

Title: Tuberculosis Control: An Indian Perspective

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Recent Advances in RNTCP

INTRODUCTION

In India, since the inception of the Revised National TB Control Program (RNTCP) in 1992, it has been revised in multiple aspects over the years in accordance with the changing dimensions of the disease to reduce the associated morbidity and mortality [1-3]. The present chapter deals with recent developments in the RNTCP in order to accomplish universal access to tuberculosis care and even accomplish Millennium Development Goal-6 [4,5]. The national program has been revised depending on the

- Epidemiological attributes of disease (viz. distribution / determinants / magnitude)
- Impact on the quality of life
- Life threatening complications
- Emergence of drug resistant forms of TB
- Practical experience acquired in field
- Increase in the budgetary allocation
- Findings of evaluation reports conducted by government
- Results of the research / thesis
- Recommendations made by the National or other specialized institutes
- Recommendations made by the Zonal / State / National task force committees (generally constituted from faculties of Medical Colleges)
- Guidance provided by the technical consultants appointed by the World Health Organization (WHO)
- WHO and international agency's recommendations and
- On the successful implementation of different strategies in the high burden countries [1,5-8].

Refinement in the program has been observed in different areas to take care of the menace

such as adoption of newer diagnostic tools; treatment regimens for drug resistant forms of TB; involvement of medical colleges; public-private partnership projects; notification of the disease; standards for TB care in India; and other innovative approaches have also been tried upon [1,3].

DIAGNOSTIC TOOLS IN RNTCP

- Although, sputum microscopy has been identified as the gold standard tool to establish the diagnosis, however, the policy makers have recommended use of only two sputum smear testing (in contrast to three samples) to establish the diagnosis (because of the operational constraints, patient related factors, and almost equivalent results) [1,9,10].
- Expansion of the public health care delivery system and decentralization of more and more diagnostic tools in different hospitals to facilitate quick diagnosis of extra-pulmonary TB [1,11].
- Offering free laboratory and radiological investigations in most of the health centers (in a graded manner) [1].
- Establishing the clear-cut guidelines regarding the use of Tuberculin test and its interpretation in terms of diagnosis / initiation of anti-TB treatment [1].
- Imposing a ban on employment of serological tests and interferon gamma release assay in either diagnosing TB or in initiating anti-tuberculosis treatment (viz. Government of India has imposed ban on three levels – doctor, manufacturing, import of the diagnostic kits, to discourage the serological tests) [12].
- Introduction of project LIGHT (LED Fluorescent Microscopy In Gaining TB Cases in High workload Teaching Hospitals) in almost 200 medical colleges where the case load is high (>25 slides per day), to fast-track the process of microscopy / reduce the burden on laboratory technicians [13].
- Diagnosis of drug resistant TB (DR-TB) using culture and drug-sensitivity testing (C & DST):
 - Even now solid culture is acknowledged as the gold standard for detecting DR-TB, however due to the delay in obtaining the results (9-12 weeks), solid culture has been replaced by liquid culture which provide results in 3-5 weeks in most of the accredited laboratories in a phased manner;
 - However, even the liquid culture results are obtained after more than 1 month, and thus chances of loss to follow-up of TB patient cannot be ruled out;
 - Thus to neutralize the excess delay in obtaining results, RNTCP adopted line probe assay (LPA) which works on the principle of amplification of DNA of Mycobacterium tuberculosis bacilli and provide results in 1-2 days; and

- The most recent incorporated element in establishing diagnosis of drug resistant TB is cartridge-based nucleic acid amplification test (CBNAAT or GeneXpert). It is a portable kind of equipment which delivers the results within two hours and enables District TB Officer and DR-TB Center committee to put on appropriate treatment without any unnecessary delay / risk to the susceptible members of the community [1,3,14-17].
- Establishing guidelines and fast-tracking the process of accreditation and certification of the private laboratories in order to establish more number of laboratories that can provide quality assured results [3,18,19].
- Formulation of standardized guidelines and time-bound training of the technicians and the program managers [1,16].
- Development of standard operating procedures for culture & drug sensitivity testing (DST) [19].
- Proposing technical specifications for laboratory consumables required for designated microscopy corners (DMCs) / intermediate reference laboratories (IRLs) and for culture sensitivity for IRLs [19].
- Release of guidelines for obtaining appropriate specimens from the presumed site of involvement for microscopy/culture in diagnosing extra-pulmonary cases of multi / extremely DR-TB [16].
- Development of standardized operating procedures for transportation of sputum sample to NRLs [16].
- Recommendation to advocate that only those culture & DST results obtained from a RNTCP certified laboratory should be considered as confirmatory evidence to initiate the therapy [19].
- Further, to lessen the burden on the three existing national reference laboratories (NRLs) at New Delhi, Bangalore & Chennai, two additional NRLs have been proposed in Bhopal and Bhubaneswar [19]. and
- Development of diagnostic standards for TB care in India [20].

TREATMENT OPTIONS IN RNTCP

Adult Tuberculosis:

- Withdrawal of Category-III anti-TB treatment regimen on account of poor effectiveness [1], and
- Alterations in the weight bands of MDR-TB treatment (viz. proposing five weight bands

contrary to the previous three weight bands) - <16kgs / 16-25kgs / 26-45kgs / 46-70kgs / >70kgs [16].

Pediatric Tuberculosis:

- Alterations in available weight bands (viz. proposing six weight bands instead of previous four weight bands) – 6-8kgs / 9-12kgs / 13-16kgs / 17-20kgs / 21-24kgs / 25-30kgs [1].
- Ensuring availability of pestle and mortars at the directly observed treatment (DOT) center and
- Increase in the dose of isoniazid chemoprophylaxis from 5mg/kg body weight to 10mg/kg body weight) [1].

Other Developments:

- Provision of quality assured and continuous supply of drugs [11,16].
- Strict inventory controls and maintenance of buffer stocks at different levels (viz. DOTS center, tuberculosis unit, district TB center, and state drug store) [2,16], and
- Development of treatment standards for TB care [20].
- Directions for storage of anti-TB drugs [16].

INVOLVEMENT OF MEDICAL COLLEGES

Medical colleges have a crucial role in the programmatic management (viz. establishment of diagnosis of extra pulmonary TB, management of adverse drug reactions, transfer in / out of patients, periodic modification in the RNTCP guidelines etc.) [21-23]. Some of the provisions / suggestions to encourage involvement of medical colleges, include

- To streamline the contribution of medical colleges, all government and private medical colleges are instructed to form an institutional core committee to overview the functioning of RNTCP in their institutions [2].
- Hike in the thesis grant from Rs 20000 to Rs 30000 to promote taking thesis on TB related topics [24].
- Provision to organize four conferences (financial assistance – Rs 4 lacs per conference) related to TB in every state with the support aid of medical college to encourage scientific exchange of knowledge [24].
- Under-graduate curriculum: Advocating early clinical exposure preferably from the first year itself; conducting periodic integrated teaching sessions / quiz / debate / poster competition; incorporating TB related exercises in theory / practical / clinical examinations; facilitating community-based training for medical students; organizing

interactive sessions and role plays; ensuring posting of students in directly observed treatment (DOTS) center during their clinical postings; and arranging field visits to the district TB center / designated microscopy center [25-27].

LINKAGES WITH THE PRIVATE SECTOR

The private sector plays a crucial role in the health sector in Indian scenario as more than 70% of country's population avail health care services in the private sector [28]. Thus, to build linkages with the private sector and other health care establishments, RNTCP has initiated multiple schemes to promote the involvement of private sector [2]. The basic idea behind these schemes is to assist the private partner financially and logistically to improve the quality of work, and hence the role of the program manager is crucial - starting from the identification of the issues that need to be addressed; joint planning with the private provider; timely release of money; and to ensure regular monitoring and evaluation [2,3]. The scheme includes:

- **TB Advocacy, Communication, and Social Mobilization Scheme:** Purpose is to increase awareness about the different dimensions of the disease among the masses
- **Sputum Collection Center Scheme:** In order to neutralize the issue of geographical inaccessibility to the designated microscopy centers (DMCs)
- **Sputum Pick-Up And Transport Service Scheme:** To ensure transportation of the collected sputum specimen to DMC for examination
- **Designated Microscopy-Cum-Treatment Center Scheme:** In areas where there are no DMCs, a laboratory technician from a private laboratory can be trained to extend diagnostic services
- **Laboratory Technician (LT) Scheme:** Employed in circumstances when there is no LT in a designated microscopy center
- **Culture And Drug Sensitivity Testing (C&DST) Scheme:** To expand the network of laboratories which can provide quality assured C&DST results
- **Treatment Adherence Scheme:** To encourage each member of the community regardless of their socio-demographic attributes so that patient need not come to the directly observed treatment (DOT) center regularly
- **Slum Scheme:** Implemented in those urban slums where the residents have limited accessibility to the public health delivery system
- **Tuberculosis Unit Scheme:** Applicable in regions with weak public health infrastructure, because of which effective implementation of RNTCP strategies cannot be guaranteed) and
- **TB-HIV Scheme:** Acknowledging the special needs of the vulnerable group, this scheme

has been developed to plan and implement targeted strategies for the welfare of these high-risk group people [2,3,11,16].

Furthermore, RNTCP program managers have attempted to widen the horizon of services by establishing linkages with multiple professional associations for expanding the gamut of services. [1,2] In addition, periodic trainings / sensitization sessions have been also organized to enlighten the private practitioners about the provisions involved in RNTCP [2,16].

TB – A NOTIFIABLE DISEASE

Subsequent to the outbreak of total drug resistant cases in Mumbai, TB has been made a notifiable disease since May 2012 [8]. It essentially means that all cases of TB diagnosed by any means (sputum examination / chest X-ray / other radiological tests / clinical judgment) have to be reported to public health authorities in a specified format [29]. The rationale behind this decision was to have an accurate estimate of the number of TB cases in the community, to help program managers to take evidence-based decisions [30]. Multiple strategies have been employed to strengthen the process of notification, like

- Orienting private medical practitioners and laboratories regarding the importance of notification
- Proactive collection of notification reports including nil-reports from private practitioners
- Preparing a list about names of all laboratories / hospitals-clinic-nursing home
- Involving non-governmental / philanthropic organizations in spreading awareness
- Involving medical colleges - motivating faculties to teach the aspiring students about notification of TB & assist the medical college for adoption of one district to supervise the notification related activities
- Conduction of monthly review meetings to monitor the process of notification and
- Innovations – like adoption of online reporting; and providing incentive / rewards to private practitioners for encouraging notification [29-31].

STANDARDS FOR TB CARE IN INDIA

Globally, the principles of care for TB patients are similar, namely prompt and accurate diagnosis; use of standardized treatment regimens; and following the response to treatment [4,11,32]. The international standards for TB care (ISTC) were framed to ensure delivery of an accepted level of care by all medical practitioners in managing either TB suspects or confirmed TB patients [32]. The ISTC comprises of 17 standards for delivering fixed standard of care [32].

The “Central TB Division” has developed standards for TB care in India (STCI) on the basic

framework prepared by the WHO & ISTC [33]. These proposed Indian standards for TB care will not replace ISTC, but will assist in the better management of TB patients diagnosed in the country [32,33]. Other than the routine international standards, special standards pertaining to “social inclusion”, have been incorporated, which can play a potential role in reducing the magnitude of the disease and improving the quality of life of people in the long-term [20,33]. Overall, STCI consists of 26 standards (viz. diagnosis – 1 to 6; treatment – 7 to 11; public health – 12 to 21; social inclusion – 22 to 26) for effective prevention and control of TB [2,5,20,32-34].

Standards for the Diagnosis of TB

1. Testing and screening of pulmonary TB: Symptoms suggestive of TB and high risk groups such as HIV patients / malnourished people, etc. which should be screened for TB
2. Technology for diagnosis: Need of microbiological confirmation for reaching the diagnosis of TB, utility of chest X-ray as a screening tool, banning serological tests / tuberculin skin test / interferon gamma release assay in making a diagnosis of TB
3. Diagnosis of extra-pulmonary TB: Obtaining appropriate specimens from the sites of involvement for microscopy / C & DST / molecular test / histo-pathological examination
4. Diagnosis of HIV-TB co-infected patients & drug resistant TB patients: Strengthening of HIV-TB intensified collaborative activities and high-risk groups for suspecting drug resistant TB
5. Probable TB: Includes presumptive TB patients without microbiological confirmation (sputum smear microscopy, culture and molecular diagnosis), but with strong clinical evidence and
6. Pediatric TB diagnosis

Standards for the Treatment of TB

1. Treatment with first-line drugs: Treatment of new / re-treated TB patients, extension of continuation phase, drug dosages and weight bands, dosage frequency, and formulation of drugs
2. Monitoring treatment during the course of treatment: Follow-up sputum microscopic examinations, extension of intensive phase, offering DST in follow-up sputum positive cases, assessing response to treatment in extra-pulmonary TB patients / children, and long term follow-up after completion of treatment at the end of 6 months and 12 months
3. Treatment of drug resistant TB: Initiation of treatment of DR-TB based on microbiological confirmation, adopting ambulatory model of care, regimen for DR-TB cases with or without resistance to second-line anti-TB drugs detected either at the beginning or

later in treatment, surgery in multi-drug resistant TB patients, treatment duration in MDR-TB, provider consultation in MDR-TB patients, ensuring treatment adherence in M/XDR TB patients, and second line DST during treatment of MDR TB

4. Treatment of TB-HIV co-infected and co-morbid patients: Treatment of HIV associated TB patients, anti-retroviral therapy and cotrimoxazole prophylaxis therapy in HIV/TB patients, and isoniazid preventive therapy in HIV patients without active TB and
5. Treatment adherence: Patient-centred approach, individualized supervision and support system with counselling, and use of information communication technology to promote treatment adherence

Standards for Public Health for TB

1. Public health responsibility
2. Maintenance of records for all TB patients
3. Contact tracing for all household & close contacts of TB patients;
4. Isoniazid prophylactic therapy
5. Airborne infection control in health care facilities
6. Notification of TB cases to the public health authorities
7. Establishment of quality assurance systems for diagnostic tests / anti-TB drugs
8. Motivating Panchayati Raj Institutions and elected representatives to share the public health responsibility for TB control
9. Health education to the TB patient and their family members and
10. Death audit of every TB patient

Standards for Social Inclusion for TB

1. Information on TB prevention and care seeking
2. Free and quality services
3. Respect, confidentiality and sensitivity
4. Care and support through social welfare programs and
5. Addressing counselling and other needs

To conclude, the adoption of standards for TB care will improve the individual patient care and aid in reducing the human suffering & economic losses attributed to tuberculosis [20,36].

INNOVATIONS / DEVELOPMENTS IN THE RNTCP

- Launch of NIKSHAY software – a case based web-based monitoring – to avoid unnecessary delay [23].
- Expansion of TB-Diabetes Mellitus collaborative activities in 100 districts every year under the National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular diseases and Stroke [35].
- Fostering liaisons with the Medical Council of India [25,27].
- Periodic revisions in the financial norms under RNTCP [24].
- Involvement of school teachers and students in the advocacy, communication, and social mobilization activities [2].
- Implementation of the airborne infection control guidelines in health care institutions [36].
- Strengthening of the existing TB-HIV collaborative activities [1,4,37].
- Appointing different cadres of health workers for the sanctioned posts [2], and
- Devising legal provisions to restrict over-the-counter sale of anti-TB drugs [11,37].

CONCLUSION

To conclude, over the years the Revised National TB Control Program has been extensively revised and multiple steps have been taken to provide people-friendly diagnostic and treatment care services.

SUMMARY

In India, since the inception of the Revised National TB Control Program (RNTCP) in 1992, it has been revised in multiple aspects over the years in accordance with the changing dimensions of the disease to reduce the associated morbidity and mortality. Refinement in the program has been observed in different areas to take care of the menace such as adoption of newer diagnostic tools; treatment regimens for drug resistant forms of TB; involvement of medical colleges; public-private partnership projects; notification of the disease; and other innovative approaches have also been tried upon. In addition, the Central TB Division has developed standards for TB care in India (STCI) on the basic framework prepared by the WHO & ISTC. These proposed Indian standards for TB care will not replace ISTC, but will assist in the better management of TB patients diagnosed in the country. To conclude, over the years the Revised National TB Control Program has been extensively revised and multiple steps have been taken to provide people-friendly diagnostic and treatment care services.

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