
- Verify that the correct patient receives the test
- Ask the patient if he/she has any allergies
- Review the patient's tuberculin skin test history. Inquire about documentation of previous tuberculin skin test results
- Provide patient education to answer questions, address fears, and ease anxieties. Discuss the purpose of the test, testing procedure, and the time frame for returning to have the test read. If the patient cannot return 48-72 hours after the test to have the indurations measured and evaluated, do not administer the test. Instead, schedule another time that is more convenient for the patient

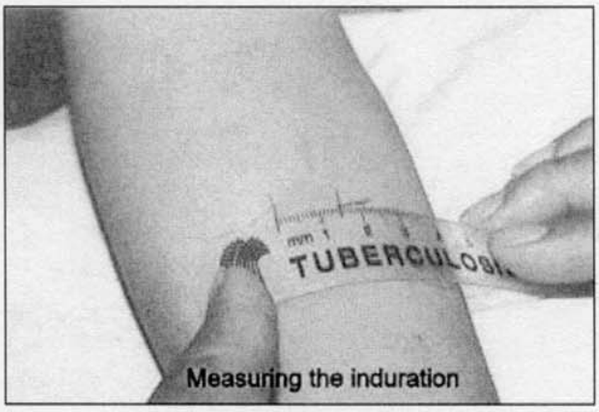
Administration of Skin Test: (Syringes must be filled immediately prior to administration)



Person administering the skin test

- Wash your hands with soap and water
- On a firm, well-lighted surface, expose the patient's arm and slightly flex at the elbow. The injection should be replaced on the palm-side-up surface of the forearm, about 2 to 4 inches below the elbow. Avoid areas of skin with veins, sores, rashes, scars, or excess hair
- Wear the gloves
- Clean the injection site with an alcohol swab, using circular motion beginning in the center and working your way outward. Allow the site to dry completely before injection
- Wipe the top of the vial with a new alcohol swab and allow it to dry thoroughly
- Fasten the needle tightly on the syringe by holding the cap and twisting it onto the tip of the syringe. Remove the needle cap and make sure that the needle bevel is facing up
- Hold vial between your thumb and fingers and insert the needle through the stopper. Inject air into the empty space, not the solution, in the vial
- Invert the vial. With the tip of the needle below the fluid level in the vial, draw out slightly more than 0.1 ml of solution
- Remove the needle from the vial. Hold the syringe in an upright position and gently tap the syringe to break up any air bubbles
- Expel all air from the syringe and excess solution from the needle, leaving exactly 0.1 ml of tuberculin solution in the syringe
- Stretch the skin taut over the injection site to provide a surface that is easy for the needle to penetrate. This can be accomplished by stretching the skin between the thumb and index finger or grasping the patient's forearm and gently pulling the skin from under the arm
- Hold the syringe between your thumb and index finger with the needle bevel facing up and the syringe parallel to the forearm

- With the needle against the patient's skin, insert the needle slowly at a 5 to 15 degree angle, just below the surface of the skin (you should be able to see the bevel of the needle just below the skin surface)
- Release the stretched skin and hold the syringe in place. Slowly inject the tuberculin solution, forming a 6 to 10 mm wheal (pale, raised area with distinct edges; has orange peel appearance and does not disappear immediately)
- If no wheal forms or if it is less than 6 mm in diameter, repeat the test approximately 2 inches from the original site or on the opposite arm
- Remove the needle without massaging or pressing the area and immediately discard the used syringe in the sharps container
- If minor bleeding occurs, use a 2x2 gauze pad or cotton ball to dab the injection site
- Do not cover the site with an adhesive bandage as it could cause irritation
- Wash your hands
- Record the following information on the record-keeping form: the date, time, location of injection site, name of manufacturer, lot number, and expiration date of PPD solution, name of person administering the skin test
- Inform the patient that mild itching, swelling, or irritation is normal and usually goes away within 1 week
- Explain how to care for the injection site: avoid scratching the site, keep the site clean and dry, and avoid creams, lotions, or adhesive bandages
- Inform the patient that it is important to return within 48 to 72 hours to have the test result read
- Give the patient a written appointment to return for the skin test reading



Measuring the induration

Annexure 7

Setting- specific screening strategy

Urban Slums

Urban slum dwellers are at higher risk of developing TB due to overcrowding, poor basic health services infrastructure and their health seeking behaviour. Health is not a priority for them and risk of TB transmission is high in slums. Urban slum-dwellers require focussed efforts and support from the tuberculosis programme.

Intensified case finding efforts in these areas can include:-

- House to house, periodic symptom screening of all the mapped urban slums to actively screen for presumptive TB cases.
- Liaising with NUHM, NPSP and other departments delivering health care services in urban slums for mapping and line listing of providers
- Utilization of Urban slum schemes as in the revised NGO-PP partnership guidelines.

Household and Close Contacts of TB

Household contact:- *A person who shared the same enclosed living space for one or more nights or for frequent or extended periods during the day with the index case.*

Close contact:- *A person who is not in the household but shared an enclosed space, such as a* ***social gathering****,* ***workplace*** *or facility, for extended periods in a day with the index case.*

-Since the transmission can happen from the index case to the contact any time (before the diagnosis of TB or during the treatment) all contacts must be evaluated. In case of Pulmonary Tuberculosis, it is recommended that contact screening is conducted for household and close contacts

It is important to screen household and close contacts for TB as they are more prone to get infected with TB. Some of them may be asymptomatic and others may ignore these symptoms. Chest X-ray screening should be done for all the contacts. Symptom screening should be done whenever X-ray facility is not available.

- The index case should be interviewed as soon as possible after diagnosis (generally within 1 week) to elicit the names of household and close contacts. Data from the contact investigation should be collected in a standardized format and should routinely be evaluated. (Information to be recorded in the treatment card)
- Reverse contact tracing should be done for all paediatric TB patients.

Health Care Workers

Health care workers are at greater risk of getting TB infection and also at a higher risk of getting active disease. The National Airborne Infection Control guidelines advocate Health Care worker Surveillance as a component of the Hospital / Health facility Infection Control Plans.

- Pre placement screening and routine annual screening with Chest radiography of all the health care workers is strongly recommended.
- If Health care worker surveillance is an existing policy in the health institution, facility or department then chest X-ray screening may be added on to the protocol.
- Healthcare workers presenting with symptoms of TB should be evaluated.

Malnourished Children

Malnutrition is a strong risk factor for progression from TB infection to disease among children. As per the TB management guidelines in the paediatric population issued by RNTCP, all malnourished children are eligible for TB screening and diagnostic evaluation.

- Active screening for TB symptoms with chest X-ray as the screening tool (or symptom screening if X- ray is not available) should be undertaken among children with malnourishment that attend any health facility .
- Engage and collaborate with Nutritional Rehabilitation Centres for routine screening of TB in malnourished children attending these centres.
- Regular symptomatic screening of malnourished children attending the Anganwadi centres.

Antenatal Clinics/MCH clinics

Antenatal clinic attendee rates are very high in the country as the RCH programme receives high priority and is a leading public health programme in the country. Screening pregnant women for TB in MCH clinics provides an exceptional opportunity to identify and reach women in need of TB case diagnosis as a majority of women access health care during pregnancy at least once. Strengthening linkages between maternal health and TB management can contribute to the reduction of maternal and newborn mortality too.

- TB Symptoms screening must be undertaken for all mothers attending the antenatal clinics at every visit and those who are symptom screen positive must be immediately linked to the nearest laboratory for early TB diagnosis and decision on TB treatment initiation.

Prison inmates

Predisposing factors such as overcrowding, long-term close contact with inmates and lack of easy access to adequate health services may lead to high rates of TB transmission in prisons. Duration of stay of inmates in the prison is unpredictable and turnover is also high, resulting in undiagnosed or delayed diagnosis of TB.

The intensified case finding activity should include:

- Symptom screening at **Entry;** when prisoners enter the prisons.
- **Periodic mass screening** with chest X-ray. If chest x-ray is not available then symptom screening should be done.

Patients with Co morbidities

Patients with chronic illness like malignancy, on dialysis, on immune-suppressants, long term steroids have higher risk of tuberculosis - Symptom screening for TB should be done on all patient visits to the health facilities for follow up examinations

Patients with past history of TB

Chances of TB relapse or recurrence is higher in people with a past history of TB. Efforts to actively screen for TB symptoms in this group could be a high case yielding activity. The programme now advocates that all TB cases after successful completion of treatment need to be followed up for a period of one year after with follow up examinations at 6^{th}, 12^{th},$18^{th}$and 24^{th}month.

- Active symptom screening by health staff may be undertaken by visiting the homes of those patients at prescribed intervals
- House to house visits may be undertaken of all patients notified and treated by private sector to screen for TB symptoms at prescribed intervals.

Occupational high risk group

Several occupations increase risk for tuberculosis. It is known that thousands of workers and local residents are exposed to hazardous silica levels during stone crushing operations and suffer from silicosis, lung cancer, and other lung diseases. Other occupations include coal and other mining works, tobacco (bidi rolling) and carpet weaving. Vulnerable and socially marginalised groups including tribal communities, children and migrant population are often working in these industries that do not have access to routine health services. Active case finding efforts in these groups will help to identify those suffering from TB early.

- Screening should be done by X-ray and in case X-ray is not available then symptom screening should be done by holding periodic health camps.

Congregate Settings

People in settings like transit camps, night shelter, old age home, orphanages and de addiction centres may have ill ventilated and unsanitary environment and hence, at higher risk of developing tuberculosis.

- In all such congregated settings Symptom screening should be done by holding periodic health camps.

Hard to Reach Areas

People living in difficult, hard to reach and inaccessible areas like certain Tribes or indigenous population delay seeking health care for their symptoms. They are also dependent on local informal providers and traditional healers as their first points of contact for health care, which can lead to delay in diagnosis. Periodic active screening programmes must be planned and implemented to detect TB cases early in this population

- Symptomatic screening may be done by holding periodic health camps or even by house to house survey

- Mobile medical units equipped with microscopes and digital X-ray machines available under NHM can be used.
- Sputum collection centres must be planned and established in strategic locations with the help of local NGOs

Missed cases in health system

Opportunity should not be missed to diagnose TB among people who approach health facility for any other illness. Systems should be strengthened and actively monitored so as to ensure all presumptive TB cases are identified timely and are referred for diagnostic evaluation

- Establish sputum collection centres in all the primary health centres which do not have DMC
- Enhancing the skills of MOs by providing special training package on interpretation of X-ray.
- Wherever X-ray &histo-pathological/FNAC services are not available then outsourcing these services should be done.

Annexure 8

Enhanced enables and incentives under programme are given below:

Item	Existing norm	Proposed by MoHFW and approved by MSG
Existing Incentives		
Revision of incentives to Community DOT provider providing treatment support to Category I TB patients	250/- for completed course of treatment	Rs1000/- for the completed course of treatment
Revision of incentives to Community DOT provider providing treatment support to Category II TB patients	250/- for completed course of treatment	Rs1500/- for the completed course of treatment
Revision of incentives to Community DOT provider providing treatment support to Drug Resistant TB patients	Rs.2500/- for completed course of treatment (Rs.1000/- at the end of IP and Rs 1500/- at the end of CP)	Rs.5000/- for completed course of treatment. (Rs.2000/- at the end of IP and Rs 3000/- at the end of CP)
Incentives to patient in tribal and difficult areas	Rs.250/patient and one attendant	Rs 750/patient and one attendant
Incentive to volunteers for sputum sample transport in tribal and difficult areas	Rs.200/month/volunteer. If less than one visit per week then Rs 100/ month	Rs.25 per sample transported to the DMC
Travel cost to MDR TB patient/suspect to DRTB centre (outside district)	Actual travel cost using any public transport	Up to Rs 1000/visit/patient restricted to actuals by a public transport
Travel cost to MDR TB patient/suspect to DRTB centre (within district)	Actual travel cost using any public transport	Up to Rs 400/visit/patient restricted to actuals by a public transport
New Incentives		
Transportation cost for co-infected TB -HIV patient travel	NIL	Up to Rs.500/patient for only the first visit restricted to actuals by a public transport
Incentive related to Injection prick	NIL	Rs.25/injection prick

Annexure 9

Ready Reckoner for General Practitioners

Important general instructions:

1. Ensure that patient completes full course of anti-TB therapy
2. Side effects of anti-TB drugs can be an important cause of patient stopping medication, especially with second line drugs.
3. Prevention and early detection of side effects are needed
4. Alcohol, smoking and use of illicit drugs increase side effects
5. Relevant history, clinical examination and lab tests are important to evaluate risk factors and diagnosis of side effects at an early stage
6. For contraception, ask patient to seek advice from family health center as oral contraceptives are less effective with some anti-TB drugs
7. Educate, counsel and reassure patients for self-limiting side effects
8. For side effects and serious side effects, take immediate action and refer patient to specialist / tertiary center; as suggested below
9. Report serious side effects to PvPI center (Procedure for reporting: Call your nearby PvPI center and provide complete information about side effects. Contact details of the nearest PvPI center are: Name of the Centre - _____; Contact no: _____; National toll free number: **1800 180 3024**)
10. Advice nutritious diet to TB patients
11. Advice patients about respiratory hygiene and provide information on preventing spread of TB (using facemask, tissue paper and cover face)

ADRs with anti-TB drugs, their prevention and management:

ADRs	Diagnosis	Suspect Drug(s)	Differential Diagnosis / Other causes	Prevention	Management
Nausea and Vomiting	Clinical, based on complaints by patient	All oral anti-TB drugs	Hepatitis	Take anti- TB medication with banana	Symptomatic management. Exclude hepatitis / hepatoxicity
Rash, urticaria	Clinical	All anti-TB drugs	Steven Johnson syndrome, Anaphylactic reaction, Exfoliative dermatitis, Herpes infection	Seek past history of allergy before starting treatment and as applicable.	If rash involves <10% body surface area (BSA) and is not associated with mucous membrane involvement, treat with anti-histaminics. Stop suspect anti-TB drug and refer patient to specialist if indicated. Desensitization can be attempted. If it fails, substitute the suspect drug with alternate drug
Diarrhea	Clinical	All oral anti-TBdrugs	Bacterial dysentery Amoebic dysentery, Malabsorption syndrome, Pseudomembranous colitis	Use of clean and potable water for drinking, washing hands before eating and drinking any thing	AdviceOral Rehydration Solution (ORS)200 ml, after each loose stool. Check for infective causes.
Liver enzymes- SGOT/ SGPT increased (up to 2xULN)	Increase of liver enzymes after starting anti-TB drugs	Frequent & Severe: PZA INH RIF Rare: EMB Ethionamide FQs PAS Cycloserine	Viral hepatitis – rule out by negative serological tests for A, B, C and E. Alcoholic hepatitis - AST:ALT > 2:1 with history of alcohol intake Amoebic liver abscess – Ultrasound / CT to detect cystic lesions / abscess	Up to 2xULN is not serious. DIH reported in 8-30% of patients. Cannot be prevented. Avoid simultaneous administration of other hepatotoxic drugs. It can worsen to severe hepatitis, which can be prevented by monitoring	Usually drugs are not withdrawn. Check for other potential hepatotoxic agents e.g. alcohol

			Mass in ultrasound/CT→ Liver biopsy to rule out Hepatoma	of LFT in high risk patients every 15 days & taking appropriate action if liver enzymes increase.	
Hepatitis (Severe)	ALT/ AST >3×ULN with symptoms of Nausea, vomiting, anorexia, jaundice, dark colored urine OR ALT/ AST >5×ULN without symptoms	Frequent & Severe: PZA INH RIF Rare: Ethionamide PAS Cycloserine Clarithromycin Clofazimine Imipenem-cilastatin	Investigate as above to rule out: Viral hepatitis Alcoholic hepatitis - Amoebic liver abscess Hepatoma	Early detection of raised liver enzymes to prevent worsening & reduce associated morbidity & mortality	Management includes withdrawal of potential causative drugs & supportive treatment. Later, when enzyme levels return to normal, then gradually reintroduce the drugs. (Refer to flowcharts)
Exfoliative and allergic dermatitis	Clinical based on symptoms- Pruritus, widespread erythema and epidermal sloughing	Frequent: FQs Rare: RIF PAS Cycloserine linezolid Amoxicillin-clavulanate clarithromycin Clofazimine	Asteatotic Eczema Contact Dermatitis, Drug-Induced Bullous Disorders Drug-Induced Photosensitivity Nummular Dermatitis Perioral Dermatitis Phytophotodermatitis	Early detection and management can prevent worsening	Topical hydrocortisone or oral antihistamines may be helpful to control pruritus. Anti-TBmedications should not be discontinued unless an equally effective drug is available for substitution. Refer to specialist if indicated.
Stevens-Johnson and Toxic epidermal necrosis	Clinical based on total body surface area (BSA)involvement of more than 10% and/ or mucous membrane	Rare: INH RIF EMB FQs Amoxicillin-clavulanateclari	Staphylococcal scalded skin syndrome Irradiation – History of radiation Trauma - History Progressive systemic sclerosis (scleroderma) –	Early detection and management can prevent worsening	Immediate drug withdrawal and referral to specialistis recommended. Reintroduction is not recommended. Supportive therapy like antihistamines, anti-inflammatory agents may be helpful in the meantime.

	involvement	thromycin imipenem-cilastatin	ANCA antibodies		
Psychosis (Severe)	Symptoms of Hallucinations, paranoia, suicidal or abnormal thoughts or actions	Frequent & Severe: Cycloserine Frequent: INH Rare: RIF, FQs Clarithromycin Clofazimine Imipenem-cilastatin	Post-traumatic Stress Disorder, Delusional disorder, Schizophrenia, Schizophreniform Disorder	Careful monitoring. Psychiatric counseling at the start of treatment in patients at risk of psychiatric disorders.	Refer to specialist for further evaluation.Consider suspectdrug withdrawal. Refer to specialist.
Peripheral neuropathy	Clinical symptoms of Burning and paresthesia in extremities. Electromyography (nerve conduction studies)for confirmation	Frequent: INH Rare: EMB FQs PAS Ethionamide Cycloserine Linezolid (Severe)	Neuropathy due to high dose of pyridoxine Diabetic neuropathy Peripheral demyelinating disease	Supplementing the anti-TBdrugs with Pyridoxine 5-10 mg orally once a day if patient is on INH, Pyridoxine 50 mg per day with Linezolid and with every 250 mg Cycloserine.	Check for Pyridoxine compliance. Give paracetamol / NSAIDsto alleviate pain. Drug withdrawal is not indicated. Start Pyridoxine 100 mg per day. If no response, increase dose of Pyridoxine to 200 mg. Refer to specialist if no response or if patient is taking Linezolid.
Ototoxicity/ Hearing loss/ Deafness	Symptoms-Tinnitus, vertigo, Loss of balance and equilibrium. Audiometry for confirmation	Frequent & Severe: AGs Rare: Linezolid clarithromycin imipenem-cilastatin	Ear wax, otitis media, Traumatic hearing loss, Meniere's disease Acoustic neuroma	Monitoring of early symptoms can prevent permanent ear damage	Consider withdrawal of the suspect drug. Refer to specialist for further evaluation
Optic neuritis	Vision loss, Peri-ocular pain, Dyschromatopsia(disorder of color vision). Based on	Frequent & Severe: EMB Rare: PAS	Brain Tumor, Giant cell arteritis, Retinal detachment, Multiple sclerosis, Closed-angle glaucoma,	Regular ophthalmologic examination	Consider withdrawal of the suspect drug. Refer to specialist for further evaluation

	symptoms and ophthalmic examination for confirmation	Ethionamide Clofazimine Linezolid (severe)	Cataract, Macular degeneration, Diabetic retinopathy		
Immune Nephrotoxicity	Serum creatinine >2×baseline. Presence of Auto-antibodies in the blood is confirmatory	RIF, especially when restarted after stopping for few weeks	Urinary tract infection, Post streptococcal glomerulonephritis, Minimal change disease, Rapidly progressing glomerulonephritis	Patients should be counseled not to stop and restart rifampicin randomly,on their own	Consider drug withdrawal and refer tospecialist.
Flu Syndrome	By symptoms-Chills, malaise, dry cough, shortness of breath, loss of appetite, body aches and nausea	Frequent: RIF(specially with intermittent regimen)	Viral infections: Influenza, Dengue Fever: Dengue NS1 antigen test positive	Patients on daily regimen have reported lower frequency and less severe flu as compared to the patients on intermittent regimen	Oral antihistaminic and paracetamol, according to the symptoms
Arthralgia / arthritis	Joint pain, swelling involving one or more joints, High uric acid levels. Demonstration of tophi crystals in joint is confirmatory of Gout	Frequent & Severe: PZA Rare: EMB INH	Osteo-arthritis Rheumatoid arthritis	Early diagnosis and management can prevent progression and can improve quality of life	Therapy with paracetamol / NSAIDs can be used for pain relief as needed / Colchicine can be given in gout.
Thrombocytopenia	Blood platelet count <50000 mg/dl indicates thrombocytopenia, Drug induced thrombocytopenia is diagnosed by excluding other causes of	Frequent & Severe: RIF FQs Rare: INH EMB PZA AGs	Dengue hemorrhagic fever – Dengue NS1 antigen test positive Malaria – Peripheral blood smear, malaria antigen test Liver Cirrhosis – Liver biopsy Thrombotic Thrombocytopenic Purpura	Patients should be advised not to skip the doses of anti-TB drugs as the incidence of drug-induced thrombocytopenia has been reported to be higher when the drug is not taken continuously	Manage with platelet transfusion and consider withdrawal of suspect drug. It is important to remember that anti-TBdrugs can cause thrombocytopenia.

	thrombocytopenia	PAS Ethionamide Cycloserine Amoxicillin-clavulanate Clarithromycin Imipenem-cilastatin Linezolid	– Blood picture showing thrombocytopenia and hemolytic anemia with clinical symptoms Acute Leukemia – Bone marrow examination	As such thrombocytopenia cannot be prevented.Regular monitoring of platelet levels can facilitate early detection & thus, reduce the associated morbidity & mortality	
Leucopenia	Leucocyte count less than 2000/mm^3 Neutropenia: Absolute neutrophil count less than 1000/mm^3 Routine blood counts	<u>Rare:</u> INH EMB RIF FQs AGs Ethionamide Linezolid Amoxicillin-ClavulanateClarithromycin Imipenem-cilastatin	Typhoid, malaria, dengue, Rickettsial infections, HIV, thyroid disorders, aplastic anemia, rheumatoid arthritis, vitamin B12 or folate deficiency, mineral deficiencies of copper and zinc etc. Bone marrow diseases: Myelodysplastic syndrome, leukemia, Autoimmune disorders: SLE Bone marrow damage or suppression Drugs like: Clozapine, Valproate, Lamotrigine, Interferons, and Bupropion.	Monitoring of the complete blood count as indicated, will help in early identification. Avoid simultaneous administration of other drugs that can cause leucopenia.	If the total leucocyte count is <2000/ mm^3 or absolute neutrophil count < 1000/mm^3. **Refer the patient to specialist as this is serious.**
Nephrotoxicity	Serum creatinine more the twice the baseline with symptoms of Oliguria, Appetite loss, General ill feeling and fatigue	<u>Frequent & Severe:</u> **AGs** <u>Rare:</u> Linezolid	Chronic renal failure, Alcoholic ketoacidosis, Diabetic ketoacidosis, Metabolic acidosis, Urinary tract infection	Dose adjustment in patients with pre-existing renal disease, monitoring of renal function as indicated	Dose adjustment in patients with pre-existing renal disease. In cases of lack of response consider drug withdrawal and refer to specialist.

Hyperglycemia	Fasting blood sugar more than 160 mg/dl with polydypsia, polyphagia, polyuria.	Rare: RIF INH FQs Moxifloxacin Clofazimine	Hyperglycemia: Uncontrolled diabetes mellitus, Impaired glucose tolerance	Regular Blood sugar monitoring in high risk patients can help in early detection.	Individualized diet, exercise, patient educationand glucose-lowering therapies.
Hypoglycemia	Blood sugar less than 55 mg/dl with weakness, palpitation, loss of consciousness, seizures.	Rare: INH Ethionamide Clarithromycin	Hypoglycemia: Prolonged starvation, Pheochromocytoma, Cushing's syndrome	Regular Blood sugar monitoring in high risk patients for early detection	In case of severe hypoglycemia, withhold all hypoglycemic medications. Glucose to be given orally or I.V. as appropriate.
Hypothyroidism	TSH level >10 mIU/L with tiredness, increased sensitivity to cold, weight gain, constipation, depression, lethargy	Rare: PAS Ethionamide Cycloserine	Hypothyroid Goitre - TSH levels high Myxoedema - Hashimotos thyroiditis – Anti-thyroid antibodies Riedels thyroiditis - Antibodies	Early diagnosis, followed by prompt treatment can help to preventworsening.	All patients with TSH >10 mIU/L, whether symptomatic or not, should be started on Levothyroxine
Pseudomembranous colitis	Watery diarrhoeawith or without blood, associated with stomach cramps and highfever,stool examination	Frequent & Severe: Amoxicillin-clavulanate ClarithromycinI mipenem-cilastatin Linezolid Rare: RIF FQs	Viral diarrhea Bacterial diarrhea, Amoebic dysentery Malabsorption syndrome – Chronic condition accompanied with weight loss	Judicious use of antibiotics, use of probiotics	Vancomycin and metronidazole are effective. Refer to specialist. Consider withdrawal of the suspect drug.

Gynaecomastia	Clinical symptoms and biopsy	Rare: INH RIF Ethionamide	Lipomas, dermoid cysts, sebaceous cysts, ductal ectasia, hematomas, and fat necrosis FNAC will provide the clear diagnosis	Resolves after stopping anti-TB drugs	Reassure patient and in severe cases, withdraw suspect drug.
Pellagra-like syndrome	Based on clinical symptoms of Dementia, Dermatitis and Diarrhea	Rare: INH Ethionamide	Chronic alcoholism – Malnutrition Amino acid imbalance - Hypoalbuminemia	Supplementation with nicotinamide and pyridoxine	Check for compliance. Increase the dose of nicotinamide and pyridoxine if required.
QT prolongation Torsade de pointes Arrhythmia	QTc≥ 501 ms on at least two separate ECGs and or arrhythmia on ECG	Rare: FQs Moxifloxacin Clofazamine Linezolid Clarithromycin	Hypokalemia, Metabolic acidosis, Atrial fibrillation, atrial flutter, ventricular arrhythmia, Paroxysmal supraventricular tachycardia	ECG of patient on FQs as and when indicated	Refer to specialist for management

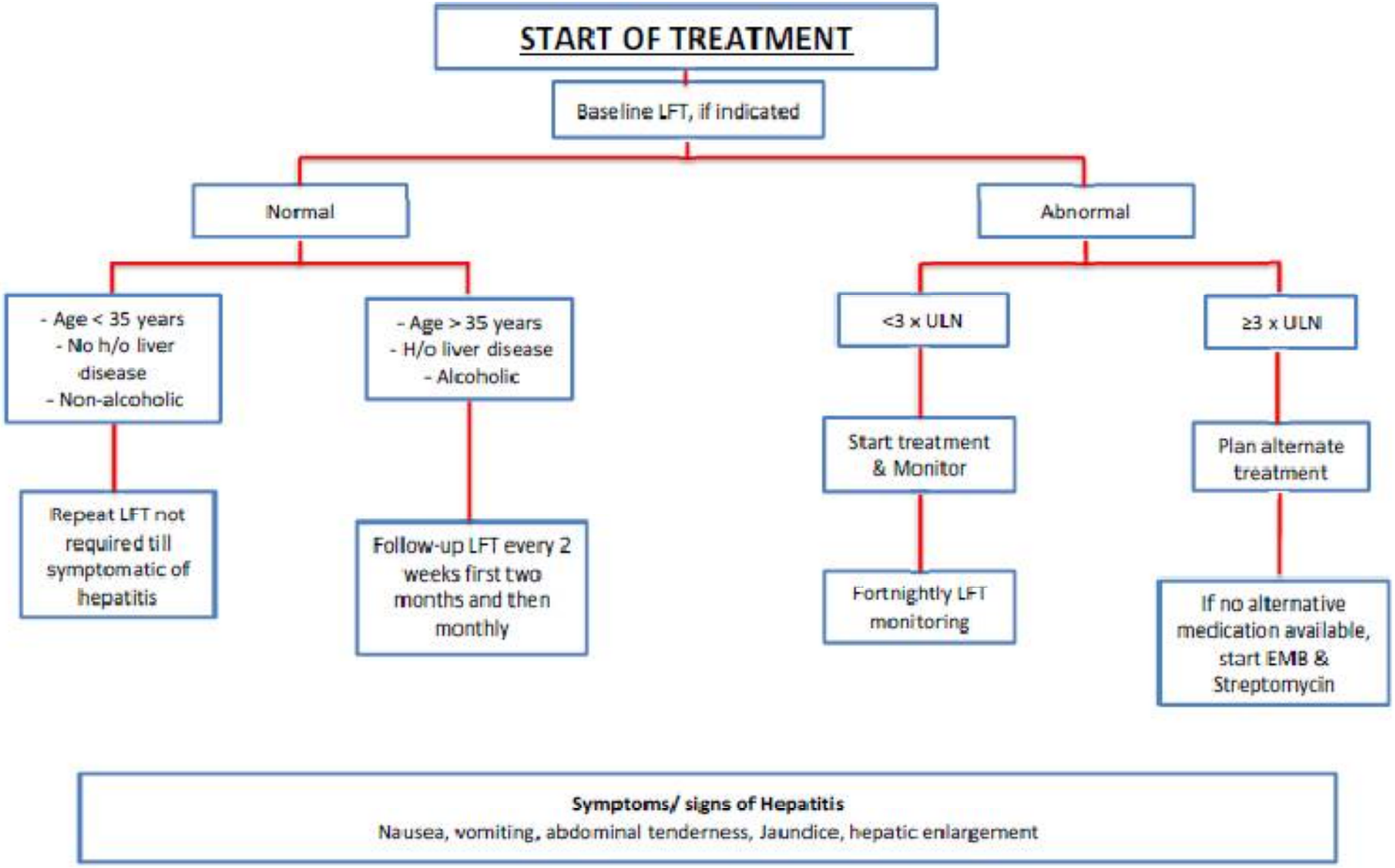
Pancreatitis, Peptic ulcer, Depression, Encephalopathy, Pneumonitis, Myopathy, Rhabdomyolysis, Congestive cardiac failure, Pericarditis have also been reported **rarely**with anti-TBdrugs.Peripheral neuropathy, anemia, thrombocytopenia, leucopenia and optic neuritis with Linezolid (2nd line drugs) can be sever and need immediate referral to specialist.
Frequent: Seen in 1-10% patients
Rare: Seen in less than 1% patients

Laboratory tests for TB patients:

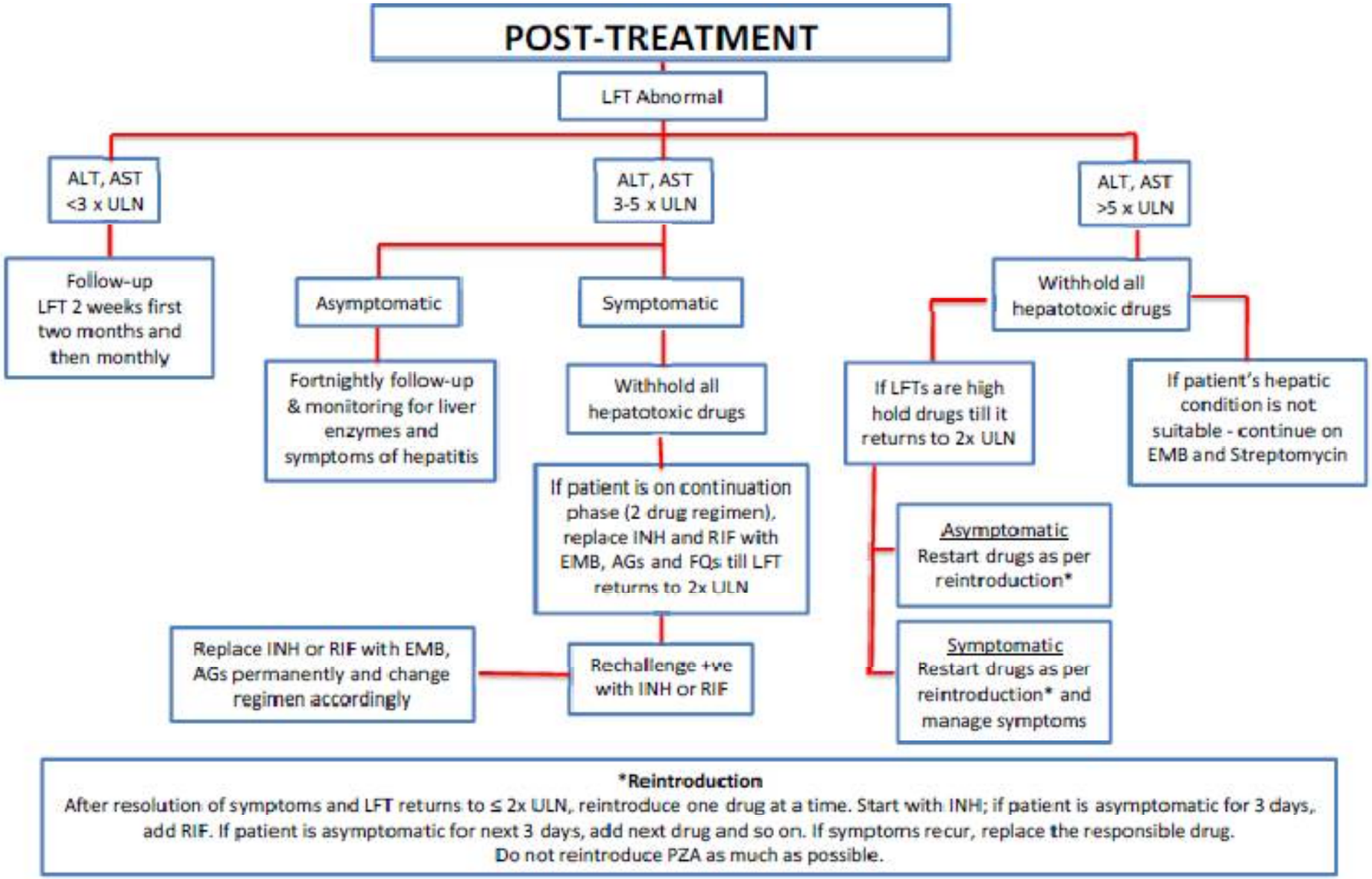
Time points	Laboratory tests
Baseline (Before initiating treatment if indicated)	1. LFT (ALT, AST, Serum bilirubin) 2. RFT (Serum creatinine, Blood Urea, Urine routine and microscopy) 3. Complete blood count, peripheral smear and Hb 4. Blood glucose: Fasting and post-prandial (Random in non-diabetics) 5. Total serum proteins, Albumin and Globulin 6. Serum uric acid 7. Serum electrolytes 8. Thyroid function tests (T3, T4 and TSH) 9. Ophthalmologic examination 10. Psychiatric consultation (before starting Cycloserine) 11. In females: Urine pregnancy test and USG of abdomen and pelvis
After 1.5 months	Ophthalmologic examination (for patients taking Ethambutol), if indicated
After 2 months of treatment as indicated	Tests 3 to 8 mentioned at the baseline will be repeated. Ophthalmologic examination: If EMB is stopped at or before 2 months, not required. If EMB is continued and ophthalmologic examination was not performed at 1.5 months, then it should be done.

Tests to be performed at 2 months will be repeated at 4 and 6 months if and as and when indicated.

Algorithm for the Management of Hepatitis: Flowchart 1:



Algorithm for the Management of Hepatitis: Flowchart 2



Warning symptoms for some serious adverse reactions:

Warning Symptoms	For Medical officer / General practitioner (GP): When to refer the patient
• Rash • Skin lesions on oral cavity, nose	If mucous membranes are involved OR rash is more than 1/10th of body surface area without mucous membrane involvement OR associated with fever and generalized swelling (edema); **refer to specialist / tertiary care center immediately.**
Pain in eye/s, Blurring of vision and Disturbance in color vision	Indicates **Eye toxicity.** **Refer the patient to specialist for evaluation.**
Loss of hearing / Diminished hearing, Ringing in the ears, Dizziness and Loss of balance	Indicates **Ear toxicity**. **Refer the patient to specialist** for evaluation.
Puffiness of face, Swelling over feet and Oliguria, Anuria	Indicates **Kidney toxicity**. Treat the symptoms and**refer the patient to specialist for evaluation.**
Hallucinations, Seeing abnormal things and Suicidal or abnormal thoughts or actions	Indicates **Psychiatric disturbances.** **Refer the patient to specialist** for evaluation.

Absolute contraindications of anti-TBdrugs:(Benefit – Risk) have to be carefully assessed.

Drug	Absolute contraindications	Reason
Rifampicin	With Saquinavir and Ritonavir	Potential for hepatotoxicity is increased. Rifampicin is CYP3A4 inducer and can decrease Saquinavir level and effect
Ethambutol	Optic neuritis	Ethambutol can cause optic neuritis
Pyrazinamide	Acute porphyria Gouty arthritis Hepatic diseases	Pyrazinamide can precipitate acute porphyria Can inhibit excretion of urates Can cause drug induced hepatitis
Neomycin Kanamycin, Tobramycin, Amikacin, Capreomycin, Streptomycin	Concurrent use of two aminoglycosides With potent diuretics e.g. Furosemide Soon after use of anesthetics and muscle relaxants	Can potentiate nephrotoxicity Can potentiate ototoxicity Can result in respiratory paralysis
Levofloxacin, Ofloxacin, Moxifloxacin	History of tendon disorders	Associated with risk of tendinitis and tendon rupture
Ethionamide	Severe hepatic impairment	Risk of worsening
Cycloserine	Epilepsy, Psychiatric illness-Depression, Severe anxiety, Psychosis Severe renal insufficiency	Can precipitate seizures Can lead to severe psychosis and depression Can lead to Cycloserine toxicity
Clarithromycin	With Pimozide, Astemizole With Lovastatin or Simvastatin Hypokalemia and in patients with prolonged QT interval	Risk of QT prolongation Can cause rhabdomyolysis Risk of further QT prolongation
Imipenem	With Valproic acid and Probenecid	Decrease in valproic acid concentration and Increase in plasma levels of imipenem
Linezolid	With Monoamine oxidases A or B inhibitors (e.g. phenelzine, isocarboxazid, selegiline, moclobemide) within two weeks	Risk of MAO inhibition leading to serotonin syndrome

Algorithm for reintroduction of anti-TB drugs - To be done by experts only:

Adverse drug reaction	Advice on reintroduction
Hepatotoxicity	• Reintroductionafter liver enzyme returns to ≤ 2 X ULN
Ocular toxicity	• Main suspect drug is EMB • Reintroduction of Ethambutol is not recommended
Immune mediated Nephritis	• Main suspect drug is RIF • Reintroduction with RIF is not recommended
Non serious cutaneous ADRs -no mucous membrane involvement or less than 10 % of BSA.	• After withholding all drugs reintroduce one drug at a time
Serious Cutaneous adverse drug reactions - mucous membrane involvement or more than 10 % of BSA.	• Reintroduction is not recommended (applies for all anti-TBdrugs).
Immune thrombocytopenia	• Main suspect drug is RIF • Reintroduction with RIF is not recommended
Gynecomastia	• Symptoms takes long time to resolve (4-12 month) hence usually reintroduction is not required.
Aplastic Anemia	• Main suspect drug is INH • Reintroduction with INH is not recommended
Nephrotoxicity	• Main suspect drugs are AGs. • AGs can be reintroduced at low doses after the renal function returns to normal.
Ototoxicity	• Main suspect drugs are AGs. • Reintroduction of AGs is not recommended.
Cardiac arrhythmias including Torsede pointes (TdP)	• Main suspect drugs are FQs. • Reintroduction with FQs is not recommended.
Diarrhea	• Reintroduction is recommended with one drug at a time every fourth day, once diarrhea is resolved
Seizures	• Main suspect drugs are FQs. • Reintroduction with FQs is not recommended.
Psychosis	• Main suspect drugs iscycloserine. • Reintroduction with cycloserine can be done at low dose but if symptoms recur than completely discontinue the drug.

Stepwise increase in the dosage for Reintroduction

1. Reintroduction of anti-TB drugs:

Drug	Day 1	Day 2	Day 3
Isoniazid	50 mg	Full dose	Full dose
Rifampicin	75 mg	300 mg	Full dose
Pyrazinamide	250 mg	1000 mg	Full dose
Ethionamide / Prothionamide	125 mg	250 mg	Full dose
Fluoroquinolones	50 mg	200 – 250 mg	Full dose
Cyclosporine	125 mg	250 mg	Full dose
Ethambutol	100 mg	500 mg	Full dose
PAS	1 g	4 g	Full dose
Capreomycin	125 mg	500 mg	Full dose
Kanamycin	125 mg	500 mg	Full dose
Amikacin	125 mg	500 mg	Full dose

If the test dose of any drug causes a reaction, discontinue this drug, unless it is deemed essential to the regimen. If that is the case, desensitization can be considered.

2. Reintroduction of the drugs should be in hospitalized patients.

3. In patients with severe rash,dose increment should be slower than stated above.

4. For key drugs, Isoniazid, Rifampicin, Ethambutol, detailed desensitization protocol with very small dose and method of dosage preparation is available on the website (http://www.who.int/topics/tuberculosis/en/)

Commonly used ancillary medicines:

Management of adverse reaction often requires use of ancillary medicines to reduce or lessen side effects. Below is list of indications and commonly used medicines for management of adverse reactions.

Indication	Drugs
Nausea, vomiting, Stomach upset	Domeperidone, metoclopramide, prochlorperazine, promethazine, ondansetron
Heartburn, indigestion and acidity	H2-blockers (ranitidine etc.), proton pump inhibitors (omeprazole, pantoprazole etc) Antacid syrups and the antacids if prescribed should be takenat least 2 hours apart from anti-TB drugs
Oral candidiasis	Fluconazole, clotrimazole lozenges, nystatin suspension
Diarrhoea	ORS sachets
Prophylaxis of neurological complications of cycloserine and isoniazid	Pyridoxine (vitamin B6)
Musculoskeletal pain, Arthralgia, headaches	Give paracetamol / ibuprofen / aspirin/ diclofenac. If caused by fluoroquinolones, refer tospecialist immediately. Tendonitis can progress to tendon rupture.
Cutaneous reactions, itching	Hydrocortisone cream, calamine lotion
Systemic hypersensitivity Reactions	Antihistamines (diphenhydramine, chlorpheniramine, dimenhydrinate) Systemic corticosteroids (prednisone, prednisolone, Dexamethasone) are reserved only for very severe reactions
Bronchospasm	Inhaled beta-agonists (salbutamol, albuterol, etc.), inhaled corticosteroids (beclomethasone, etc.)
Hypothyroidism	Levothyroxine
Electrolyte wasting	Potassium and magnesium replacement therapy (oral formulations)
Depression	Selective serotonin reuptake inhibitors (fluoxetine, sertraline), tricyclic antidepressants

	(amitriptyline)
Severe anxiety	Lorazepam, diazepam, clonazepam
Insomnia	Any hypnotic
Psychosis	Haloperidol, thorazine, risperidone (consider benzotropine or biperiden to prevent extrapyramidal Effects), Buromazine, thioridazine
Seizures	Phenytoin, carbamazepine, valproic acid, phenobarbital
Peripheral neuropathy	Amitriptyline, gabapentin
Vestibular symptoms	Meclizine, dimenhydrinate, prochlorperazine, Promethazine

Ready Reckoner for Health Worker

Annexure 10

Important general instructions:

Common side effects of anti-TB drugs and their management

1. Ensure that patient completes full course of anti-TB therapy
2. Side effects of anti-TB drugs are important cause of patient stopping medication
3. Prevention and early detection of side effects are needed
4. Alcohol, smoking and use of illicit drugs increaseside effects
5. Relevant history, clinical examination and lab tests are important to evaluate risk factors and diagnosis of side effects at an early stage
6. For contraception, ask patientto seek advice from family health center as oral contraceptives are less effective with some anti-TB drugs
7. Educate, counsel and reassure patients for self-limiting side effects
8. Side effects and serious side effects requiring immediate action ⟶ **refer patients to Medical officer**
9. Report serious side effects to PvPI center (Procedure for reporting: Call your nearby PvPI center and provide complete information about side effect. Contact details of the nearest PvPIcenter are: Name of the Centre **-** _____;Contact no: _____;

   National toll free number:**1800 180 3024**)
10. Advice nutritious diet to TB patients
11. Advice patients about respiratory hygiene and provide information on preventing spread of TB (use facemask, tissue paper and cover face)

Ready Reckoner for Health Worker

Table 1: Some common and rare side effects of anti-TB drugs are as follows:

Common (Seen in 1-10% patients)	Rare (Seen in less than 1% patients)
Nausea, Vomiting, Gastritis, Hepatitis, Hypersensitivity reactions, Cutaneous reactions	Flu like syndrome, Peripheral neuropathy, Ocular toxicity, Dysglycemia, Gynaecomastia, Hypothyroidism, Joint related side effects, Tendinopathy and tendinitis, Myelo-suppression, Anaemia, Thrombocytopenia, Psychosis, Seizures, Prolongation of QT interval

Table 2: Symptoms, causative drugs and action to be taken by Health worker:

Symptoms	Which drugs cause	Action by Health Workers
Upper abdominal pain - Frequent	All oral anti-TB drugs	Indicates **gastritis.** Advise patients to increase fluid intake. Patients should not take antacids / acid lowering agents together with first line anti-TB drugs as it reduces the absorption of drugs. **Refer to Medical Officer**
Nausea, vomiting	All oral anti-TB drugs	Reassure patient. Advice patient to take drugs embedded in a banana. Give drugs with less water and over a longer period of time (e.g. 20 minutes). However, later in the day, patients should take sufficient water. **If above measures fail, refer to Medical Officer.**
Nausea, vomiting with yellowness of skin and dark colour urine	Mainly by Pyrazinamide, Rifampicin and Isoniazid	Indicates**Liver toxicity** **Refer to Medical officer urgently**
Loose motions frequency >4 times, liquid stools	Mainly by PAS, Ethionamide, Isoniazid, Rifampicin, Ofloxacin, Levofloxacin,	Counsel patients on food and personal hygiene. Advice 200 ml Oral rehydration solution (ORS) after every loose

	Moxifloxacin	stool to maintain hydration. **Refer to Medical officer**
Loose motions associated with dryness of skin and mouth, decreased urination, tiredness and sunken eyes	Same as above	Indicates**Dehydration(Serious)** **Refer to Medical officer urgently**
Itching / Rashes	Mainly by Ethambutol, Rifampicin, Streptomycin	Reassure patient **If rash persists, refer to Medical Officer**
Itching / Rashes involving very large body area or present in mouth, nose associated with swelling and fever	Mainly by Ethambutol, Rifampicin, Streptomycin	Indicates systemic involvement (**Serious**) **Refer to Medical officer urgently**
Tingling /burning /numbnessin hands and feet	Mainly Isoniazid, Cycloserine	Check that patient is taking Pyridoxine. **Refer to Medical officer.**
Pain in Joints	Mainly Pyrazinamide	Paracetamol can be given if only 1-2 joints are involved. Reassure patient that it is a self-limiting condition. If > 2 joints are involved or pain is not relieved, **refer to Medical officer.**
Impaired vision: Pain, Blurring of vision, Disturbance in color vision	Mainly Ethambutol	Indicates**Eye toxicity**. **Refer to Medical officer urgently**
Flu-like syndrome: Chills, dry cough, shortness of breath, loss of appetite, body ache, malaise	Mainly Rifampicin	Reassure patient. If not controlled, refer patient to **Medical Officer** for evaluation.
Swelling of face or legs, less or no urine	Amikacin, Kanamycin, Capreomycin, Streptomyin	Indicates**Kidney toxicity**. **Refer to Medical officer urgently**

Ready Reckoner for Health Worker

Seeing abnormal things, change of thoughts, suicidal thoughts	Mainly Cycloserine	Indicates **Psychiatric disturbances.** **Refer to Medical officer urgently**
Tiredness, lethargy, headache, giddiness, pale look, palpitations	Mainly Linezolid, Isoniazid, Rifampicin, Pyrazinamide, Ofloxacin, Levofloxacin, Moxifloxacin	Indicates**Anemia.** Patients can be advised rest in DOTS center post-dosing to avoid giddiness. Advice patients on nutrition Refer **to Medical Officer** for evaluation.
Ringing in ears, Loss of hearing, dizziness and loss of balance leading to recurrent fall	Mainly Streptomycin, Amikacin, Kanamycin, Capreomycin	Indicates**Ear toxicity.** **Refer to Medical officer urgently**
Slowness of activities, swelling of face, swelling in neck, disproportionate weight gain	Mainly PAS and Ethionamide	Indicates **Thyroid involvement.** **Refer to Medical officer urgently**
Pain and swelling in muscles and Tendons, difficulty in movement	Ofloxacin, Levofloxacin and Moxifloxacin	Indicates **Tendonitis** **Refer to Medical officer urgently**
Seizure: Convulsion	Isoniazid, Cycloserine, Ofloxacin, Levofloxacin, Moxifloxacin	**Refer to Medical officer urgently**
Orange and reddish color of urine sweat, phlegm (sputum), saliva or tears may be noticed. As this is quite common with rifampicin and reassure patients.		

Annexure 11

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by healthcare professionals

CDSCO
Central Drugs Standard Control Organization
Directorate General of Health Services,
Ministry of Health & Family Welfare, Government of India,
FDA Bhavan, ITO, Kotla Road, New Delhi
www.cdsco.nic.in

(AMC/ NCC Use only
AMC Report No.
Worldwide Unique no.

A. Patient Information

1.Patient Initials _____	2.Age at time of Event or date of birth ----------	3. Sex ☐M ☐ F 4. Weight ____Kgs

12. Relevant tests / laboratory data with dates

B .Suspected Adverse Reaction

5. Date of reaction stated (dd/mm/yyyy)
6. Date of recovery (dd/mm/yyyy)
7. Describe reaction or problem

13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)

14. Seriousness of the action
- ☐ Death (dd/mm/yyy)____
- ☐ Life threatening
- ☐ Hospitalization-initial or prolonged
- ☐ Disability
- ☐ Congenitial anomaly
- ☐ Required intervention to prevent permanent impairment / damage
- ☐ Other (specify)

15. Outcomes
- ☐ Fatal
- ☐ Continuing
- ☐ Recovering
- ☐ Recovered
- ☐ Unknown
- ☐ Other (specify)____

C.Suspected medication(s)

S.No	8. Name (brand and /or generic name)	Manufacturer (if known)	Batch No./ Lot No. (if known)	Exp. Date (if known)	Dose used	Route used	Frequency	Therapy dates (if known give duration)		Reason for use of prescribed for
								Date started	Date stopped	
i.										
ii.										
iii.										
iv.										

Sl.No As per C	9. Reaction abated after drug stopped or dose reduced					10. Reaction reappeared after reintroduction				
	Yes	No	Unknown	NA	Reduced dose	Yes	No	Unknown	NA	If reintroduced dose
i.										
ii.										
iii.										
iv.										

11. Concomitant medical product including self medication and herbal remedies with therapy dates (exclude those used to treat reaction)

D. Reporter (see confidentiality section in first page)

16. Name and Professional Address :_____
_____
Pin code : _____ E-mail _____
Tel. No. (with STD code): _____
Occupation _____Signature _____

17. Causality Assessment

18. Date of this report (dd/mm/yyyy)

ADVICE ABOUT REPORTING

- **Report adverse experiences with medications**
- **Report serious adverse reactions. A reaction is serious when the patient outcome is:**

  - death
  - life-threatening (real risk of dying)
  - hospitalization (initial or prolonged)
  - disability (significant, persistent or permanent
  - congenital anomaly
  - required intervention to prevent permanent impairment or damage

- **Report even if:**

  - You're not certain the product caused adverse reaction
  - you don't have all the details, however, point nos. **1, 5, 7, 8, 11, 15, 16 & 18** (see reverse) are essentially required.

- **Who can report:**

  - Any health care professional (Doctors including Dentists, Nurses and Pharmacists)

- **Where to report:**

  - Please return the completed form to the nearest ***Adverse drug reaction Monitoring Centre (AMC)*** or to ***National Coordinating Centre***
  - A list of nationwide AMCs is available at: http://cdsco.nic.in/pharmacovigilance.htm

- **What happens to the submitted information:**

  - Information provided in this form is handled in strict confidence. The causality assessment is carried out at Adverse Drug Reaction Monitoring Centres (AMCs) by using WHO-UMC scale. The analyzed forms are forwarded to the National Coordinating Centre through the ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Center in Sweden.

  - The reports are periodically reviewed by the National Coordinating Centre (PvPI). The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.

  - The information is submitted to the Steering

interventions that may be required.

Reaction Reporting Form

For VOLUNTARY reporting
of suspected adverse drug reactions by
health care professionals

Central Drugs Standard Control Organization
Directorate General of Health Services,
Ministry of Health & Family Welfare, Government of India
FDA Bhawan, ITO Kotla Road, New Delhi – 110002
www.cdsco.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

(PvPI)

***National Coordinating Centre*,**
Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare,
Govt. of India
Sector-23, Raj Nagar, Ghaziabad-201 002.Tel.:0120-2783400, 2783401, 2783392, FAX: 0120-2783311
E.mail: ipclab@vsnl.net

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not ex-
and will not disclose the reporter's identity in response to a request from the public. **Submission of a report does not constitute**

caused or contributed to the reaction.

Annexure 12 A

Line-List Of Persons Referred From ICTC To RNTCP

REPORTING MONTH: YEAR NAME OF ICTC: NAMEOF DISTRICT:

	TO BE COMPLETED BY ICTC COUNSELLOR							***TO BE COMPLETED BY the STS***					
1	***2***	***3***	***4***	***5***	***6***	***7***	***8***	***9***	***10***	***11***	***12***	***13***	***14***
Sr. No.	*PID NO*	*Complete Name & Complete Address*	*Age*	*Sex*	*HIV status (R / NR / Unknown)*	*Date of referral to RNTCP*	*Name of facility referred to*	*Is patient diagnosed as TB –Yes or No*	*If diagnosed as TB, specify type of TB and basis of diagnosis*	*Is patient initiated on RNTCP treatment*	*Date of Starting Treatment*	*TB No.*	*Remarks*
	Sign of Counsellor *Date of completion:*					*Sign of MO- ICTC*		*Name of the TU:* *Signature of STS* *Date of Completion:*			*Signature of DTO/CTO/MO-TU*		

Basis of diagnosis – Microbiologically confirmed, Clinically diagnosed

Type of TB – Pulomary, Extrapulomary

Annexure 12B

ICTC TB-HIV monthly report

REPORTING MONTH: _____ *YEAR _____*

NAME OF ICTC:_____ *DISTRICT:_____*

I. TOTAL NUMBER OF GENERAL CLIENTS ATTENDING ICTC:

a) Total no. of clients who attended ICTC in the month (excluding PPTCT clients)	

II.REFERRAL OF PRESUMPTIVE TUBERCULOSIS CASES FROM ICTC TO RNTCP

	HIV positive	HIV Negative
a) No. of persons presumptive diagnostic services		
b) Of the referred presumptive TB patients, No. diagnosed as having:		
(i) Pulmonary TB (Microbiologically confirmed)		
(ii) Pulmonary TB (Clinically diagnosed)		
(iii) Extra-Pulmonary TB (Microbiologically confirmed)		
(iv) Extra Pulmonary (Clinically diagnosed)		
c) Out of above (b), diagnosed TB patients, number receiving RNTCP treatment		

Signature of Medical Officer – In charge ICTC*Name of Medical Officer In-charge ICTC*

HIV-TB Line List (Referrals)

Annexure 13 A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	19	20	20	21
Date of Registration in HIV Care *(dd/mm/yyyy)*	HIV Registration Number	Name	Date of Birth (or Age)	Sex (M/F/TG)	Contact Number	Address - Block, District, State	Status at the time of referral (Pre-ART/ART)	ART Number *(If on ART at time of referral)*	Symptoms Present[1] *(You can select more than one symptoms)*	Whether any past history of TB? (Y/N)	Date of referral for TB Examination (dd/mm/yyyy)	Type, Name of facility where referred to *(Give code and name of all facilities)*[2]	Date of sample	Testing details		Drug Resistance status[4] Mention drug to wich the TB resistant to	Type of TB diagnosed[5]	Date of final diagnosis (dd/mm/yyyy)	If drug resistant TB, then date of referral to DRTB center? (dd/mm/yyyy)	Name of DRTB center where the patient has been referred for treatment	Date of starting ATT (dd/mm/yyyy)	Type of treatment (Category I/II/IV/V)	TB Number / NIKSHAY ID	Place of registration
														Type of test & Result[3] *(Enter all test results)*	Date of test (dd/mm/yyyy)										

Note:

1. (A)Cough of any duration, (B)Low grade fever, (C)Weight Loss, (D)Night sweats, (E)Lymph Nodes, (F) Anorexia, (G)Others: Specify
2. (A)DMC, (B)CBNAAT, (C)DST, (D)Radiology, (E)Histopathology, (F)ART Center, (G)Others
3. For type of test details enter code of test and corresponding test results
   (c)Invalid*(d)Error*(e)No result* (*not conclusive results, need repeat test), (ii)CBNAAT (Rif Resistance) - (a)RR(b)RS(c)Indeterminate, (iii)Smear- (a)Positive(b)Negative
   (iv)Culture-(a)Positive(b)Negative,
   (vii)TST (for children under 5 years of age)-(a)Positive(b)Negative, (viii)Others (Specify)-(a)Positive(b)Negative
4. (i)First Line DST-RIF only/INH only/RIF and INH, (ii)Second Line DST-Ofloxacin, Capreomycin, Kanamycin, Ethambutol, Levofloxacin, Moxifloxacin
   Microbiological diagnosis through Culture, CBNAAT, Smear, TST and histopathology & **Clinical** diagnosis through X-Ray, USG etc. Kindly pick the relevant code from below -
   Microbiologically Microbiologically confirmed), (iv)Extra Pulmonary TB (Clinically diagnosed)

Annexure 13 B

3 b. HIV/TB -Intensified TB Case Finding				
TB Diagnosis & Treatment				
(From Completed HIV/TB Line-List- 1 month prior to reporting month)				
3b.1) Number of PLHIV attending ART Centre during the month (Pre ART and ART)				
3b.2) Out of above number of PLHIV screened for 4 symptoms				
3b.3) Out of above, number of PLHIV with presumptive TB (those with anyone/more symptoms out of 4S)				
3b.4) Out of above,number of PLHIV with presumptive TB referred from ART centre for TB diagnosis				
3b.5) Out of above, number of PLHIV with presumptive TB, tested for TB diagnosis				
3b.6) Out of the above number of PLHIV diagnosed as having TB :		**In Pre ART Care at time of TB diagnosis**	**Already on ART at time of TB diagnosis**	**Total**
	(i) (Microbiologically confirmed)			0
	(ii) Pulmonary TB (Clinically diagnosed)			0
	(iii) (Microbiologically confirmed)			0
	(iv) Extra Pulmonary (Clinically diagnosed)			0
3b.7) Total PLHIV Diagnosed with TB		0	0	0
3b.8) Out of **(3b.7)**,, number of TB patients receiving RNTCP treatment				
3b.9) Out of **(3b.7)**,, number of TB patients receiving Non-RNTCP treatment				
3b.10) Out of **(3b.7)**, number of TB patients with RRTB (Rif Resistant TB)				
3b.11) Out of **(3b.10)**, number of TB patients with RRTB (Rif Resistant TB) receiving Cat IV treatment				
3 c. Treatment of HIV in HIV TB co-infected PLHIV				
(From the HIV- TB register data -2 months prior to reporting month)				
3c.1) Total number of TB patients enrolled in HIV/TB register 2 months prior to reporting month				
3c.2) Out of **(3c.1)** number of TB patients initiated on CPT				
3c.3) Out of **(3c.1)** number of TB patients initiated on ART				
3 d. IPT Status (From Master Line List of Reporting Month)				
3d.1) Number of PLHIV newly initiated on IPT during this month				
3d.2) Number of PLHIV completed IPT during this month				

HIV TB Register (Confirmed)

Annexure 13 C

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
Date of Registration in HIV Care *(dd/mm/yyyy)*	HIV Registration Number	Name	Date of Birth (or Age)	Sex (M/F/TG)	Contact Number	Address - Block, District, State	From where the patient has been referred? (Pick appropiate code and provide name of facility)[1]	Testing details		Drug resistant Status	Type of TB diagnosed[5]	Date of final diagnosis	Patient category[4]	If DRTB, then date of referral to DRTB center	Date of anti TB treatment (ATT) initiation	If not initiated on ATT , reason for the same[9]	Type, Name of facility for TB treatment[6]	Weight band[7]	Type of treatment (Category I/II/IV/V)	NIKSHAY Number/ TB Number/ PMDT Number *(if applicable)* **Any one of these**	Date of treatment completion	If patient faced any side effects please mention (A)Toxicity (B)Others: Specify	If discontinued, date of discontinuation and reason for discontinuation[8]	Treatment outcome[9]	Is the patient on CPT? (Y/N)	Date of ART initiation	ART Registration Number	CD4 Count (A)Baseline (B)At the time of diagnosis (C)At the time of completion *(Provide all three counts)*		If not initiated on ART, reason for the same[10]	Remarks
								Type of test & Result[2] *(Enter all test results)*	Date of test																				Count	Date		

Note:

1.(A)Referred by ART center for TB diagnosis, (B)Referred by ICTC for TB diagnosis, (C)K/C/O TB referred by RNTCP to ICTC (D)Referred from private practioner/Other

2. For type of test details enter code of test and corresponding test results

(c)Invalid*(d)Error*(e)No result* (* not conclusive results, need repeat test) (ii)CBNAAT (Rif Resistance) - (a)RR(b)RS(c)Indeterminate, (iii)Smear - (a)Positive(b)Negative

(iv)Culture-(a)Positive(b)Negative,(v)First Line DST-RIF only/INH only/RIF and INH,(vi)Second Line DST-Ofloxacin, Capreomycin, Kanamycin, Ethambutol, Levofloxacin, Moxifloxacin

(vii)TST (for children under 5 years of age)-(a)Positive(b)Negative,(viii)Others (Specify)-(a)Positive(b)Negative

Microbiological diagnosis through Culture, CBNAAT, Smear, TST and histopathology & **Clinical** diagnosis through X-Ray, USG etc. Kindly pick the relevant code from below -

Microbiologically confirmed), (iv)Extra Pulmonary TB (Clinically diagnosed)

Microbiologicall)

Retreatment Others

6. (A).ART center (B) RNTCP, (C)Private institution, (D) DRTB, (E)Others

7.(A) <25kg, (B)25-39kg, (C)40-54kg, (D)55-69kg, (E) >70Kg

8.(A)Death, (B)LFU, (C)Transferred out, (D)Side effects, (E)Others: Specify

9.(A)Cured, (B)Treatment completed, (C)Died, (D)Treatment failure, (E) Lost to follo up, (F) Transfer out, (G)Switched over to MDR TB treatment(H)Others: Specify

5,10. (A)Patient transferred out to other ART center, (B)Patient not reporting for treatment/LFU,(C)Patient died before ATT/ART initiation,(D)Patient taking treatment in the private sector,(E)Others

Annexure 14 A

MONTHLY STOCK STATEMENT (MSS)

(REPORT SHOWING RECEIPTS & ISSUES OF ANTI-TB DRUGS AS AT)

State: State Drug Store:

Sl. No.	Drug	UOM	Opening Balance	Receipts		Total Stores	ISSUES		Balance Stores with DOE
				Receipts During the Month	Drugs Trfd. In		Store Supplied	Drugs Trfd. Out	
(a)	(b)	(c)	(d)	(e)	(f)	(g = d+e+f)	(h)	(i)	[j = g- (h+i)]
1	PC-1 Treatment box for New Cases	PWB							
2	PC-1 D-I Daily regimen treatment Box for New Cases (25-39kg)	PWB							
3	PC-1 D-II Daily regimen treatment Box for New Cases (40-54kg)	PWB							
4	PC-1 D-III Daily regimen treatment Box for New Cases (55-69kg)	PWB							
5	PC-1 D-IV Daily regimen treatment Box for New cases (≥70 Kg)	PWB							
6	PC-2 Treatment box for Re-Treatment Cases	PWB							
7	PC-2 D-I Daily regimen treatment Box for Re-Treatment Cases (25-39kg)	PWB							
8	PC-2 D-II Daily regimen treatment Box for Re-Treatment Cases (40-54kg)	PWB							
9	PC-2 D-III Daily regimen treatment Box for Re-Treatment Cases (55-69kg)	PWB							

Annexure 14 A

10	PC-2 D-IV Daily regimen treatment Box for Re-Treatment Cases (≥70 Kg)	PWB							
11	Prolongation Pouches	Pouch							
12	PC-5 Inj. Streptomycin 750 mg	Vials							
13	PC-5D-I Inj. Streptomycin 500 mg	Vials							
14	PC-5D-II Inj. Streptomycin 750 mg	Vials							
15	PC-5D-III Inj. Streptomycin 1 gm	Vials							
16	Pyrazinamide 750 mg	Tablet							
17	Rifampicin 150 mg	Caps							
18	Rifampicin 450 mg	Caps							
19	Isoniazid 100 mg	Tablet							
20	Ethambutol 800 mg	Tablet							
21	Isoniazid 300 mg	Tablet							
22	PC-13 Pediatrics Drug	PWB							
23	PC-14 Pediatrics Drug	PWB							
24	PC-15 Pediatrics Drug	Pouch							
25	PC-16 Pediatrics Drug	Pouch							

KEY: UOM: Unit of Measurement

Note: In the case of Inj. SM, please maintain stock at the rate of 24 injections for each PC-2 box and 56 injections for each PC-2 D-I/ PC-2 D-II / PC-2 D-III / PC-2 D-IV in stock

QUARTERLY REPORT ON PROGRAMME MANAGEMENT AND LOGISTICS **Annexure 14 B**
DTC Level: Medication

ADULT PATIENT WISE BOX

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during the quarter	Stock transferred in	Reconstitution of boxes during Quarter	Stock Transferred Out *	Patients started on treatment	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)= (c+d+e+f) - (g+h)	(j)= (h/3 x 7) - i
PC-1 Treatment box for New Cases	PWBs								
PC-2 Treatment box for Re-Treatment Cases	PWBs								

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during the quarter	Stock transferred in	Reconstitution of boxes during Quarter	Stock Transferred Out *	Patients started on treatment	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)= (c+d+e+f) - (g+h)	(j)= (h/3 x 5) - i
PC-1 D-I Daily regimen treatment Box for New Cases (25-39kg)	PWBs								
PC-1 D-II Daily regimen treatment Box for New Cases (40-54kg)	PWBs								
PC-1 D-III Daily regimen treatment Box for New Cases (55-69kg)	PWBs								
PC-1 D-IV Daily regimen treatment Box for New cases (≥70 Kg)	PWBs								
PC-2 D-I Daily regimen treatment Box for Re-Treatment Cases (25-39kg)	PWBs								
PC-2 D-II Daily regimen treatment Box for Re-Treatment Cases (40-54kg)	PWBs								
PC-2 D-III Daily regimen treatment Box for Re-Treatment Cases (55-69kg)	PWBs								
PC-2 D-IV Daily regimen treatment Box for Re-Treatment Cases (≥70 Kg)	PWBs								

Prolongation Pouches and Inj SM

Item	Unit of Measure-ment	Stock on first day of Quarter	Stock received during the quarter	Stock transferred in	Reconstitution during Quarter	Stock Transferred Out *	Consumption during the Quarter	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)= (c+d+e+f)-(g+h)	(j)= (h/3 x 7) - i
PC-4 (Prolongation Pouches)	Pouches each with 12 blister strips								
PC-5 Inj. Streptomycin 750 mg	Vials								
PC-5D-I Inj. Streptomycin 500 mg	Vials								
PC-5D-II Inj. Streptomycin 750 mg	Vials								
PC-5D-III Inj. Streptomycin 1 gm	Vials								

Paediatric Patient Wise Boxes (Including PWBs for Adult Patients <30kgs)

ITEM	Unit of Measure-ment	Stock on first day of Quarter	Stock received during the quarter	Stock transferred in	Reconstitution during Quarter	Stock Transferred Out *	Consumption during the Quarter	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)= (c+d+e+f)-(g+h)	(j)= (h/3 x 7) - i
Paediatric PC 13	Paediatric PWB								
Paediatric PC 14	Paediatric PWB								
Paediatric PC 15	Paediatric Prolongation Pouches								
Paediatric PC 16	Paediatric Prolongation Pouches								

RNTCP Loose drugs

ITEM	Unit of Measure -ment	Stock on first day of Quarter	Stock received during the quarter	Stock transf erred in	Stock Transfer red Out *	Consumption during the Quarter	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)= (c+d+e)-(f+g)	(i)= (g/3 x 7) - h
INH 300 mg	Tablets							
INH 100 mg	Tablets							
Rifampicin 150mg	Capsules							
Pyrazinamide 750 mg	Tablets							
Ethambutol 800 mg	Tablets						`	

Annexure 14 C

QUARTERLY REPORT ON PROGRAMME MANAGEMENT AND LOGISTICS

TU Level : Medications

Adult Patient Wise Boxes

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during the Quarter	Patients started on treatment	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)=(c+d)-e	(g)=(e/3 x 4) - f
PC-1 Treatment box for New Cases	PWBs					
PC-1 D-I Daily regimen treatment Box for New Cases (25-39kg)	PWBs					
PC-1 D-II Daily regimen treatment Box for New Cases (40-54kg)	PWBs					
PC-1 D-III Daily regimen treatment Box for New Cases (55-69kg)	PWBs					
PC-1 D-IV Daily regimen treatment Box for New cases (≥70 Kg)	PWBs					
PC-2 Treatment box for Re-Treatment Cases	PWBs					
PC-2 D-I Daily regimen treatment Box for Re-Treatment Cases (25-39kg)	PWBs					
PC-2 D-II Daily regimen treatment Box for Re-Treatment Cases (40-54kg)	PWBs					
PC-2 D-III Daily regimen treatment Box for Re-Treatment Cases (55-69kg)	PWBs					

PC-2 D-IV Daily regimen treatment Box for Re-Treatment Cases (≥70 Kg)	PWBs					

Prolongation Pouches and Inj SM

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during the Quarter	Patients started on treatment	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)=(c+d)-e	(g)=(e/3 x 4) - f
PC-4 (Prolongation Pouches)	Pouches each with 12 blister strips					
PC-5 Inj. Streptomycin 750 mg	Vials					
PC-5D-I Inj. Streptomycin 500mg	Vials					
PC-5D-II Inj. Streptomycin 750mg	Vials					
PC-5D-III Inj. Streptomycin 1 gm	Vials					

PAEDIATRIC PATIENT WISE BOXES (INCLUDING PWBS FOR ADULT PATIENTS <30KGS)

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during the Quarter	Patients started on treatment	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)=(c+d)-e	(g)=(e/3 x 4) - f
Paediatric PC 13	Paediatric PWB					
Paediatric PC 14	Paediatric PWB					
Paediatric PC 15	Paediatric Prolongation Pouches					
Paediatric PC 16	Paediatric Prolongation Pouches					

RNTCP Loose drugs

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during the Quarter	Patients started on treatment	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)=(c+d)-e	(g)=(e/3 x 4) - f
INH 300 mg	Tablets					
INH 100 mg	Tablets					
Rifampicin 150mg	Capsules					
Pyrazinamide 750 mg	Tablets					
Ethambutol 800 mg	Tablets				`	

Annexure 14 D

MONTHLY REPORT ON PROGRAMME MANAGEMENT AND LOGISTICS

PHI Level : Medications

Adult Patient Wise Boxes

Item	Unit of Measure ment	Stock on first day of month	Stock received during month	Patients initiated on treatment	Stock on last day of month	Quantity Requested
(a)	(b)	(c)	(d)	(e)	f= (c+d)-e	g= (e X 2) - f
PC-1 Treatment box for New Cases	PWBs					
PC-1 D-I Daily regimen treatment Box for New Cases (25-39kg)	PWBs					
PC-1 D-II Daily regimen treatment Box for New Cases (40-54kg)	PWBs					
PC-1 D-III Daily regimen treatment Box for New Cases (55-69kg)	PWBs					
PC-1 D-IV Daily regimen treatment Box for New cases (≥70 Kg)	PWBs					
PC-2 Treatment box for Re-Treatment Cases	PWBs					
PC-2 D-I Daily regimen treatment Box for Re-Treatment Cases (25-39kg)	PWBs					
PC-2 D-II Daily regimen treatment Box for Re-Treatment Cases (40-54kg)	PWBs					
PC-2 D-III Daily regimen treatment Box for Re-Treatment Cases (55-69kg)	PWBs					
PC-2 D-IV Daily regimen treatment Box for Re-Treatment Cases (≥70 Kg)	PWBs					

Prolongation Pouches and Inj SM

Item	Unit of Measurement	Stock on first day of month (a)	Stock received during month (b)	Consumption during the month (c)	Stock on last day of month (d)= (a+b)-c	Quantity Requested (e) = (c X 2) – d
PC-4 (Prolongation Pouches)	Pouches					
PC-5 Inj. Streptomycin 750 mg	Vials					
PC-5D-I Inj. Streptomycin 500mg	Vials					
PC-5D-II Inj. Streptomycin 750mg	Vials					
PC-5D-III Inj. Streptomycin 1 gm	Vials					

PAEDIATRIC PATIENT WISE BOXES (INCLUDING PWBS FOR ADULT PATIENTS <30KGS)

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during the Quarter	Patients started on treatment	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)=(c+d)-e	(g)=(e/3 x 2) -f
Paediatric PC 13	Paediatric PWB					
Paediatric PC 14	Paediatric PWB					
Paediatric PC 15	Paediatric Prolongation Pouches					
Paediatric PC 16	Paediatric Prolongation Pouches					

RNTCP Loose Drugs

Item	Unit of Measurement	Stock on first day of month (a)	Stock received during month (b)	Consumption during the month (c)	Stock on last day of month (d)= (a+b)-c	Quantity Requested (e) = (c X 2) – d
INH 300 mg	Tablets					
INH 100 mg	Tablets					
Rifampicin 150 mg	Capsules					
Ethambutol 800 mg	Tablets					

For MRPML of PHI-level, all information is available from the stock register of the PHI stores.

Annexure 14 E

Monthly Stock Statement for stocks at SDS Level
(To be submitted to CTD each month by SDS)

				Receipts during the month		Issues during the month						
Sr. No.	Nomenclature	A/U	Opening Balance	Receipt from Mfrs	Transfer In / Returns	Qty issued for boxes	Qty Issued to DRTB centre	Transfer Out	Balance Stock	DOM (One row for each drug)	DOE (One row for each drug)	Remarks
			(a)	(b)	(c)	(d)	(e)	(f)	(g)= (a+b+c-d-e-f)			
	Loose Drugs											
1	KANAMYCIN (Km) - 500 mg	Vials										
2	KANAMYCIN (Km) - 1000 mg	Vials										
3	LEVOFLOXACIN (Lfx)-250mg	Tabs										
4	LEVOFLOXACIN (Lfx)-500mg	Tabs										
5	CYCLOSERINE (Cs) -250 mg	Caps										
6	ETHIONAMIDE (Eto) - 125 mg	Tabs										
7	ETHIONAMIDE (Eto) - 250 mg	Tabs										
8	PYRAZINAMIDE (Z) - 500 mg	Tabs										
9	PYRAZINAMIDE (Z) - 750 mg	Tabs										
10	ETHAMBUTOL(E) - 200 mg	Tabs										
11	ETHAMBUTOL(E) - 400 mg	Tabs										
12	ETHAMBUTOL(E) - 800 mg	Tabs										
13	PYRIDOXIN-50mg	Tabs										
14	PYRIDOXIN - 100 mg	Tabs										
15	SODIUM PARA-AMINOSALICYLATE(NA PAS) 4gm Sachets (Box of 250 sachets)	Sachets										
16	SODIUM PARA-AMINOSALICYLATE (NA PAS) 10gm Sachets (Box of 100 sachets)	Sachets										
17	SODIUM PARA-AMINOSALICYLATE (NA PAS)-100gm jars	Box (100g)										
	Substitute Drugs											
18	CAPREOMYCIN (Cm)-750 mg	Vials										
19	CAPREOMYCIN (Cm)-1000 mg	Vials										
20	MOXIFLOXACIN (Mfx)-400mg	Tabs										

No.	Nomenclature	A/U	Opening Balance	Receipt during the month	Qty issued	Closing Balance	D.O.E (One row for each box)
			(A)	(B)	(C)	(D = A+B-C)	
	Monthly Patient Wise Boxes						
1	Type-A (<16 Kg Body Weight Patient)	Drug Boxes					
2	Type-A (16-25 Kg Body Weight Patient)	Drug Boxes					
3	Type-A (26- 45 Kg Body Weight Patient)	Drug Boxes					
4	Type-A (46-70 Kg Body Weight Patient)	Drug Boxes					
5	Type-A (>70 Kg Body Weight Patient	Drug Boxes					
6	Type-B (<16 Kg Body Weight Patient)	Drug Boxes					
7	Type-B (16-25 Kg Body Weight Patient)	Drug Boxes					
8	Type-B (26- 45 Kg Body Weight Patient)	Drug Boxes					
9	Type-B (46- 70 Kg Body Weight Patient)	Drug Boxes					
10	Type-B (> 70 Kg Body Weight Patient)	Drug Boxes					
11	Type-C (Na PAS)	Drug Boxes					

Weight Band	**< 16 kg**	**16-25 kg**	**26-45 kg**	**45-70 kg**	**>70 kg**
Number of MDR TB patients initiated on treatment during the month					

Monthly Stock Report for Stocks & Indenting of Cat IV drugs at DR-TB Centre
(To be submitted to SDS/STO by DOTS- PMDT Site)

Monthly Report showing the receipt & Issue of MDR Drugs as on _____Qtr ____ -(month/year) for DRTB Centre ..... DTC _____									
Sr.No	Nomenclature	A/U	Opening Balance	Receipt during the month	Qty issued	Balance Stock	D.O.M (One row for each drug)	D.O.E (One row for each drug)	Qty required
			(A)	(B)	(C)	(D= A+B-C)			(E=C x 2)-D
1	KANAMYCIN (Km) - 500 mg	Vials							
2	KANAMYCIN (Km) - 1000 mg	Vials							
3	LEVOFLOXACIN (Lfx)-250mg	Tabs							
4	LEVOFLOXACIN (Lfx)-500mg	Tabs							
5	CYCLOSERINE (Cs) -250 mg	Caps							
6	ETHIONAMIDE (Eto) - 125 mg	Tabs							
7	ETHIONAMIDE (Eto) - 250 mg	Tabs							
8	PYRAZINAMIDE (Z) - 500 mg	Tabs							
9	PYRAZINAMIDE (Z) - 750 mg	Tabs							
10	ETHAMBUTOL(E) - 200 mg	Tabs							
11	ETHAMBUTOL(E) - 400 mg	Tabs							
12	ETHAMBUTOL(E) - 800 mg	Tabs							
13	PYRIDOXIN-50Mg	Tabs							
14	PYRIDOXIN - 100 mg	Tabs							
15	SODIUM PARA-AMINOSALICYLATE(NA PAS) 4gm Sachets (Box of 250 sachets)	Sachets							
16	SODIUM PARA-AMINOSALICYLATE (NA PAS) 10gm Sachets (Box of 100 sachets)	Sachets							
17	SODIUM PARA-AMINOSALICYLATE (NA PAS)-100gm jars	Box (100g)							
	Substitute Drugs								
18	CAPREOMYCIN (Cm)-750 mg	Vials							
19	CAPREOMYCIN (Cm)-1000 mg	Vials							
20	MOXIFLOXACIN (Mfx)-400mg	Tabs							

Quarterly PMR for stocking & indenting of Cat IV drugs at DTC Level

(To be submitted to CTD & STO/SDS by District) State:DTC:_____Qtr-_____

Cat-IV Regimen - TU Level							
Monthly Patient Wise Boxes							
S.No	**Item**	**UOM**	**Stock on first day of the Qtr**	**Stock received during the Qtr**	**Consumption during the Qtr**	**Stock on last day of the Qtr** (c+d) –e	**Quantity Requested for DTC (e/3 x 5) – f**
	(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f)**	**(g)**
1	Type-A (<16 Kg Body Weight Patient)	Drug Boxes					
2	Type-A (16-25 Kg Body Weight Patient)	Drug Boxes					
3	Type-A (26- 45 Kg Body Weight Patient)	Drug Boxes					
4	Type-A (46-70 Kg Body Weight Patient)	Drug Boxes					
5	Type-A (>70 Kg Body Weight Patient	Drug Boxes					
6	Type-B (<16 Kg Body Weight Patient)	Drug Boxes					
7	Type-B (16-25 Kg Body Weight Patient)	Drug Boxes					
8	Type-B (26- 45 Kg Body Weight Patient)	Drug Boxes					
9	Type-B (46- 70 Kg Body Weight Patient)	Drug Boxes					
10	Type-B (> 70 Kg Body Weight Patient)	Drug Boxes					
11	Type-C (Na PAS)	Drug Boxes					

Quarterly PMR for stocking & indenting of Cat IV drugs at TU Level

(To be submitted to DTC by DOTS-PMDT implementing TU)D.T.C.TU: _____Qtr-_____

Cat-IV Regimen - TU Level							
Monthly Patient Wise Boxes							
S.No	**Item**	**UOM**	**Stock on first day of the Qtr**	**Stock received during the Qtr**	**Consumption during the Qtr**	**Stock on last day of the Qtr** (c+d) –e	**Quantity Requested for TU (e/3 x 4) – f**
	(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f)**	**(g)**
1	Type-A (<16 Kg Body Weight Patient)	Drug Boxes					
2	Type-A (16-25 Kg Body Weight Patient)	Drug Boxes					
3	Type-A (26- 45 Kg Body Weight Patient)	Drug Boxes					
4	Type-A (46-70 Kg Body Weight Patient)	Drug Boxes					
5	Type-A (>70 Kg Body Weight Patient	Drug Boxes					
6	Type-B (<16 Kg Body Weight Patient)	Drug Boxes					
7	Type-B (16-25 Kg Body Weight Patient)	Drug Boxes					
8	Type-B (26- 45 Kg Body Weight Patient)	Drug Boxes					
9	Type-B (46- 70 Kg Body Weight Patient)	Drug Boxes					
10	Type-B (> 70 Kg Body Weight Patient)	Drug Boxes					
11	Type-C (Na PAS)	Drug Boxes					

Monthly PMR for stocking & indenting of Cat IV drugs at PHI Level
(To be submitted to TU by DOTS- PMDT implementing PHI)

D.T.C. **TU:** **PHI:** **Month-**

Cat-IV Regimen - PHI Level					
Monthly Patient Wise Boxes					
S.No	Item	UOM	Stock on first Day of the Month	Stock received during the Month	Consumption during the month
	(a)	(b)	(c)	(d)	(e)
1	Type-A (<16 Kg Body Weight Patient)	Drug Boxes			
2	Type-A (16-25 Kg Body Weight Patient)	Drug Boxes			
3	Type-A (26- 45 Kg Body Weight Patient)	Drug Boxes			
4	Type-A (46-70 Kg Body Weight Patient)	Drug Boxes			
5	Type-A (>70 Kg Body Weight Patient	Drug Boxes			
6	Type-B (<16 Kg Body Weight Patient)	Drug Boxes			
7	Type-B (16-25 Kg Body Weight Patient)	Drug Boxes			
8	Type-B (26- 45 Kg Body Weight Patient)	Drug Boxes			
9	Type-B (46- 70 Kg Body Weight Patient)	Drug Boxes			
10	Type-B (> 70 Kg Body Weight Patient)	Drug Boxes			
11	Type-C (Na PAS)	Drug Boxes			

Annexure 15 A

RNTCP Request Card for examination of biological specimen for TB

(Required for Diagnosis of TB, Drug Sensitivity Testing and follow up)

Patient Information			
Patient name		**Age (in yrs):_____**	**Gender: ☐ M ☐ F ☐TG**
Patient mobile no. or other contact no.		**Specimen Date of collection** (DD/MM/YY)_____	**☐ Sputum ☐ Other (specify)** _____
Patient address with landmark		**HIV Status: ☐ Reactive ☐ Non-Reactive ☐ Unknown**	
		Key populations:☐Contact of known TB Patient ☐ Diabetes ☐ Tobacco ☐ Prison ☐ Miner ☐ Migrant ☐ Refugee ☐ Urban slum ☐ Health-care worker ☐Other (specify) _____	

Name referring facility (PHI/DMC /DR-TB Centre /Laboratory/other): **Health Establishment ID (NIKSHAY): _ _ _ _**	**CDL NIKSHAY ID: _ _ - _ _ _ - _ - C - _ _ - _ _ _ _ _** **RNTCP TB Reg No. _____** **Or** ☐ Not Applicable
State: _____ District:_____Tuberculosis Unit (TU): _____	

Reason for Testing:

Diagnosis and follow up of TB	
Diagnosis (NIKSHAY ID_____)	Follow up (Smear and culture)
H/O anti TB Rx for >1 month: ☐ Yes ☐ No	RNTCP TB Reg No _____ NIKSHAY ID:_____
☐ Presumptive TB ☐ Private referral ☐ Presumptive NTM Predominant symptom _____ Duration _____ days	Regimen: ☐New ☐ Previously Treated Reason: ☐ End IP ☐ End CP Post treatment:☐ 6m ☐ 12m ☐ 18m ☐ 24m

Diagnosis and follow up Drug-resistant TB		
Drug Susceptibility Testing (DST)		Follow up (Culture)
☐ Presumptive MDR TB	☐ New ☐ Previously treated ☐ At diagnosis ☐ Contact of MDR/RR TB ☐ Follow up Sm+ve ☐ Private referral ☐ Discordance resolution	PMDT TB No _____ DR TB NIKSHAY ID: _____ Regimen: ☐Regimenfor INH mono/poly resistant TB ☐Regimenfor MDR/RR TB ☐ Modified Regimenfor MDR/RR-TB + FQ/SLI resistance ☐Regimenfor XDR TB ☐ Modified Regimenfor mixed pattern resistance ☐Regimenwith Bedaquiline for MDR-TB Regimen + FQ/SLI resistance ☐Regimenwith Bedaquiline for XDR-TB ☐Regimen with Bedaquiline for failures of regimen for MDR-TB ☐Regimen with Bedaquiline for failures of regimen for XDR-TB ☐Other Treatment ☐month☐ Week :_____
☐ Presumptive H mono/poly		
☐Presumptive XDR TB	☐ MDR/RR TB at Diagnosis ☐ ≥ 4 months culture positive ☐ 3 monthly for persistent culture positives (treatment month _____) ☐ Culture reversion ☐ Failure of MDR/RR-TB regimen ☐ Recurrent case of second line treatment ☐ Discordance resolution	

Test requested:

☐ Microscopy ☐ TST ☐ IGRA ☐ Chest X-ray ☐ Cytopathology ☐ Histopathology ☐CBNAAT ☐ Culture ☐ DST
☐ Line Probe Assay ☐ Gene Sequencing ☐ Other (Please Specify) _____

Requestor Name, Designation and Signature: _____
Contact Number:_____ Email ID:_____

Results: **CDL NIKSHAY ID**Generated: _ _ - _ _ _ - _ - C - _ _ - _ _ _ _ _

Microscopy(☐ZN☐Florescent)							
	Lab Sr. No	Visual appearance	Result				
			Negative	Scanty	1+	2+	3+
Sample A							
Sample B							

Date tested: _____ **Date Reported:**_____ **Reported by:**_____
(Name and Signature)

Cartridge Based Nucleic Acid Amplification Test (CBNAAT)

Sample	☐ A ☐ B
M. Tuberculosis	☐ Detected ☐ Not Detected☐ N/A
Rif Resistance	☐ Detected ☐ Not Detected☐ Indeterminate ☐ N/A
Test	☐ Error (Please arrange for fresh sample)

Date tested: _____ **Date Reported:**_____ **Reported by:**_____
(Name and Signature)

Culture (☐ LJ☐ LC)

Lab Sr. No	Results			
	Negative	Positive	NTM (write species)	Contamination

Date Result: _____ **Date Reported:**_____ **Reported by:**_____
(Name and Signature)

Line Probe Assay (LPA)

☐ Direct ☐ Indirect Lab serial _____

First line LPA

RpoB: — locus control: present absent

WT1: present absent **WT2:** present absent **WT3:** present absent **WT4:** present absent

WT5: present absent **WT6:** present absent **WT7 :** present absent **WT8 :** present absent

MUT1 (D516V): present absent **MUT2A (H526Y):** present absent **MUT2B (H526D):** present absent **MUT3 (S531L):** present absent

KatG: — locus control: present absent

WT1 (315): present absent

MUT1 (S315T1): present absent
MUT2 (S315T2): present absent

InhA:— locus control: present absent

WT1 (-15, -16): present absent **WT2 (-8):** present absent

MUT1 (C15T): present absent **MUT2 (A16G):** present absent
MUT3A (T8C): present absent **MUT3B (T8A):** present absent

Second line LPA

gyrA:-—

locus control: present absent

WT1 (85-90): present absent
WT2 (89-93): present absent
WT3 (92-97): present absent

MUT1 (A90V): present absent
MUT2 (S91P): present absent
MUT3A (D94A): present absent
MUT3B (D94N/Y): present absent
MUT3C (D94G): present absent
MUT3D (D94H): present absent

gyrB:—-

locus control: present absent

WT1 (536-541): present absent

MUT1 (N538D): present absent
MUT2 (E540V): present absent

rrs:—-

locus control: present absent

WT1 (1401-02): present absent
WT2 (1484): present absent

MUT1 (A1401G): present absent
MUT2 (G1484T): present absent

eis:—-

locus control: present absent

WT1 (37): present absent
WT2 (14, 12, 10): present absent
WT3 (2): present absent

MUT1 (C-14T): present absent

Final LPA Interpretation: —

MTB result MTB positive MTB Negative
RIF Sensitive Resistant Indeterminate**INH** Sensitive Resistant Indeterminate
Quinolone Sensitive Resistant Indeterminate**SLID** Sensitive Resistant Indeterminate

Date Result: _____ **Date Reported:**_____ **Reported by:**_____
(Name and Signature)

Drug Susceptibility Test (DST) results

Lab Sr. No	1st line drugs						SLI			FQ			Other										
	S	H1	H2	R	E	Z	Km	Cm	Am	Lfx	Mfx (0.5)	Mfx (2)	PAS	Lzd	Cfz	Eto	Cla	Azi					

Date Result: _____ **Date Reported:**_____ **Reported by:**_____
(Name and Signature)

R: Resistant; S: Susceptible; C: Contaminated; – Not done

Other tests for TB diagnosis

Test(Please Specify): _____
Result:_____

Date reported:_____ **Reported by:**_____
(Name and Signature)

REFERRAL SLIP SR NO xxxxx

(Referring health facility copy)

Date: .....Lab referred to : .....
Name of referring HF: .....
Name of Patient: .....
Age: ..... yrs Sex: M / F
Address of patient (with landmarks)

.....

.....

.....
Patient's / Contact person's Mobile number :

_ _ _ _ _ _ _ _ _ _
Kindly tick

- ☐ Cough.....days
- ☐ Fever.....days
- ☐ Loss of weight .....days
- ☐ Night sweat.....days
- ☐ Blood in sputum/ cough.....days

☐ Contact of TB / MDR TB

Stamp of HF Referred by (Name & Sign)

REFERRAL SLIP SR NO xxxxx

(Patient copy)

Date: .....Lab referred to : .....
Name of referring HF: .....
Name of Patient: .....
Age: ..... yrs Sex: M / F
Address of patient (with landmarks)

.....

.....

.....
Patient's/ Contact person's Mobile number :

_ _ _ _ _ _ _ _ _ _
Kindly tick

- ☐ Cough.....days
- ☐ Fever.....days
- ☐ Loss of weight .....days
- ☐ Night sweat.....days
- ☐ Blood in sputum/ cough.....days

☐ Contact of TB / MDR TB

Stamp of HF Referred by (Name & Sign)

REFERRAL SLIP SR NO xxxxx

(Lab Copy)

Date: .....Lab referred to : .....
Name of referring HF: .....
Name of Patient: .....
Age: ..... yrs Sex: M / F
Address of patient (with landmarks)

.....

.....

.....
Patient's/ Contact person's Mobile number :

_ _ _ _ _ _ _ _ _ _
Kindly tick

- ☐ Cough.....days
- ☐ Fever.....days
- ☐ Loss of weight .....days
- ☐ Night sweat.....days
- ☐ Blood in sputum/ cough.....days

☐ Contact of TB / MDR TB

Stamp of HF Referred by (Name & Sign)

Annexure 15 C

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME
Treatment Card

TB Notification No / NIKSHAY ID _____

State_____ City / District _____ TB Unit _____ PHI _____

Name _____Sex ☐ M ☐ F☐TGAge:____ Occupation_____ Socioeconomic status: APL/ BPL

Complete Address: House No. _____ Road: _____Ward/Village: _____ Town/City: _____ Taluka/Mandal:_____ District:_____

State: _____ Pin code _____ Important landmark:_____ Mobile:- _____Aadhar No. _____Area :Slum/Tribal/Migrant/Refugee

Name andAddress of contact person _____Mobile No. _____

Name of Treatment Supporter _____Designation _____Mobile No.: _____

Initial home visit by _____ Date _____Type of Treatment Adherence – DOT / Family DOT / ICT supported, specify _____ / Other ___

Date of onset of first symptom: Number of health care providers visited before diagnosis for current episode:

Disease Classification

☐ Pulmonary
☐ Extra Pulmonary
Site _____

Type of Patient

☐ New ☐Recurrent
☐ Transfer in ☐ Treatment AfterFailure
☐Treatment ☐ Others, previously treated
After LFU (Specify)_____

Basis of Diagnosis

☐Microbiologically confirmed
☐Clinical TB

Investigations (ZN / FM / CBNAAT / Liquid C / Solid C)	Lab	Lab. No.	Test result	Sample sent to CDST (date)	DST result
Pre-treatment					
End of Intensive Phase					
End of treatment					

H/O of Previous ATT:___ months of treatment___ months since end of last episode
Source of treatment:-❑ Public ❑ Private Previous regimen: _____

Other investigations (if any) with result

HIV related information

HIV Status: ❑Unknown❑Reactive❑NR Date_____ PID_____

CPT delivered on: (1) (2) (3) (4) (5) (6)

Initiated on ART: ☐ No ☐ Yes Date & ART No._____

Diabetes related information

Diabetes Status: ❑Unknown❑Diabetic❑Non-Diabetic

RBS_____ FBS_____

Initiated on ADT: ☐ No ☐ Yes Date & ADT No._____

Other co-morbidity

Details_____

Signature of MO with date _____

	<6yrs	>6yrs
No of household contacts		
No screened		
No with symptoms		
No evaluated		
No diagnosed		
No put on treatment		

No of children less than 6 years given chemoprophylaxis = _____

Name	Wt (Kg)	Dose (mg)	1	2	3	4	5	6

Addiction related information

Current Tobaccouser❑ Yes ❑ No
If yes,❑Smoking❑Smokeless Linked for cessation ❑ Yes ❑ No
If tobacco user, status of tobacco use at end of treatment ❑Quit❑ Not quit

H/o Alcohol intake❑ Yes ❑ No
If yes, linked for deaddiction❑ Yes ❑ No

Date of initiation of intensive phase _____ **Date of initiation of continuation phase** _____

Dosage frequency ❑ Daily ❑ Intermittent Drug formulations ❑ FDC ❑Combipack❑ Loose drugs Drug packaging ❑ PWB ❑ Strips

Weight Band: Adult: ☐ 25-39 Kg ☐ 40-54 Kg ☐ 55-69 Kg ☐≥70 Kg Pediatric: ☐4-7 Kg ☐8-11 Kg ☐12-15 Kg ☐16-24 Kg ☐ 25-39 Kg ☐30-39 Kg

Dosages: FDC / Combipack _____ per day Height_____ (cm)

Loose drugs							
	Dose						
	Pills						
		H	R	Z	E	S	

Mark✓when doses are taken under direct observation, ⊘ when the dose was not observed, O when missed the dose
Record CP from fresh line

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	Wt

Retrieval Actions for Missed Doses

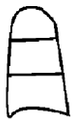
Date	By Whom	Whom contacted	Reason for missed doses	Outcome of retrieval action

Details of Adverse events

Date of adverse event	Details of symptoms	Action taken	Duration of management for adverse event	Outcome of adverse event

Post treatment follow up clinical & sputum

Follow up	Clinical	Sputum	CXR	Impression
6 mths of Rx				
12 mths of Rx				
18 mths of Rx				
24 mths of Rx				



Findings _____

Remarks

_____
_____
_____
_____
_____

Nutrition support (if any, give details) _____

Treatment outcome with date: _____ **signature of the MO with date:** _____

TB identity card

Name: _____

Sex ☐ M ☐ F ☐ TGAge:____

Address:_____

_____

_____

Contact No: _____

PHI _____ TU _____ District _____

NIKSHAY ID:_____

Name and designation of treatment supporter:

_____

Contact number and address of treatment supporter:

_____

☐ CPT ☐ ART ☐ Diabetic ☐ Smoker

Date of starting treatment: (DD/MM/YYYY)

Weight Band:

Adult: ☐ 25-39 Kg ☐ 40-54 Kg ☐ 55-69 Kg ☐ ≥70 Kg

Pediatric: ☐4-7 Kg ☐8-11 Kg ☐12-15 Kg ☐16-24 Kg ☐ 25-39 Kg ☐30-39 Kg

Site of Disease

☐Pulmonary
☐Extra pulmonary

Type of Patient

☐New
☐Recurrent
☐Treatment after Lost to Follow up
☐Treatment after Failure
☐Previously treated other
☐Transfer in

Treatment regimen:☐New
☐Previously treated

_____

Smear follow-up results			
End IP		End Rx	
Post Rx Month __		Post Rx Month __	
Post Rx Month __		Post Rx Month __	

Treatment outcome: _____

Date:_____

Appointment dates

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

In case of side effects or queries please contact

Name and contact number:

_____
_____

RNTCP PMDT Treatment Card

NIKSHAY ID	CDL NIKSHAY ID	PMDT NIKSHAY ID	PMDT TB No

Patient's name: _____

Age: _____yrsGender: ☐ Male ☐ Female ☐ Transgender

Address: _____

_____

Marital status: _____

Occupation: _____

Contact No: _____

Name, designation of treatment supporter:_____

_____

Contact no:_____

State:_____District: _____

TB Unit: _____ PHI:_____

Initial home v: Date _____By:_____

DR TB Centre:_____

Reason for Testing	
☐ New ☐ Previously Treated	
☐ Presumptive TB ☐ Private Referral ☐ Presumptive NTM	
☐ Presumptive MDR TB	☐ At diagnosis ☐Contact of MDR/RR TB ☐ Follow up Sm+ve at end IP ☐ Private referral
☐ Presumptive H mono/poly	
☐ Presumptive XDR TB	☐ MDR/RR TB at diagnosis ☐ ≥ 4 months culture positive ☐ 3 monthly, for persistent culture positives (treatment month _____) ☐ Culture reversion ☐ Failure of MDR/RR-TB regimen ☐ Recurrent case of second line treatment

☐ Transfer in from Other DR TB Centre

Name of DR TB Centre _____

PMDT NIKSHAY ID_____

HIV Testing: Date:_____ Result:_____ PID no._____

Date of starting CPT: _____ Date of starting ART:_____

Contact tracing:

No of household contacts				
No of members screened				
No of presumptive TB cases identified				
No of presumptive TB cases evaluated				
No diagnosed with TB				
No of DR-TB diagnosed				

TB Site: ☐ Pulmonary ☐ Extra Pulmonary If extra pulmonary, please specify _____

Treatment regimen

☐Regimen for INH mono/poly resistant TB☐Regimen for MDR/RR TB ☐ Modified Regimen for MDR/RR-TB + FQ/SLI resistance ☐Regimen for XDR TB ☐ Modified Regimen for mixed pattern resistance ☐Regimen with Bedaquiline for MDR-TB Regimen + FQ/SLI resistance☐Regimen with Bedaquiline for XDR-TB☐Regimen with Bedaquiline for failures of regimen for MDR-TB☐Regimen with Bedaquiline for failures of regimen for XDR-TB☐Regimen for mixed pattern resistance

Initiation Date: _____

Registration Date: _____

Drugs and Dosages																				
Drugs	H	R	E	Z	mK	mA	mC	xf L	xf M	s C	α E	$ AP	z L d	zf C	x mA vl c	rl C	QDB			
Dose (mg)																				

Patient eligible and consented for BDQ ☐ Yes ☐ No
If No, reason_____

Name & Signature of Treating Physician:_____

DR-TB Centre Committee meetings – dates and decisions

Date	Decision	Duration of indoor stay

Month of Treatment	Culture Results			Other Investigations					
	Date	Lab No	Culture	S. Cr	LFT	ECG*-QTC Interval	CBC/ Platelets	Electrolyte (K, Mg, Ca)	Urine Gravindex
Diagnosis									
1st week									
2nd week									
3rd week									
4th week									
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
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22									
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24									
25									
26									
27									
28									
29									
30									
31									
32									
33									
34									
35									

Patient's Name:_____

Blood Sugar Testing:

Date:_____

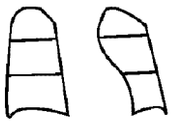
RBS:_____

FBS:_____

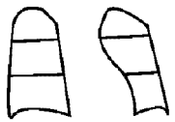
ADT*

(*write date of starting)

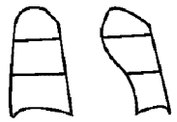
Thyroid Function Test		
Month	Zero	Six
Date		
T3		
T4		
TSH		



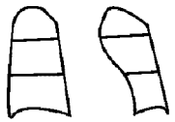
Date of X-ray
Findings_____



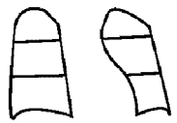
Date of X-ray
Findings_____



Date of X-ray
Findings_____



Date of X-ray
Findings_____



Date of X-ray
Findings_____

*ECG to be done daily (first two weeks), weekly (for 3 months) then monthly

Patient's name:_____

Initial Weight: _____kgs Height:_____cms

Weight band:

☐<16 Kg ☐ 16-25 Kg ☐ 26-45 Kg ☐ 46-70 Kg ☐>70 Kg

Date of starting intensive phase: _____

Date of starting continuation phase:_____

Details of rchange		
Date	Changed regimen	Reason for change

Drug Susceptibility Testing (DST) Results						
Drug	Date of specimen collection &type of DST (LJ/LC/LPA/CBNAAT)					
	Diagnosis	Month___	Month___	Month___	Month___	Month___
S						
H1						
H2						
R						
E						
Z						
Km						
Am						
Cm						
Lfx						
Mfx (0.5)						
Mfx(2.0)						
Eto						
PAS						
LZD						
CFZ						

ADMINISTRATION OF DRUGS (one line per month) **Patient's Name:**_____

Month/Yr	Day																													Weight in kg
	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	

Mark in the boxes: ✓= directly observed; (✓)Unsupervised; =◯gs not taken; X=initiation of new box; Recording of CP should start from fresh line.

Month/Yr	Day																													Weight in kg
	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	

Mark in the boxes: ✓= directly observed; ✓ = unsupervised; ◯ = drugs not taken; X=initiation of new box; Recording of CP should start from fresh line.

Date of retrieval action	By whom	Who contacted	Reason for missed doses	Outcome of retrieval action

Date of adverse drug reaction	Details of symptoms	Action taken

Treatment outcome	Date	Remarks
Cured		
Treatment completed		
Died		
Failed–Culture non conversion		
Failed – Culture reversion		
Failed – Additional drug resistance		
Failed – Adverse Drug Reaction		
Lost to follow up		
Regimen Change		
In remarks column, provide cause of death, reason for lost to follow up, latest TB no. in case of failure and put on treatment further		

Comments:

_____

_____

_____

_____

Name & Signature of Treating Physician:

_____

Post treatment follow up clinical & sputum				
Follow up	Clinical	Sputum	CXR	Impression
6 months of Rx				
12 months of Rx				
18 months of Rx				
24 months of RX				

RNTCP PMDT TB identity card

Name: _____

Address: _____

_____

_____

Contact No: _____

PMDT TB number: _____

PMDT NIKSHAY ID: _____

DR TB Centre: _____

District: _____

TB Unit: _____

DOT Centre: _____

Name of Treatment Supporter:

_____

Contact Number of Treatment Supporter:

_____

Treatment regimen: ☐ Regimen for H mono/poly resistant TB
☐ Regimen for MDR/RR TB
☐ Regimen for MDR/RR-TB + FQ/SLI resistance
☐ Regimen for XDR TB
☐ Regimen with Bedaquiline for MDR-TB + FQ/SLI resistance
☐ Regimen with Bedaquiline for XDR-TB
☐ Regimen with Bedaquiline for failures of regimen for MDR-TB ± FQ/SLI resistance
☐ Regimen with Bedaquiline for failures of regimen for XDR-TB
☐ Regimen for mixed pattern resistance

☐ CPT ☐ ART ☐ Diabetic ☐ Smoker

Date of starting treatment: (DD/MM/YYYY)

_____

Culture follow-up results			
Month __		Month __	
Month __		Month __	
Month __		Month __	
Month __		Month __	
Month __		Month __	
Month __		Month __	
Month __		Month __	

Treatment outcome: _____

Date: _____

Appointment dates

_____

_____

_____

_____

_____

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_____

_____

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_____

_____

_____

In case of side effects or queries please contact

Name and contact number:

_____

_____

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Referral / Transferform for treatment Serial Number

*To be filled **in** triplicate. One copy to be sent to the DTO receiving the patient, one copy to the health facility where the patient is referred to, and one copy to the patient*

Name and address of referring health facility _____

Contact Number and e-mail address of referring health facility: _____

Name and address of health facility to which patient is referred _____

_____

Name of patient_____ **Age**_____ **Sex M F TG**

Complete Address_____

_____**Contact no.**_____

Patient detail	
Site of disease ☐ Pulmonary ☐ Extra Pulmonary, Site _____ **Type of Patient** ☐ New ☐ Recurrent ☐ Transfer in ☐ Treatment After Failure ☐ Treatment After LFU ☐ Others, previously treated (Specify)_____ **Basis of Diagnosis** ☐ Microbiologically confirmed ☐ Clinical TB **H/O of ATT:** ___ months of treatment ___ months since end of last episode	**Diagnosis details** Date of diagnosis: __/__/___ Name of laboratory: Type of test: ZN / FM / CBNAAT / Culture Result : _____ TB notification number:_____ **HIV Status:** ☐ R ☐ NR ☐ Unknown **DST Status:** ☐ Rif Sensitive ☐ Rif Resistant ☐ Unknown, if unknown **Sample sent for DST to** _____ Date: __/__/__ **Treatment regimen:** ☐New☐Previously Treated **Date of treatment initiation: :** __/__/__ **Number of doses:**_____

Referred for:

- ☐ Initiation of treatment
- ☐ Adverse drug reaction (give details) _____
- ☐ Transfer out (give details)_____
- ☐ Any other (give details)_____

Name and designation of the referring doctor_____

Date referred

----------✂----------✂----------

Serial Number_____

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

Name of receiving health facility_____ Name of TB Unit and District_____

Name of patient _____ TB No (if available)_____

Age_____ Sex M ☐ F ☐ Date of receipt of patient_____

Date of initiation of treatment _____Treatment regimen_____ _____

Result of End IP specimen examination _____ Date of end IP specimen examination _____

Treatment outcome _____Date of treatment outcome _____

Signature_____Designation_____Date_____

This portion of the form has to be sent back to the referring unit as soon as the patient has been initiated on RNTCP treatment

Annexure 15 H

RNTCP PMDT Referral for treatment form

(Fill in duplicate. Send one copy to the concerned facility receiving the patient, and file the duplicate.)
Name and address of referring unit (District TB Centre/DR TB Centre):_____
e-mail address of referring unit: _____
Name of the facility where patient is referred: _____
Name of patient: _____ Age:_____ Gender: _____
Complete address:_____

Patient detail

Disease classification: ☐ Pulmonary
☐ Extra pulmonary (site_____)

Type: ☐ New ☐ Recurrent ☐TA LFU ☐ Failure ☐ Others

Reason for testing:
☐ New ☐ Previously Treated

☐ Presumptive TB
☐Private referral
☐ Presumptive NTM
☐Presumptive MDR-TB
☐ At diagnosis
☐ Contact of MDR/RR TB
☐ Follow up Sm+ve
☐ Private referral
☐Presumptive H mono/poly
☐ Presumptive XDR-TB
☐ MDR/RR TB at diagnosis☐ = 4 months culture positive☐ 3-monthly for persistent culture positives (treatment month _____)☐ Culture reversion☐ Failure of MDR/RR-TB regimen☐ Recurrent case of second line treatment

Latest TB No:_____

Latest regimen:
☐Regimen for INH mono/poly resistant TB
☐Regimen for MDR/RR TB
☐Regimen for MDR/RR-TB + FQ/SLI resistance ☐Regimen for XDR TB ☐Regimen with Bedaquiline for MDR-TB + FQ/SLI resistance
☐Regimen with Bedaquiline for XDR-TB
☐Regimen with Bedaquiline for failures of regimen for MDR-TB±FQ/SLI resistance
☐Regimen with Bedaquiline for failures of regimen for XDR-TB
☐Regimen for mixed pattern resistance

Sputum, culture and DST details

Date of culture result: __/__/___
Date of DST/LPA/CBNAAT result: __/__/___
DST/LPA/CBNAAT result* :
☐ S ☐ H1☐ H2☐ R ☐ E ☐ Z
☐ Km ☐ Am ☐ Cm
☐ Lfx ☐ Mfx (0.5) ☐ Mfx (2.0)
☐ Eto ☐ PAS ☐ LZD ☐ CFZ ☐ ___☐ ___☐___
(* Tick the drugs to which resistance is demonstrated)

DR TB treatment details

PMDT NIKSHAY ID: _____

DR TB Centre:_____

Date of DR TB regimen initiation: : __/__/__

Number of doses:_____

Date of regimen change and details of change: _____
Past exposure to second-line a-ntiTB drugs: Drugs (duration)_____
HIV Status: Pos Neg Not known Date of CPT initiation:_____ Date of ART initiation:_____
Date of referral to DR-TB Centre / DTC: Day _____ Month _____ Year _____

Referred for:
Initiation of treatment
Adverse drug reaction (give details) _____
Transfer out (give details)_____
Ambulatory treatment (if the patient is referred to DTC)
Any other (give details)_____
Name and designation of the referring doctor_____

Reminder for the health facility where the patient has been referred

Please send an e-mail to the referring unit, informing the referring doctor of the date that the above-named pa tient reported at the receivinghealth facility.

Revised National Tuberculosis Control Programme – TB Notification Register Year ___________ PHI_________

TB notification no. (NIKSHAY)	Name (in full)	Age	Sex (M/F/TG)	Complete Address	Pin code	Mobile/Landline Number	Key population#	Type of patient*	Site (P/EP)	Regimen N/PT /Outside RNTCP	Weight at beginning of treatment	Microbiological confirmation test results				Basis of diagnosis other than Microbiological (CXR/Histopatho/ Cytology/ Clinical/ /Other, specify)	HIV Status± (P/N/U)	Diabetes Status^ (D/N/U)	Date of sample sent for DST (NO if not sent, NA if not applicable)	Result of DST@	Status of treatment ***	Date of treatment initiation	Dosage Frequency (Daily / Intermittent)
												Date	Lab Name	Test (ZN / FM / Culture / CBNAAT)	Results of Test#								
	…………………………			………………………																			
	…………………………			………………………																			
	…………………………			………………………																			
	…………………………			………………………																			
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	…………………………			………………………																			
	…………………………			………………………																			
	…………………………			………………………																			
	…………………………			………………………																			

*** Type of patient (use complete words)**
New, Recurrent, Failure, LFU, Other PT, Transferred in

 # Test of result
For Smear result – Grades for smear positive, NEG for smear negative
For GX result – MTB detected Rif Resistance, MTB detected Rif sensitive, MTB detected Rif Indeterminate, MTB not detected, Error, Invalid, No result
For Culture result – Grades for culture positive, NEG for culture negative

± HIV Status
HIV status as reported before or during TB treatment P – Positive, N – Negative, U – Unknown.

^Diabetes Status
D=Diabetes, N=NonDiabetes, U = Unknown

@ Sensitive= if sensitive to tested drugs, Name of drug if resistant to any – R= Rifampicin, H=Isoniazide, E=Ethambutol, Z=Pyrazinamide, S=Streptomycin Lx=Levofloxacin, Mx=Moxifloxacin, Km=Kanamycin, Cm=Capreomycin

*****Status of treatment-**
1. Initiated on First line treatment in the same Health Facility
2. Initiated on second line treatment in the same Health Facility
3. Initiated on treatment outside Health Facility
4. Treatment initiated outside RNTCP
5. Incomplete/ incorrect address
6. Died
7. Migrated & untraceable
8. Repeat diagnosis
9. Patient already on treatment/ Follow up patient
10. Wrong diagnosis
11. Referred for treatment with pending feedback
12. Other

#Key population
PLHIV/Diabetes/Contact/Miner/Prison inmate/Health worker/Migrant/Refugee/Urban slum/Other, specify_____

Revised National Tuberculosis Control Programme – TB Notification Register Year_____ PHI_____

Follow-up smear examinations										Treatment Outcome#		If HIV-Pos		Post treatment follow up														Treatment supporter details		Remarks
End of IP					End of Treatment Exam									At 6 months Date____				At 12 months Date____				At 18 months Date____				At 24 months Date____						
Date	DMC Name	Smear result	Date of sample collected for DST	Result of DST@	Date	DMC Name	Smear results	Date of sample collected for DST	Result of DST@	Outcome	Date	CPT (y/n) date	ART (y/n) date	Symptoms*	CXR	Smear	Culture	Symptoms	CXR	Smear	Culture	Symptoms	CXR	Smear	Culture	Symptoms	CXR	Smear	Culture	Name	Designation	

Treatment Outcome –
Cured, Treatment Completed, Died, Lost to follow up, Failure, Not evaluated or Treatment change

± **Additional treatments if patient HIV-positive**
Required only for patients known to be HIV positive. If provided by any source during TB treatment, enter "Y" and approximate date. If not provided / unknown, enter "N".
***Symptoms-** Mention predominant system- Cough-C, Fever-F, Haemoptysis-H, Weight loss-W, Night Sweat - N Others-O, No symptoms - NS

Annexure 15J

RNTCP PMDT Treatment Register

Month _____Quarter _____ Year _____ District: _____ C-DST Lab: _____ DR-TB Centre:_____ State: _____

PMDT TB No	PMDT NIKSHAY ID	CDL NIKSHAY ID	Patient's name in full	Gender (M/F/TG)	Age in yrs	Complete address & mobile number	Name of health facility, TU, district	@ Reason for Testing	Site of Disease (P/EP)	Type (New, Recurrent, TALFU, Failure, Others)	DST Details																		
											Type (LJ/LC/ LPA/ CBNAAT)	Date of DST	Results																
													S	H	R	E	Z	Km	Am	Cm	Lfx	Mfx (0.5)	Mfx (2)	Eto	PAS	Lzd	Cfz	____	____

@ Presumptive TB – 1; Private referral – 2; Presumptive NTM – 3;

@ Presumptive MDR TB, At diagnosis–4; Contact of MDR/RR TB – 5; Follow up Sm+ve at end IP – 6; private referral – 7; Discordance resolution – 8; Presumptive H mono/poly –9; MDR/RR TB at diagnosis – 10; ≥ 4 months culture positive –11; 3-monthly for persistent culture positives –12; Culture reversion –13: Failure of MDR/RR-TB regimen –14; Recurrent case of second line treatment –15

Type of DR TB Patient RRTB/MDRTB/XDR TB	DRTB Regimen #	Date of Treatment initiation	Culture and DST Results at initiation and during DR TB Treatment (Treatment months)																														TB/HIV Collaborative activities					Final Treatment Outcome	Remarks
			0	3	4	5	6	7	9	12	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	Date of Test	PID No	HIV Status	Date of CPT initiation	Date of ART initiation		
			Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy	Culture dd/mm/yy							

#Cases put on:Regimen for H mono/poly resistant TB–**1;** Regimen for MDR/RR TB –**2;** Regimen for MDR/RR-TB + FQ/SLI resistance –**3;** Regimen for XDR-TB –**4;** Regimen with Bedaquiline for MDR-TB + FQ/SLI resistance–**5;** Regimen with Bedaquiline for XDR-TB–**6;** Regimen with Bedaquiline for failures of regimen for MDR-TB ± FQ/SLI resistance–**7;** Regimen with Bedaquiline for failures of regimen for XDR-TB – **8;** Regimen for mixed pattern resistance – **9**

Annexure 15 K

TB Laboratory Register

Lab. Serial No.	Date of collection of first specimen	Name in Full	Sex M/ F/TG	Age	Complete address (for diagnosis patients) Phone No.	Key Population	Name of referring health facility (PHI/ICTC/ART/Medical College / Private Others, specify)	Reasons for Examination								Type of specimen	Visual appearance	
											Follow-up						a	b
								Presumptive TB / RE / Presumptive NTM	Predominant symptom & its duration	History of >1 month ATT (Yes/No)	Nikshay ID	Regimen New / Previously Treated	Month	Post Treatment follow up month				

Notes

1. a- stands for supervised spot sample, b- stands for early morning sample
2. Remarks column can include date of starting treatment, treatment regimen, TB no., referral details with date, remarks on un blinded rechecking, etc
3. Visual appearance- mention M, B, or S., Mucopurulent, Blood stained or Saliva
4. Predominant symptoms: Cough-C, Fever-F, Haemoptysis-H, Weight loss-W, Night Sweat - N Others-O, No symptoms - NS
5. Key population - ☐Contact of TB/DRTB case ☐ Diabetes ☐ Tobacco ☐ Smoker ☐ Prison inmates ☐ Miner ☐ Migrant ☐ Refugee ☐ Urban slum ☐ Health-care worker ☐Other (specify) _____
6. Sensitive= if sensitive to tested drugs, Name of drug if resistant to any – R= Rifampicin, H=Isoniazide, E=Ethambutol, Z=Pyrazinamide, S=Streptomycin Lx=Levofloxacin, Mx=Moxifloxacin, Km=Kanamycin, Cm=Capreomycin
7. Duration of predominant symptoms should be recorded in days

Results		Date of Result	HIV status (Reactive / Non Reactive / Unknown)	Diabetic status (Diabetic /Non Diabetic / Unknown)	Sample for DST sent (Y/N) with date	DST result (write the drugs to which resistance is demonstrated)	NIKSHAY ID (notification no.)	Treatment initiation details (TB No. & TU details)/ Referral for treatment	Signature	Remarks
a	b									

Annexure 15 L

TB Laboratory Register

Lab. Serial No.	Date of collection of first specimen	Name in Full	Sex M/ F/TG	Age	Complete address (for diagnosis patients) Phone No.	Key Population	Name of referring health facility (PHI/ICTC/ART/Medical College / Private Others, specify)	Reasons for Examination								Type of specimen	Visual appearance	
											Follow-up						a	b
								Presumptive TB / RE / Presumptive NTM	Predominant symptom & its duration	History of >1 month ATT (Yes/No)	Nikshay ID	Regimen New / Previously Treated	Month	Post Treatment follow up month				

Notes

1. a- stands for supervised spot sample, b- stands for early morning sample
2. Remarks column can include date of starting treatment, treatment regimen, TB no., referral details with date, remarks on un blinded rechecking, etc
3. Visual appearance- mention M, B, or S., Mucopurulent, Blood stained or Saliva
4. Predominant symptoms: Cough-C, Fever-F, Haemoptysis-H, Weight loss-W, Night Sweat - N Others-O, No symptoms - NS
5. Key population - ☐Contact of TB/DRTB case ☐ Diabetes ☐ Tobacco ☐ Smoker ☐ Prison inmates ☐ Miner ☐ Migrant ☐ Refugee ☐ Urban slum ☐ Health-care worker ☐Other (specify) _____
6. Sensitive= if sensitive to tested drugs, Name of drug if resistant to any – R= Rifampicin, H=Isoniazide, E=Ethambutol, Z=Pyrazinamide, S=Streptomycin Lx=Levofloxacin, Mx=Moxifloxacin, Km=Kanamycin, Cm=Capreomycin
7. Duration of predominant symptoms should be recorded in days

RNTCP Laboratory Register for Culture, CBNAAT and Drug Susceptibility Testing

Rapid DST Results						Culture Results			Standard DST Results (R/S)																					Reporting of results		
Test performed (LPA/CBNAAT)	Date of receipt & CDL NIKSHAY ID	Valid* (Y/N)	TB † (Y/N)	RIF ‡ (R / S / I / N A)	INH (R/S/NA)	Type (LJ/LC)	CDL NIKSHAY ID	Results §	Type (LJ/LC)	Date of receipt & CDL NIKSHAY ID	Streptomycin	Isoniazid 1	Isoniazid 2	Rifampicin	Ethambutol	Pyrazinamide	Kanamycin	Amikacin	Capreomycin	Levofloxacin	Moxifloxacin (0.5)	Moxifloxacin (2.0)	Ethionamide	PAS	Linezolid	Clofazimine	Other _____	Other _____	Other _____	Date of reporting culture result	Date of reporting DST result	Remarks

* **Valid = Y** if both Amplification Control (AC) band & Conjugate Control (CC) band present; if either are missing, record **N**, and record no additional LPA results for this specimen.

† **TB = Y if** M. tuberculosis (TUB) band on LPA strip confirming identity as M. Tb or MTB Detected in CBNAAT, **N** if no TUB band on LPA strip or MTB Not Detected in CBNAAT

‡ **R** = Resistant, **S** = Sensitive, I = Indeterminate, **NA** = no result, judged by no locus control band on LPA strip for *rpo-B* (RIF), or for *inh-A* or *kat-G* (INH) or for *gyr-A* or *gyr-B* for FLQ or *eis* for ETH, or rrs for SLI. In case of CBNAAT, specify for NA, i.e. Error, Invalid, No Result

§ **Negative** = no growth, **Conta** = contaminated, **NTM** = Non-Tuberculosis Mycobacteria/fast grower, **3+** = confluent growth, **2+** = >100 colonies, **1+** = 10–100 colonies; **Sc#**Scanty<10 . Positive culture results should only be reported after identity for *M. tuberculosis* is confirmed with PNB, Niacin, Catalase, Rapid Immunoassay, or other methods.

Annexure 16

Monitoring Indicators

Sr. No.	Indicator name	Numerator	Denominator	Source of data	Remarks
1	Estimated incidence rate	Estimated incidence TB cases occurred in a year	Population in lac in year	State wide estimation by DHR	Annually
2	Estimated prevalence rate	Estimated number of TB cases prevalent in a year	Population in lac in year	State wide estimation by DHR	Annually
3	Estimated TB mortality rate	Estimated number of TB cases died due to TB in a year	Population in lac in year	State wide estimation by DHR	Annually
4	Estimated MDR-TB incidence rate	Estimated MDR-TB cases	Population in million in year	State wide estimation by DHR	
5	Estimated HIV-TB case incidence rate	Estimated HIV-TB cases	Population in lac in year	State wide estimation by DHR	
6	Annualized Total TB Case Notification Rate	All forms of TB Cases Notified during specified Period * multiplier to convert it annualized	Population in Lac in year	NIKSHAY	
7	Proportion of estimated incident TB cases notified	Number of TB cases notified	Estimated number of TB cases in a year	NIKSHAY	

8	New TB Case Notification Rate A)MicrobiologicallyConfirmed B)Clinically Diagnosed	Number of New TB Cases Notified during specified Period A) Microbiologically Confirmed B)Clinically Diagnosed	Population in lac in a year	NIKSHAY	
9	Recurrent TB Case Notification Rate A)Microbiologically Confirmed B)Clinically Diagnosed	Number of retreatment TB Cases Notified during specified Period A) Microbiologically Confirmed B)Clinically Diagnosed	Population in lac in a year	NIKSHAY	
10	Number of notified cases of all forms of TB - microbiologically confirmed plus clinically diagnosed, new and recurrent (By Age, SEX, HIV status)			NIKSHAY	
11	Proportion of microbiologically confirmed TB cases notified	Number of microbiologically confirmed TB cases notified	Total number of TB cases notified	NIKSHAY	
12	Presumptive TB Cases Examination Rate	Number of Presumptive TB Cases Examined during specified Period	Population in Lakh during mid of specified Period	NIKSHAY (PMR)	
13	Average time to diagnosis of TB patients from the onset of symptoms	Summation of (difference between date of onset of symptoms and date of diagnosis of TB)	Total number of TB patients diagnosed	E-NIKSHAY	
14	Average time to initiation of treatment from diagnosis	Summation of (difference between date of diagnosis and date of initiation of	Total number of TB patients initiated on treatment	NIKSHAY	

		treatment of TB)			
15	Proportion of New TB Cases with RR/MDR TB	Number of RR/MDR TB Cases diagnosed among New TB Cases during specified Period × 100	Number of New TB Cases Diagnosed during specified Period	NIKSHAY	
16	Proportion of patients reported any ADR affecting treatment during month (partially or complete discontinuation of treatment)	Total number of patients reported any ADR affecting treatment continuation.	Total number of patients on treatment	E- NIKSHAY	
17	Proportion of patients interrupted treatment (missed doses >3 doses) during month	Number of patients missed doses (>3 doses) during month	Total number of patients on treatment	E- NIKSHAY	
18	Proportion of TB patients screened for Diabetes	Number of TB patients screened for Diabetes	Number of TB patients notified	E-NIKSHAY	
19	Proportion of patients diagnosed with Diabetes	Number of TB patients diagnosed with Diabetes	Number of TB patients tested for Diabetes	E- NIKSHAY	
20	Proportion of TB-Diabetes patients linked with diabetes care services	Number of TB-Diabetes patients linked with diabetes care services	Number of TB-Diabetes patients notified	E-NIKSHAY	
21	Proportion of Paediatric Cases among Total TB Cases	Number of Paediatric TB Cases Notified during specified Period × 100	Number of Total TB Cases Notified during specified Period	E-NIKSHAY	
22	Proportion of pulmonary TB patients whose household contacts were screened for TB within one month of initiation of treatment	Number of pulmonary TB patients whose house hold contacts were screened	Number of TB patients registered for treatment one month prior	E- NIKSHAY	
23	Proportion of TB patients diagnosed out of household	Number of TB patients diagnosed during household	Number of household contacts screened for TB	E-NIKSHAY	

	contact screening	contact screening			
24	Proportion of eligible children given chemoprophylaxis for 6 months	Number of eligible children given chemoprophylaxis for 6 months	Number of children eligible for chemoprophylaxis	E-NIKSHAY	
25	Percentage of notified TB cases, all forms, contributed by non-NTP providers - private/non-governmental facilities	Number of TB cases notified by non-NTP providers	Number of TB cases notified in a period	NIKSHAY	
26	Number of TB cases (all forms) notified among key affected populations/high risk groups (HIV, prisoners/ migrants/refugees.IDPs)			E-NIKSHAY	

Interim outcome indicators

Sr. No.	Indicator name	Numerator	Denominator	Source of data	Remarks
1	Proportion of microbiologically confirmed patients converted	No. of microbiologically confirmed patients converted at end of 3 months	Total number microbiologically confirmed patients initiated on treatment 3 months prior	NIKSHAY	
2	Proportion of mono- / poly-drug resistant pulmonary TB patients converted	No. of mono- / poly- drug resistant TB patients converted at end of 6 months	Total number of mono- / poly- drug resistant TB patients initiated on treatment 6 month prior	E-NIKSHAY	
3	Proportion of RR/MDR pulmonary TB patients	No. of RR / MDR pulmonary TB patients	Total number RR / MDR pulmonary TB patients	E-NIKSHAY	

	converted at end of 6 months	converted at end of 6 months	initiated on treatment 12 month prior		
4	Proportion of RR/MDR TB patients died by 6 months	No. of RR / MDR TB patients died by 6 months	Total number RR / MDR TB patients initiated on treatment 12 month prior	E-NIKSHAY	
5	Proportion of RR/MDR TB patients lost to follow up by 6 months	No. of RR / MDR TB patients lost to follow up by 6 months	Total number RR / MDR TB patients notified 12 month prior	E-NIKSHAY	

HIV-TB

Sr. No.	Indicator name	Numerator	Denominator	Source of data	Remarks
1	Proportion of notified new and recurrent TB patients with documented HIV status	Number of notified new and recurrent TB patients with documented HIV status x 100	Number of new and recurrent TB patients notified	NIKSHAY	
2	Proportion of notified new and recurrent TB patients with documented HIV-positive status	Number of notified new and recurrent TB patients with documented HIV-positive status	Number of new and recurrent TB patientsnotified	NIKSHAY	
3	Proportion of HIV-positive new and recurrent TB patients on ART during TB treatment	Number of HIV-positive new and recurrent TB patients on ART during TB treatment	Number of HIV-positive new and recurrent TB patients notified	NIKSHAY	
4	Proportion of people living with HIV newly enrolled in HIV care and screened negative for TB, started on TB preventive therapy	Number of people living with HIV newly enrolled in HIV care and screened negative for TB, started on TB preventive therapy	Number of people living with HIV newly enrolled in HIV care and screened negative for TB	NACP (Patient visit register / monthly report)	

5	Mortality among HIV-positive new and recurrent TB patients	Number of HIV-positive new and recurrent TB patients died	Number of HIV-positive new and recurrent TB patients notified	NIKSHAY	
6	Risk of TB among health care workers relative to the general population, adjusted for age and sex	Number of TB patients notified per 100,000 health care workers in a year	Number of TB patients notified per 100,000 population in a year		
7	Proportion of people living with HIV in care who are screened for TB in HIV care or treatment settings *1.ICTC/FICTC* *2.ART* *3.TI settings* *4.CSCs*	Number of persons enrolled in HIV care whose TB status was assessed and recorded at their last visit during the reporting period	Number of persons enrolled in HIV care and seen for care during the reporting period	NACP (Patient visit register / monthly report)	
8	Proportion of people living with HIV who are TB symptom screen positive out of those who are screened for TB	Number of people living with HIV found to have anyone of the symptoms suggestive of TB	Number of people living with HIV who were screened for presence of TBsymptoms during their last visit to HIV care or treatment facility	NACP (Patient visit register / monthly report)	
9	Proportion of people living with HIV who are tested for TB out of those who are symptom screen positive	Number of people living with HIV who are investigated for TB	Number of people living with HIV who were TB symptom screen positive during the reporting period	NACP (HIV-TB line list / monthly report)	
10	Proportion of people living with HIV diagnosed with active TB out of those who are tested	Number of people living with HIV diagnosed as having active TB	Number of people living with HIV investigated for presence of active TB during the reporting	NACP (HIV-TB line list / monthly report)	

			period		
11	Proportion of people living with HIV who are started on TB treatment out of those diagnosed as having active TB	Number of people living with HIV started on TB treatment and registered in the TB register	Number of people living with HIV diagnosed to have active TB through intensified TB case finding	NACP (HIV-TB line list / monthly report)	
12	Proportion of people living with HIV having TB symptoms who receive a rapid molecular test (e.g. CBNAAT)as a first test fordiagnosis of TB	Number of people living with HIV having TB symptoms who were investigated using a rapid molecular test (e.g. CBNAAT) as a first test	Number of people living with HIV having TB symptoms identified through intensified case finding at HIV care and treatment facilities during the reporting period	NACP (HIV-TB line list)	
13	Proportion of HIV-positive new and recurrent TB patients detected and notified out of the estimated number ofincident HIV-positive TB cases	Number of HIV- positive new and recurrent TB patients registered during the reporting period	Estimated number of incident TB cases among people living with HIV (with low and high uncertainty bounds)		
14	Proportion of HIV-positive new and recurrent TB patients who receive co-trimoxazole preventive therapy	Number of HIV- positive new and recurrent TB patients notified during the reporting period who are started or continued on co-trimoxazole preventive therapy during TB treatment	Number of HIV- positive new and recurrent TB patients notified during the reporting period	NIKSHAY	
15	Proportion of health care facilities providing services for	Number of health care facilities having	Number of health care facilities evaluated	NIKSHAY	

	people living with HIV that have TB infection control practices	"demonstrable" TB infection control practices that are consistent with international guidelines	for TB infection control practices during the reporting period		
16	Proportion of people living with HIV who complete a course of TB preventive therapy	Total number of persons who completed the course of treatment for latent TB infection during the reporting period	Total number of persons in HIV care who were newly started on treatment for latent TB infection 12 to 15 month earlier	NIKSHAY	
17	Proportion of people living with HIV in care who ever received a course of TB preventive therapy	Number of persons who received at least one complete course of treatment for latent TB infection ever, by the end of the reporting period	Number of persons currently in HIV care at the end of the reporting period	NIKSHAY	
18	Proportion of presumptive TB patients having documented HIV status	Total number of presumptive TB patients who have a documented HIV test result	Total number of presumptive TB patients who are investigated for TB during the reporting period	E-NIKSHAY (PMR)	
19	Proportion of patients having multidrug-resistant or rifampicin-resistant TB with known HIV status	Total number ofmultidrug-resistant and rifampicin-resistant TB patientshaving documentedHIV status	Total number of multidrug- resistant and rifampicin- resistant TBpatients registered duringthe reporting	NIKSHAY	

			period		
20	Proportion of HIV-positive patients treated for multidrug-resistant or rifampicin-resistant TB who are also on ART	Number ofHIV-positive multidrug- resistant and rifampicin- resistant TB patientswhoare onsecond-line TBtreatmentand newlystartedor alreadyonART	Number of HIV-positive multidrug- resistant and rifampicin- resistant TBpatients registered duringthe reporting period	NIKSHAY	
21	Proportion of HIV-positive TB patients on protease inhibitor-based ART regimen receiving rifabutin-containing anti-TB treatment	Number of HIV-positive TB patients on protease inhibitor- based ART who received rifabutin-containing anti-TBtreatment regimen	Number of people living with HIV on protease inhibitor-based ARTwhoare diagnosedas havingactive TBduring thereporting period	NIKSHAY	

Drug resistant -TB

Sr. No.	Indicator name	Numerator	Denominator	Source of data	Remarks
1	Proportion of previously treated microbiologically-confirmed cases receiving DST at the start of treatment	No. of previously treated microbiologically-confirmed cases receiving DST at the start of treatment x 100	No. of previously treated TB cases notified	E-NIKSHAY	

2	Proportion of new microbiologically-confirmed cases receiving DST at the start of treatment	No. of new microbiologically-confirmed cases receiving DST at the start of treatment x 100	No. of new TB cases notified	E-NIKSHAY	
3	Proportion of Previously Treated TB Cases with RR/MDR TB	Number of RR/MDR TB Cases diagnosed among Previously Treated TB Cases during specified Period × 100	Number of Previously Treated TB Cases Diagnosed during specified Period	NIKSHAY	
4	Proportion of New TB Cases with RR/MDR TB	Number of RR/MDR TB Cases diagnosed among New TB Cases during specified Period × 100	Number of New TB Cases Diagnosed during specified Period	NIKSHAY	
5	Number of microbiologically confirmed, drug resistant TB cases (RR-TB and/or MDR-TB) notified (By Sex and Age)			NIKSHAY	
6	Proportion of diagnosed MDR-TB patients initiated on treatment	Number of MDR-TB patients initiated on treatment	Number of MDR-TB patients diagnosed	NIKSHAY	
7	Annualized MDR TB case notification rate	Number of MDR TB cases notified in a specified period x multiplier to convert annualized	Population in a year	NIKSHAY	
8	Proportion of estimated MDR TB cases notified	Number of MDR TB cases notified in a year	Estimated number of MDR-TB cases in a year		
9	Proportion of MDR-TB patients tested for second line Drug susceptibility at initiation of treatment	Number of MDR-TB patients tested for second line DST	Number of MDR-TB patients notified	E-NIKSHAY	

10	Proportion of MDR TB cases diagnosed as XDR TB	Number of MDR TB cases diagnosed as XDR	Number of MDR patients notified	NIKSHAY	
11	Proportion of diagnosed XDR TB cases put on treatment	Number of XDR TB cases started on treatment	Number of XDR TB cases diagnosed	NIKSHAY	
12	Proportion of MDR TB cases diagnosed with additional drug resistance	Number of MDR TB cases diagnosed with additional drug resistance	Number of MDR patients notified	NIKSHAY	

Outcome of treatment indicators

Sr. No.	Indicator name	Numerator	Denominator	Source of data	Remarks
	Drug sensitive patients				
1	Proportion of TB patients declared **(treatment outcome)** *Cured* *Treatment completed* *Successfully treated* *Died* *Failure* *Lost to follow up* *Regimen changed* *Not evaluated*	No. of TB cases declared **(treatment outcome)**	Total No. of TB patients registered in a quarter that ended 12 months prior	NIKSHAY	
2	Proportion of patients followed at 6 / 12 / 18 month after completion of treatment	No. of patients followed at 6/12 month after completion of treatment	Total number of patients who had completed treatment 6/12/18 months prior	E-NIKSHAY	
3	Proportion of TB patients **developing recurrence of TB**	No. of TB Patients developing recurrence	Total no. of Notified Patients completed	E-NIKSHAY	

	within 1 year of completion of treatment	of TB within one year of completion	treatment before one year prior		
4	Proportion of HIV-TB patients declared **(treatment outcome)** *Cured* *Treatment completed* *Successfully treated* *Died* *Failure* *Lost to follow up* *Regimen changed* *Not evaluated* **by Age / Sex / HIV status*	No. of HIV-TB cases declared **(treatment outcome)**	Total No. of HIV-TB patients registered in a quarter that ended 12 months prior	E-NIKSHAY	
	Drug resistant TB				
5	Proportion of DRTB Patients declared **(treatment outcome)** *Cured* *Treatment completed* *Successfully treated* *Died* *Failure* *Lost to follow up* *Regimen changed* *Not evaluated*	No. of DRTB Patients declared **(treatment outcome)**	Total No. of DRTB patients cohort registered 33 months prior	E-NIKSHAY	
6	Proportion of DRTB patients declared **Failure due to** *culture non-conversion at end of IP* *culture reversion in CP*	No. of DRTB cases declared Failure due to **(reason)**	Total No. of DRTB patients cohort registered 33 months prior	E-NIKSHAY	

	Additional drug resistance *Adverse drug reaction*				
	Drug resistance other than MDR				
7	Proportion of DRTB patients declared **(treatment outcome)** *Cured* *Treatment completed* *Successfully treated* *Died* *Failure* *Lost to follow up* *Regimen changed* *Not evaluated*	No. of DR-TB cases declared cured	Total No. of DR-TB patients registered in a quarter that ended 15 months prior	E-NIKSHAY	

Private sector indicators

Sr. No.	Indicator name	Numerator	Denominator	Source of data	Remarks
1	Proportion of private sector health facilities registered in NIKSHAY (health facility wise) - Single clinic - Multiple - Laboratory	Number of private health registered in NIKSHAY	Number of private health facilities in area	NIKSHAY	
2	Proportion of private sector health facilities notifying TB out of registered (health facility wise) - Single clinic - Multiple - Laboratory	Number of private health facilities notifying TB	Number of private health facilities registered	NIKSHAY	
3	Proportion of TB patients notified from private sector	Number of TB patients notified from private sector	Total number of TB patients notified	NIKSHAY	
4	Proportion of new and recurrent TB patients notified from private sector	Number of TB new and recurrent TB patients notified from private sector	Total number of new and recurrent TB patients notified	E-NIKSHAY	

5	Proportion of microbiologically confirmed among TB cases among total notified cases from private sector	Number of microbiologically confirmed TB patients notified from private sector	Total number of TB patients notified from private sector	NIKSHAY	
6	Proportion of the DRTB patients notified from private sector	Number of DR-TB patients notified from private sector	Total number of DR-TB patients notified	NIKSHAY	
7	Proportion of the pediatric TB patients notified from private sector	Number of pediatric TB patients notified from private sector	Total number of pediatric TB patients notified	NIKSHAY	
8	Proportion of TB patients (notified from private sector) with known HIV status	Number of TB patients (notified from private sector) with known HIV status	Total number of TB patients notified from private sector	NIKSHAY	
9	Proportion of previously treated TB patients (notified from private sector) received DST at the beginning of treatment	Number of previously treated TB patients (notified from private sector) received DST at the beginning of treatment	Total number of TB patients notified from private sector	NIKSHAY	
10	Proportion of new TB patients (notified from private sector) received DST at the beginning	Number of new TB patients (notified from private sector) received DST at the beginning of	Total number of TB patients notified from private sector	E-NIKSHAY	

	of treatment	treatment			
11	Proportion of TB patients declared (treatment outcome) *Cured* *Treatment completed* *Successfully treated* *Died* *Failure* *Lost to follow up* *Regimen changed* *Not evaluated*	Number of TB patients declared (treatment outcome) *Cured* *Treatment completed* *Successfully treated* *Died* *Failure* *Lost to follow up* *Regimen changed* *Not evaluated*	Total number of TB patients notified from private sector	E-NIKSHAY	

Review meeting Protocol for all Program staff

Level	Type of Review	Chairperson	Participants	Frequency
National	RNTCP performance review	DDG (TB)	STOs	Biannual
	Medical College performance review	DDG (TB)	ZTF members	Annual
	TB-HIV collaborative activities	DDG-TB	Members of National Working Group for TB-HIV collaborative activities	Quarterly
	Laboratory Committee	Chairperson Laboratory Committee / DDG (TB)	Members of Laboratory Committee	Biannual
	National DOTS-Plus Committee	Chairperson National DOTS- Plus Committee / DDG (TB)	Members of National DOTS-Plus Committee	Biannual
	National Technical Working Group (NTWG) for PPM Activities	Chairperson NTWG for PPM Activities / DDG (TB)	NTWG for PPM Activities members	Biannual
	National Operational Research Committee	Chairperson National OR Committee / DDG (TB)	National OR Committee members	Biannual
	National Airborne Infection Control (AIC) Committee Members	National AIC Committee Chairperson / DDG (TB)	National AIC Committee members	Biannual
Zonal	Medical College performance review	ZTF Chairperson	STF members	Annual
	RNTCP Performance Review including one day exclusively for PMDT activities	DDG (TB)	Regional Directors, STOs, DTOs of selected districts	Annual
State	State Health Society Review (RNTCP included as an agenda item)	PS (Health), MD-NRHM	Director Health Services, CMHO , All programme heads in state,	Quarterly

Level	Type of Review	Chairperson	Participants	Frequency
	RNTCP performance review	STO	DTO	Quarterly
	Performance review of Under-performing districts	STO	DTO	Biannual
	Medical college performance review	STO/ STF Chairperson	Nodal Officers from all medical colleges	Quarterly
	State Operational Research Committee Meeting	STO/ STF Chairperson	State OR Committee Members	Quarterly
	State TB-HIV Co-ordination committee meeting	PS (Health)	Members of State TB-HIV Cordination Committee	Biannual
	State Working Group Meeting for HIV/TB collaborative activities	PD-SACS / STO	Members of State Working Group for HIV/TB collaborative activities	Quarterly
	State DOTS-Plus Committee meeting	PS (Health)	State DOTS-Plus Committee members	Quarterly
	Review of RNTCP Accounting	State Accountant	District level Accountant	Biannual Review and One for PIP
	Review of Drug management	State Drug Store Manager	District Drug Storekeepers	Biannual
	Review of data management	State epidemiologist and state Statistical Assistant	District DEO/Statistical assistant	Biannual
	Workshop for Other Sector Health Facilities such as Railways, ESI, CGHS, Mines, etc...	STO	Representatives from Other sector Health facilities	Annual
	Review Meeting of Partners	STO	All Partners	Biannual
District	District Health Society Review (RNTCP included as an agenda item)	District Magistrate / Chairman District Health Society.	CMHO, All programme heads in district, Block Medical Officers, MO-PHIs (infrequently)	Quarterly

Level	Type of Review	Chairperson	Participants	Frequency
	CMHO Monthly Meeting with Block Medical Officers and MO-In charge PHCs (RNTCP included as an agenda item)	CMHO	All Block Medical Officers, MO-In-charge PHC, and Superintendent CHC.	Monthly
	RNTCP performance review	DTO	MOTC, STS and STLS	Monthly
	Medical college performance review	Core Committee Chairman of the respective Medical College	Core Committee Members of the respective Medical College and DTO	Quarterly
	TB-HIV District Coordination Committee meeting	Chairperson of TB-HIV District Coordination Committee	Members of District TB-HIV Coordination Committee	Quarterly
	Review of Drugs and Logistics	DTO and DTC Pharmacist	Pharmacists/Incharge Storekeeper of all TUs and PHIs	Quarterly
	DOTS-Plus site committee meeting	Chairperson/Coordinator DOTS-Plus site	DOTS-Plus site committee members, DTOs / Sr.DOTS-Plus-TB-HIV Coordinator	Monthly
	Workshop with Partners and other sector hospitals such as Railways, ESI, CGHS, IMA, AYUSH, NGOs, External funded projects etc…	CMHO/DTO	Representative from Partners	Biannual
	Review of TB-HIV collaborative activities along with RNTCP monthly meeting	DAPCU/DTO	ICTC/CCC Counsellors, STS,_DOT-Plus-TB-HIV Coordinator	Monthly
Block	Block Level Meeting with MO-In-charge PHI and other staff. (RNTCP included as an agenda item)	Block Medical Officer	MO-I/C-PHC and other staff.	Monthly
PHI	Monthly Meetings with Staff (RNTCP included as an agenda item)	MOIC, PHC	MPHS/ANM/MPW/ASHA	Monthly

Annexure I8 A

TB Notification reporting format for **Laboratory**

Period of reporting: From ...../...../..... To ...../...../.....

Health Establishment code for TB Notification

Name of the Laboratory :.....

Registration Number:..... Telephone (with STD):.....

...../.....

Mobile number:.....

Complete Address: .....

.....

Sr No	Name of TB Patient (surname first)	Father / Husband's name	Age (yrs)	Sex (M/F/O)	GoI issued identification number *	Complete residential address	PIN number	Patient Phone number	Date of TB Diagnosis	Date of sputum collection	Date of result	Type of Test result (smear microscopy positive / culture positive / MTB on LPA / MTB on Xpert / MTB in FNAC / TB on Histopath/ DST	DST results for each drug tested (R=resistant / S=sensitive/NA=not available) Rif, INH, SM, EMB, Ofx, Km, Eto, Cipro, Capr, etc $							
													Rif	INH	SM	EMB	Ofx	Km	—	—

*** Aadhaar, driving license, voter ID, ration card, PAN no, passport no etc**

Laboratories include those Health Establishments carrying out any of the RNTCP endorsed TB diagnostics

Signature:.....Date: ...../...../.....

Annexure I8 B

TB Notification reporting format for Medical practitioners / Clinics/Hospitals/Nursing homes

Period of reporting: From ...../...../..... To ...../...../.....

Name of the health facility / practitioner :.....(single/Multi)
Registration Number:..... Telephone (with STD):.....
Mobile number:.....
Complete Address: .....

Health Establishment code for TB Notification

...../.....

Sr No	Name of TB Patient (surname first)	Father / Husband's name	Age (yrs)	Sex (M/F/O)	GoI issued identification number *	Complete residential address	PIN no	Patient Phone number	Date of TB Diagnosis	Date of TB treatment initiation	Site of Disease (P / EP)	Patient Type (New TB case/ Recurrent TB case/ Treatment change)	Basis of diagnosis (Smear microscopy / culture / PCR / LPA/ FNAC/Histo-pathology/Clinical exam/X-Ray)	Weight in Kg	Drugs and dosages (in mg) H/R/Z/E/S/ O/K/Cs/Eto/ Levo/Mx/Cpr/ Other (specify)

*** Aadhaar, driving license, voter ID, ration card, PAN no, passport no etc**

Private practitioner / Clinic (single) will include any Health Establishments where TB cases are treated or diagnosed clinically / radiologically and the medical services are provided by single medical practitioner
Hospital / Clinic / Nursing Home (multi-practitioners) will include any Health Establishments where TB cases are treated or diagnosed clinically / radiologically & medical services are provided by more than one practitioner

Signature:.....Date: ...../...../.....

Page 1

TB Notification reporting format for
Medical practitioners / Clinics/Hospitals/Nursing homes

Period of reporting: From ...../...../..... To ...../...../.....

Health Establishment code for TB Notification

Name of the health facility / practitioner :.....(single/Multi)

Registration Number:..... Telephone (with STD):.....

...../.....

Mobile number:.....

Complete Address: .....

Patient ID	Patient home visit Done (Y/N)	If Yes, done by	Patient counselling Done (Y/N)	Type of treatment adherence (DOT/ SMS/ Phone/ Nil)	Status of patient (regular/ Not regular / defaulted)	Month at which FU examination done	Status at FU examination (SM/Cult) (Pos/Neg)	Clinical improvement (Yes/No)	No of contacts	No of contact symptomatic	No found to have TB among contact	No of contacts initiated on anti-TB treatment	No of contacts offered chemoprophylaxis	HIV testing offered (No/Neg /Pos)	DST testing offered (No/RIF resistance /RIF sensitive/ Indeterminate)	Treatment Outcome (C/TC /F/D /LTFU/TO /RC)

C=Cured, TC=Treatment Completed F=Failure D=Died LTFU=Lost to FollowUp TO=Transferred Out RC=Regimen Change

This information on page 2 is to be submitted during treatment and after treatment completion with sosupdation in Nikshay with public health action support by local public health staff.

Signature:.....Date: ...../...

Page 2

Financial Reporting requirements under RNTCP at various levels

Annexure 19

Level I-At State TB Cell

	Name of report	Basis of Preparation and Key Checks	Frequency/Timelines	Responsibility	Assisted by	To Whom
1	Financial Monitoring Report(FMR)	• Should be prepared from Book of Accounts • Only actual expenditures to be reported • Proper classification of expenditure/sub heads to be ensured	Quarterly, to be submitted within 21 days from the close of quarter.	STO/ APO	State accountants	FMG NHM , GoI with copy to CTD
2	Statement of Expenditure(SOE)	Consolidated SOE along with individual SOE of STCS, DTCS/MTCS	Quarterly, to be submitted within 21 days from the close of quarter.	STO	State accountants	CTD-MoHFW & State NHM
3	Statement of Fund position	To be submitted with FMR and SOE Should be duly reconciled with FMR, SOE and books of accounts	Monthly	STO	State accountants	CTD-MoHFW & State NHM
4	Utilisation certificate	Should be prepared sanction wise Should be as per Form 19A Final UC should be as per the expenditures certified in audit report	Annual By 31st July along with the audited statements	STO/APO	State accountants	CTD-MoHFW & State NHM
5	Statement confirming State's contribution	Should provide details of instruments indicating the fund transfer to STC through SHS NHM.	Quarterly	STO/APO	State accountants	CTD-MoHFW & State NHM
6	Preparation of Final Accounts	This will be prepared by STC for the purpose of Annual Audit		STO	State accountants	
7	Audited statement of accounts and Audit reports of STC	As per Audit Format given in NRHM Financial Manual	Annual , to be submitted by 31st July of following year	STO	State accountants	CTD-MoHFW & State NHM

- Format of all these will be provided in updated guideline for NRHM Financial Management for state and districts.
- Bank Reconciliation Statement should be submitted on a quarterly basis along with the FMR.
- Executive Summary of concurrent audit report should be submitted on a quarterly basis. This is being carried by NHM.

Level II - at district Level

	Name of report	Basis of Preparation and Key Checks	Frequency/Timelines	Responsibility	Assisted by	To Whom
1	Financial Monitoring Report(FMR)	• Should be prepared from Book of Accounts • Only actual expenditures to be reported • Proper classification of expenditure/sub heads to be ensured	Quarterly, to be submitted within 15 days from the close of quarter.	DTO	District accountant	State/State TB Cell
2	Statement of Expenditure(SOE)	SOE of District TB Cell	Quarterly, to be submitted within 15 days from the close of quarter.	DTO	District accountant	STC
3	Statement of Fund position	To be submitted with FMR and SOE Should be duly reconciled with FMR, SOE and books of accounts	Monthly	DTO	District accountant	STC
4	Utilisation certificate	Should be prepared sanction wise Should be as per Form 19A Final UC should be as per the expenditures certified in audit report	Annual By 21st July along with the audited statements	DTO	District accountant	STC
6	Preparation of Final Accounts	This will be prepared by STC for the purpose of Annual Audit		DTO	District accountant	
7	Audited statement of accounts and Audit reports of DTC	As per Audit Format provided in NRHM financial guidelines	Annual , by 21st July of following year	DTO	District accountant	STC

Guidelines on activities under ACSM

District teams must formulate ways to strengthen the planning and implementation of the programme initiatives listed below reported in the Quarterly Report on Programme Management and Logistics (QRPML). All efforts need to be made to ensure that the outcome of the initiatives listed below contribute to the achievement of programmatic objectives including better case finding, treatment adherence, notification etc.

Activities	Objective
Patient Provider Meetings	Patient support and improving case holding/treatment adherence
Community Meetings	Improving levels of awareness about TB in the community to improve referrals, adherence and address stigma
School-based activities	Improving levels of awareness, referrals
Sensitisation of PPs, NGOs, PRIs, Others	For advocacy, building allies for support, additional resources, improving case finding, case notification etc.
Outdoor Publicity	Improving levels of awareness about TB, referrals, adherence and addressing stigma etc.

Patient Provider Meetings

Facilitators: These meetings are organized by the DOT Provider. STS/ Medical Officer are to conduct these meetings. **Purpose:** The purpose of the meeting is to counsel patients in a group who are on treatment or who are about to begin treatment. This is an opportunity for free interaction between provider and patient and also an opportunity for patients to clarify their doubts, if any.

Target Group: Patients on treatment or who are about to begin treatment. There could be 5- 10 patients (minimum) in each such meetings. *(If there is large number of patients at one centre, small groups of about 10 patients may be made so that better interaction takes place between patients and providers*)

Place: These meeting are to be organized at the health facility. **Duration and Frequency**: These meetings can be organized once a month so that each patient who is on treatment has the opportunity to attend one such meeting during the intensive phase. ***(Frequency of such meeting would be more than one in a month when the number of patients is large at one health facility)***

Each meeting can be for half hour to one hour. The patient may be provided refreshments (tea etc.)

Kindly note that patient provider interaction meetings are additional to and are different from interpersonal communication that provider has with the patient while administering treatment.

Messages for Patients:

1. Basic information about tuberculosis, cough etiquette etc.
2. Importance of completing treatment
3. Side-effects of drugs and how to manage these
4. Importance of follow up sputum examination
5. Prophylaxis for children in the family
6. Do's and don'ts including protective measures, role of nutritious diet etc.

Health Communication Materials: Flip Book; Banner; Posters on TB etc.

Report writing: At the end of each meeting, a report may be prepared stating date and time of meetings, number of patients, name of facilitators and topic covered along with major concerned mentioned by the patients. The report is to be prepared by the STS. The list of patients who attended the meeting may be attached with the report. It may be more convenient to have register at each centre for such meetings and patients can put their name in the same register.

The STS should indicate organization of these meetings in their tour dairy indicating place, number of patients, presence of MO in the meeting and main points discussed in the meetings. These may be submitted by STS to MOTC on a monthly basis for onward submission to DTO to be included in quarterly PMR report.

Community Level Meetings

Facilitators: These meetings are organized by the STS and conducted by the Medical Officer.

Purpose: The purpose of the meeting is to create awareness about signs and symptoms of TB, availability of diagnosis and free treatment in the health facilities, availability of good quality drugs under the direct observation of the DOT provider. Provision of drugs in patient wise boxes, option of community DOT Providers can also be highlighted in these meetings.

Target Group: General public, patients, community leaders/ people's representative including SHGs, NGOs, Community Volunteers, Traditional healers, people practicing other systems of medicine. There should be at least 20-25 people in these meetings.

Place: These meeting are to be organized at the village or block level. These can be organized in the community centre, or any other important place in the community.

Duration and Frequency: These meetings can be organized once a month and each meeting could be for one hour to two hours.

The participants may be provided refreshments (tea/ snacks etc.)

Messages for Patients:

TB signs and symptoms; availability of diagnosis of good quality treatment in the health facility; location of nearest health facility; provision of drugs in patient-wise boxes; Importance of treatment under direct observation; Importance of completing of treatment; option of community DOT providers

(These may be given in the form of discussion, lecture. Street play can also be organized followed by discussion and question answer session)

Health Communication Materials:

Banner; Posters on TB; Pamphlets; mike; exhibition material; audio visual materials where possible

Report writing: At the end of each meeting a report may be prepared stating date and time of meetings, number of persons, name of facilitators and topic covered along with major concerned mentioned by the people. The report is to be prepared by the STS. List of persons who attended the meeting may be attached with the report.

STS should indicate organization of these meetings in their tour dairy indicating place, number of persons, presence of MO in the meeting and main points discussed in the meetings. These may be submitted by STS to MOTC on a monthly basis for onward submission to DTO to be included in Quarterly Report on Programme Management and Logistics (QRPML) or Programme Management Report.

School-based Activities

Awareness generation amongst students and teachers of schools and colleges regarding tuberculosis

Steps for organizing school activities

- ✓ Contact the department of school education at state/district level (whichever applicable) to bring them on board in the fight against TB.
- ✓ Take necessary approvals to enlist schools and colleges in the district.

- ✓ Organize training of trainers (TOT) for school teachers, who can also conduct school activities in a planned and coordinated manner to maximize impact. These can also be done in coordination with the school health programme.
- ✓ Display and distribute appropriate support materials like posters/charts/videos/pamphlets, etc. in local language that may be provided by the state government and for which the prototype may have been prepared by the centre.
- ✓ Help the schools utilize the opportunity innovatively by involving students in group activities like painting competitions, dramas/plays, road shows etc.

The initial visit to the school may include simple messages through quiz contests, games, essay writing, drawing and slogan competitions etc. on TB and related issues. Conclude the event with take home messages and how the students can participate in awareness generation; students and teachers can convey TB related key messages to parents, discuss the issue in the Village Health and Sanitation Committee meetings or with prominent people in the community etc. Some token gifts like pen, pencils, key rings, colour boxes, notebooks etc. can be distributed as prizes to the students.

The subsequent visit to the school/college can be done after 2-3 months to follow up and re-sensitization. Follow up visit should start with a quiz to gauge recall level of the information shared during the previous visit followed by planned activities and distribution of prizes.

In this context, following activities need to be carried out in time bound manner:

1. Issue letter with details from STOs to all the DTOs and municipal health officers, with copy to state/UT Education Director and CTD annually
2. DTO should ensure the preparation of block-wise enlisting of all the schools and colleges in the district to make sure no government/private school/college is missed out. For this purpose, DTOs can seek help from the District Education Officers.
3. Preparation of a detailed district specific action and monitoring plan containing – name of the district and block, name of the school, name of the health functionaries responsible to visit, date of visit, activity planned (specific), resource material required, name of the officials responsible for monitoring (monitoring on random basis covering nearer and remote areas). For this purpose can involve STS, Axshaya project and CBCI functionaries. The action and monitoring plan can be developed block-wise. At least 2 school activities should be monitored on monthly basis.
4. Submission of the district-wise action and monitoring plan by DTOs to the STOs.
5. Submission of the state/UTwise action and monitoring plan by STOs to the CTD.
6. Activity to be undertaken during the month of Aug/Sep 2012 (first visit) and Nov/Dec 2012 (second visit).
7. Submission of the district-wise report on outcome of the activity (covering both the visits) by DTOs to the STOs.

8. Submission of the state-wise report on outcome of the activity (covering both the visits) by STOs to the CTD.

Sensitisation of PRIs, NGOs, PPs etc.

Facilitators: These meetings are to be organized by the District PPM Coordinators/STS in consultation with DTO and other relevant cadres at the District and Sub-District levels.

Purpose: The purpose of these meetings/interactions is to create greater awareness about the need for public action on TB and generate specific commitment from target audience on how they would support TB control and care efforts.

Target Group: Elected representatives under the 3-tier Panchayati Raj System, community leaders, SHGs, NGOs, Community Volunteers etc.

Place: These meetings can be organized at the District, village or block level. These may be done individually, in groups or at any other available forums such as IMA meetings, hospitals/Clinics, NGO forums/offices, Gram Panchayat meetings etc.

Duration and Frequency: Meetings with each of these stakeholders must be organized a minimum one with each group per month. These meetings may be done individually but it is preferable to do this in groups.

Key Messages:

1. Facts about TB
2. RNTCP programme and services
3. The need to support the TB programme for a TB-free India

Health Communication Materials:

Banner, posters on TB, pamphlets, exhibition and audio visual materials where possible

Report writing: At the end of each meeting a report may be prepared stating date and time of meetings, number of persons met, name of facilitators and topic covered along with details of any commitments made by any participant. The report is to be prepared by the District PPM Coordinator/ STS. List of persons who attended the meeting may be attached with the report.

District PPM Coordinator/ STS should indicate organization of these meetings in their tour dairy indicating place, number of persons, presence of RNTCP officials/cadres in the meeting and main points discussed in the meetings. These may be submitted by District

PPM Coordinator to DTO and by STS to **DTO or MOTC** on a monthly basis for onward submission to be included in Quarterly Report on Programme Management and Logistics (QRPML) or Programme Management Report.

World TB Day

The World TB Day is observed each year globally on March 24. In India, numerous events and activities are organized at national, state, district, and community levels to draw public attention to TB as a major health problem and efforts being made under RNTCP for TB care and control. The World TB Day represents a worldwide call to action as well as helps mobilize political and social commitment at the national level. It is necessary to plan it well, to derive maximum benefit. As a major media event, the World TB Day provides a good opportunity to draw attention towards:

1. Good work done under RNTCP
2. Local/regional/national TB scenario to inform and emphasize the urgency
3. Role of different sections of society and service providers to bridge gaps
4. Gaps and what more needs to be done
5. Mobilize support of stakeholders and increase commitment from local leaders/health managers/ administrators to fight TB
6. Attract media attention/coverage to emphasize the urgency of TB control for wider understanding, support, and commitment
7. Co-opt new groups as partners such as businesses, private practitioners etc.
8. NGOs and professional bodies, which are important in the fight against TB

Plan for World TB Day at the start of the year while formulating the District Annual Action Plan and PIP.

Essential reading material:

1. Operational Handbook on ACSM for RNTCP
2. RNTCP Health Communication Strateg

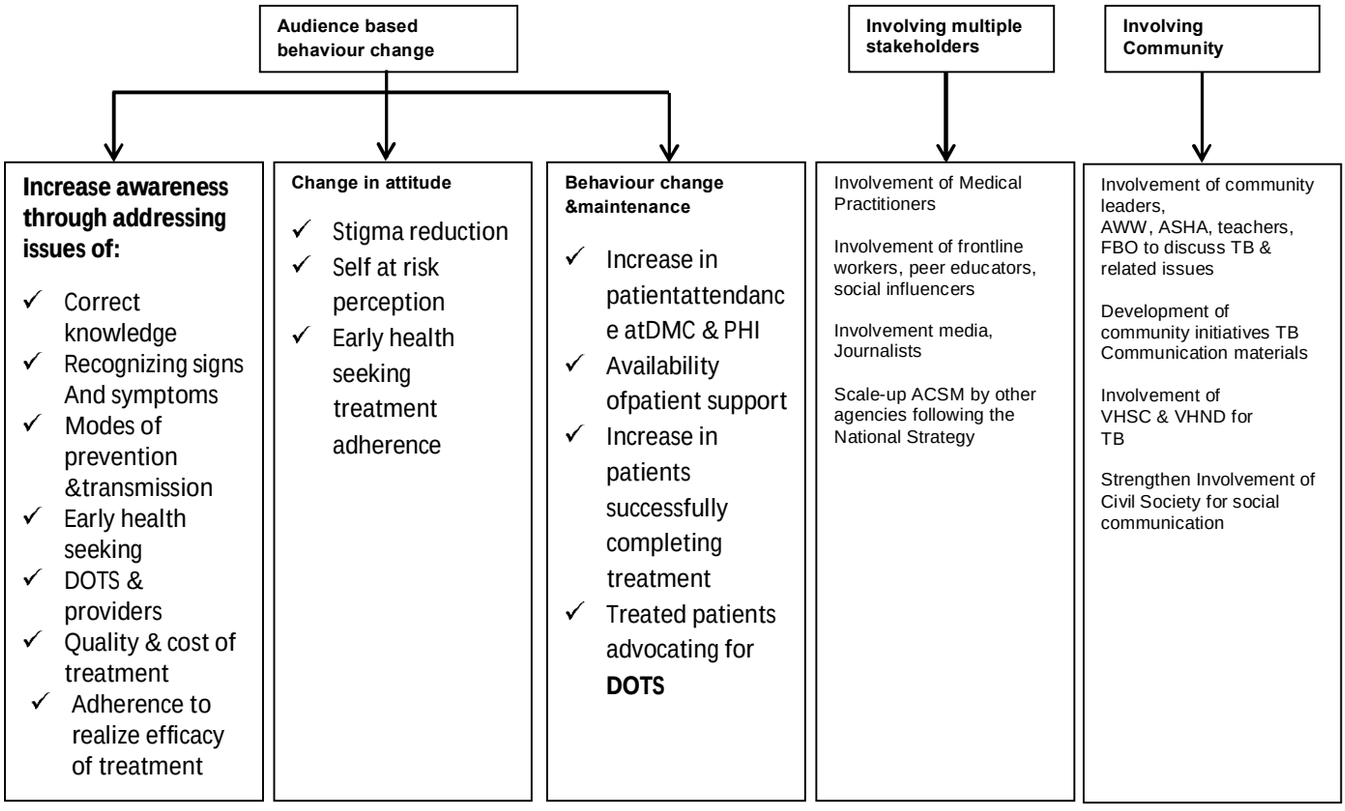
Strategic approach to plan ACSM activities

Strategies are broadly classified in to two groups

For greater demand for early diagnosis and treatment, improvement in thehealth seeking behaviourthrough empowered community structures andother stakeholders, using evidence based BCC strategies will be adopted.

For ensuring supply of quality assured diagnosis andtreatment,enhancement of political will and commitment of policy makers atnational, state and community levelwill be focussed. This will be achievedby effectively engaging with other stakeholders including media, NGOs, patient support groups etc to support advocacy and communication.

The diagram below is an illustration of the broad strategy that would be adopted for designing activities.



Annexure 21

Bio Medical Waste Management

Categories of Bio-Medical Waste- There are 10 categories of the bio medical waste which as tabulated as below-

Option	Treatment & Disposal	Waste Category
Cat. No. 1	Incineration /deep burial	Human Anatomical Waste (human tissues, organs, body parts)
Cat. No. 2	Incineration /deep burial	Animal Waste Animal tissues, organs, Body parts carcasses, bleeding parts, fluid, blood and experimental animals used in research, waste generated by veterinary hospitals / colleges, discharge from hospitals, animal houses)
Cat. No. 3	Local autoclaving/ micro waving/ incineration	Microbiology & Biotechnology waste (wastes from laboratory cultures, stocks or specimens of micro-organisms live or attenuated vaccines, human and animal cell culture used in research and infectious agents from research and industrial laboratories, wastes from production of biological, toxins, dishes and devices used for transfer of cultures)
Cat. No. 4	Disinfections (chemical treatment /autoclaving/micro waving and mutilation shredding	Waste Sharps (needles, syringes, scalpels blades, glass etc. that may cause puncture and cuts. This includes both used & unused sharps)
Cat. No. 5	Incineration / destruction & drugs disposal in secured landfills	Discarded Medicines and Cytotoxic drugs (wastes comprising of outdated, contaminated and discarded medicines)
Cat. No. 6	Incineration , autoclaving/micro waving	Solid Waste (Items contaminated with blood and body fluids including cotton, dressings, soiled plaster casts, line beddings, other material contaminated with blood)
Cat. No. 7	Disinfections by chemical treatment autoclaving/micro waving& mutilation shredding.	Solid Waste (waste generated from disposable items other than the waste sharps such as tubing, catheters, intravenous sets etc.)
Cat. No. 8	Disinfections by chemical treatment and discharge into drain	Liquid Waste (waste generated from laboratory & washing, cleaning , house-keeping and disinfecting activities)
Cat. No. 9	Disposal in municipal landfill	Incineration Ash (ash from incineration of any bio-medical waste)
Cat. No. 10	Chemical treatment & discharge into drain for liquid & secured landfill for solids	Chemical Waste (chemicals used in production of biological, chemicals, used in disinfect ion, as insecticides, etc)

Note-

- Chemicals treatment using at least 1% hypochlorite solution or any other equivalent chemical reagent. It must be ensured that chemical treatment ensures disinfections.
- Mutilation/shredding must be such so as to prevent unauthorised reuse.
- There will be no chemical pre-treatment before incineration. Chlorinated plastics shall not be incinerated.
- Deep burial shall be an option available only in towns with population less than five lakhs and in rural areas.
- Chemicals treatment using at least 1% hypochlorite solution or any other equivalent chemical reagent. It must be ensured that chemical treatment ensures disinfections.
- Mutilation/shredding must be such so as to prevent unauthorised reuse.
- There will be no chemical pre-treatment before incineration. Chlorinated plastics shall not be incinerated.
- Deep burial shall be an option available only in towns with population less than five lakhs and in rural areas.
- The most essential part of hospital waste management is the segregation of Bio-medical waste. The segregation of the waste should be performed within the premises of the hospital/nursing homes. The colour coding, type of container to be used for different waste category and suggested treatment options are listed below.

COLOR CODING & TYPE OF CONTAINER FOR DISPOSAL OF BIO-MEDICAL WASTE

Colour Coding	Type of containers	Waste Category	Treatment Options as per Schedule 1
Yellow	Plastic bag	1,2,3,6	Incineration/deep burial
Red	Disinfected Container/ Plastic bag	3,6,7	Autoclaving/Micro waving/ Chemical Treatment
Blue/ White translucent	Plastic bag/puncture proof container	4,7	Autoclaving/Micro waving/ chemical treatment and destruction/shredding
Black	Plastic bag	5,9,10 (Solid)	Disposal in secured landfill

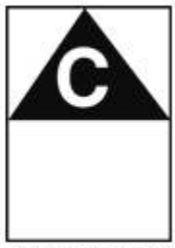
LABEL FOR BIO-MEDICAL WASTE CONTAINERS/BAGS-

Different labels for Bio-medical waste containers and bags shall be required for identification and safe handling of this waste. These labels for storage/transportation of Biomedical waste are as under-

BIOHAZARD SYMBOL
जैविक परिसंकट चिन्ह

BIOHAZARD
जैविक परिसंकट

CYTOTOXIC HAZARD SYMBOL
कोषिकाविष परिसंकट चिन्ह



CYTOTOXIC
कोषिकाविष

LABEL FOR TRANSPORT OF BIO-MEDICAL WASTE CONTAINERS/BAGS

	Day:_____ Month _____
	Year _____
Waste Category No. _____	Date of generation_____
Waste Class	
Waste Description	
Sender's Name & Address	Receiver's Name & Address
Phone No.:_____	Phone No.:_____
Telex No. _____	Telex No. :_____
Fax No. _____	Fax No. :_____
Contact Person _____	Contact Person:_____
In case of emergency please Contact:	
Name & Address:	
Phone No.	

Appendix

Drug dosages for first line anti-TB drugs

Drugs	Adult	Children
Isoniazid	5 mg/kg (4 to 6 mg/kg) daily	10 mg/kg (7-15 mg/kg) daily
Rifampicin	10 mg/kg (8-12 mg/kg) daily	15 mg/kg (10-20 mg/kg) daily
Pyrazinamide	25 mg/kg (20-30 mg/kg) daily	30 mg/kg (30-40 mg/kg) daily
Ethambutol	15mg/kg (12-18 mg/kg) daily	20 mg/kg (15-25 mg/kg) daily
Streptomycin	15 mg/kg (15-20 mg/kg) daily	15 mg/kg (12-18 mg/kg) daily