



Revised National TB Control Programme
**Technical and
Operational Guidelines
for Tuberculosis
Control in India
2016**

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

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 smear microscopy for diagnosing tuberculosis, National Framework for Joint HIV/TB Collaborative 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 nuclei which are discharged in the air when a patient with untreated TB coughs 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 the lymph nodes, pleura, bones and joints, the genito-urinary tract, the nervous system (meningitis, tuberculoma), abdominal TB (intestines, mesentery, solid organs), skin, etc. All those who get infected do not necessarily develop TB disease. The life time risk of breaking down to disease among those infected with TB is 10–15%, which gets increased to 10% per year amongst those co-infected with HIV. Other determinants such as diabetes mellitus, smoking tobacco products, alcohol abuse and malnutrition also increase the risk of progression 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 death worldwide. 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 had created 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; and Enabling 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 and national 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 serodiagnostic test 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 for TB 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				
<ol style="list-style-type: none"> 1. <i>Government stewardship and accountability, with monitoring and evaluation</i> 2. <i>Strong coalition with civil society organizations and communities</i> 3. <i>Protection and promotion of human rights, ethics and equity</i> 4. <i>Adaptation of strategy and targets at country level, with global collaboration</i> 				
PILLARS AND COMPONENTS				
1. INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION <ol style="list-style-type: none"> 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 <ol style="list-style-type: none"> 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 <ol style="list-style-type: none"> A. Discovery, development and rapid uptake of new tools, interventions and strategies B. Research to optimize implementation and impact, and promote innovations 				