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Title: Tuberculosis Control: An Indian Perspective

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Revised National Tuberculosis Control Program

INTRODUCTION

India launched a National TB Program in the year 1962 to counter the rising trends of the disease [1]. However, this initiative was not very much successful in improving the case detection rate or bringing down the treatment relapse rate / default rate [2]. This led to an evaluation of the program in all aspects and many weaknesses were highlighted, namely

- No political support on a sustained level,
- Over-reliance on chest X-ray for establishing a diagnosis which had serious concerns of intra-observer & inter-observer variability and lack of diagnostic accuracy
- Interruptions in treatment duration as patients were issued drugs on a monthly basis
- No in-built mechanism to ensure follow-up of the patient during their course of treatment
- Negligible monitoring and supervision on other aspects of the program (viz. health workers, laboratory technicians, quality of the drugs, implementation of the program at different levels, etc.)[1,2].

This eventually led to the launch of the Revised National TB Control Program (RNTCP) in the year 1997 after a pilot phase of five years from 1993 to 1997. Since then, the program has been gradually scaled up in a phase-wise manner to cover the entire country and this was successfully achieved in March 2006 [1,2].

GOAL AND OBJECTIVES OF RNTCP

The ultimate goal of the RNTCP is to reduce the morbidity and mortality due to tuberculosis and interrupt the chain of transmission until TB ceases to be a public health problem (viz. one case infects less than one new person annually; and the prevalence of infection in the age group below 14 years is brought down to < 1%) [1].

The proposed goal can be achieved once following objectives are attained

1. Augmentation of case finding activities through quality assured sputum microscopy to detect at least 70% of the estimated PTB cases in a community, and
2. Achieve and maintain a cure rate of at least 85% among newly detected sputum-positive (infectious) pulmonary TB cases.

Despite existence of the program for more than 15 years, we are still striving to achieve and maintain the proposed case detection & cure rate on a sustained level across all parts of the country [1]. In-fact, to accomplish the Millennium Development 6 and to ensure universal access to quality assured TB diagnosis and treatment services, a future target has been proposed – to achieve detection and cure rate of 90% among all forms of TB cases (viz. sputum positive, sputum negative, extra-pulmonary, pediatric) [3,4].

DIRECTLY OBSERVED TREATMENT SHORT COURSE (DOTS) STRATEGY

On recommendation of the World Health Organization and after obtaining favorable results all across the world, India has adopted a slightly modified version customized to the nation's requirements under the RNTCP [1,2]. The DOTS strategy is a systematic plan to control TB disease across the nation and essentially comprises of five components, namely:

1. Political and administrative commitment
2. Good quality diagnosis, primarily by sputum smear microscopy
3. Uninterrupted supply of quality drugs
4. Directly observed treatment (DOT)
5. Systematic monitoring and accountability

These components will be discussed in detail in Chapter 3.

STRUCTURAL ORGANIZATION UNDER RNTCP

The structure of RNTCP comprises of five levels: National level, State level, District level, Sub-district level and Peripheral health institution level [1,2]. The organization has been revealed in the flowchart 1 for better understanding.

Broadly, the program has two arms – Diagnostic and Treatment. For exercising both of these responsibilities, different centers and stakeholders have been identified which not only ensure the smooth implementation of the program but even plays a crucial role in supervision and monitoring at different levels.

Diagnostic

a) **Designated Microscopy Center (DMC) –** There is one RNTCP Designated Microscopy Center for every 100,000 population under a TU. DMCs are also established in Medical Colleges, Corporate hospitals, ESI and Railway health facilities, NGOs, private hospitals etc, depending upon

the requirement. DMCs are constituted at TB Unit level and are manned by a trained laboratory technician, and supervised by a Senior Treatment Laboratory Supervisor [1].

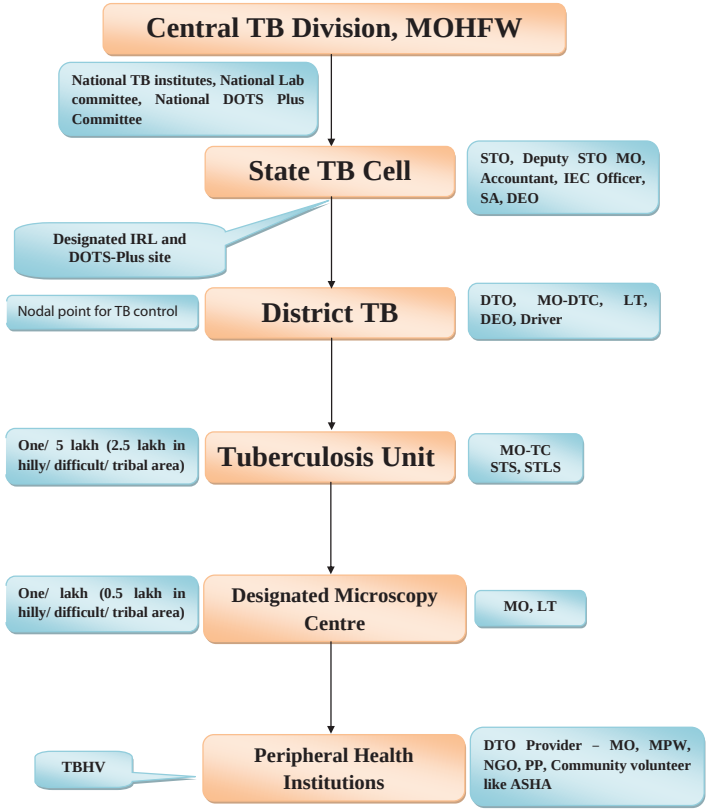
b) Intermediate Reference Laboratories (IRLs) – These are constituted at State level and their main work is to ensure External Quality Assurance (viz. On-site evaluation, Panel testing, and Random Blinded Re-Checking of stained slides) in maintaining the quality of diagnosis [2,5]. It will be dealt in Chapter 3.

c) National Reference Laboratories (NRLs) – In the entire country, four NRLs have been identified, namely - National Institute for Research in Tuberculosis, Chennai; National Tuberculosis Institute, Bangalore; and Lala Ram Sarup Institute of Tuberculosis and Allied Sciences, New Delhi; and National JALMA Institute of Leprosy and other Mycobacterial Diseases, Agra. These NRLs supervise sputum microscopy related External Quality Assurance (EQA) across all the states of the country [1,2].

Treatment

a) Directly Observed Treatment (DOT) center – It is present at the peripheral health institution level and its main role is to initiate the anti-TB treatment and follow-up them during the entire course of treatment. Different cadre of workers like Multi-purpose worker, Public Health Nurse, Community volunteer, etc. have to exercise this duty. Their work is generally supervised by a Senior TB Treatment Supervisor [1,6].

b) Tuberculosis unit / District TB center / State TB cell / Central TB division – The population norm for establishing a TB Unit (TU) is approximately 0.5 million [1]. The activities at the District TB Center, State TB Cell, and Central TB Division is generally supervised by District TB Officer, State TB Officer, and Director-General TB respectively [1]. In addition, State Drug Stores (SDS) has also been established depending on the number of districts in the state to ensure appropriate storage and supply of first and second line anti-TB drugs [5].



Flowchart 1: Structural Organization in RNTCP

MOHFW – Ministry of Health and Family Welfare; IRL – Intermediate Reference Laboratories; STO – State TB Officer; MO – Medical Officer; IEC Officer – Information, Education and Communication Officer; SA – Statistical Assistant; DEO – Data Entry Operator; MO-DTC – Medical Officer-District TB Center; LT – Laboratory Technician, MO-TC – Medical Officer-TB Cell; STS – Senior Treatment Supervisor; STLS – Senior TB Laboratory Supervisor; TBHV – TB Health Volunteer; MPW – Multi-Purpose Worker; NGO – Non-Governmental Organization; PP – Private Practitioner; ASHA – Accredited Social Health Activist.

TUBERCULOSIS SUSPECT UNDER RNTCP

India being a developing country there is an immense need to allow judicial allocation of resources [1]. At the same time, India also contributes a maximum percentage of TB cases to the global burden, and thus we cannot take chances to miss any of the TB cases [2]. Hence, there is a need to frame some guidelines regarding the type of patients who will be subjected to laboratory testing for ruling out the presence of active TB lesions [2]. Under RNTCP, criteria have been laid down to suspect TB [2], namely

Pulmonary TB:

a) An individual having cough of 2 weeks or more

b) Cough of any duration for: Contacts of smear-positive TB patients; Suspected/confirmed extra-pulmonary TB cases; HIV positive patient / Immuno-compromised patients; Diabetics; Renal failure; Cancers; Malnutrition

Extra-Pulmonary TB:

A patient with extra-pulmonary TB may have general symptoms like weight loss, fever with evening rise and night sweats. However, depending on the organ affected, symptoms can be variable.

PASSIVE CASE FINDING VERSUS ACTIVE CASE FINDING

National TB Institute - Bangalore, observed that 95 percent of infectious TB patients are conscious of their symptoms and most of them report to the nearest health establishment to seek medical aid within a few weeks of the onset of their symptoms, indicating that active case finding is not necessary [7]. Furthermore, owing to the infrastructure and human resource constraints, RNTCP recommends passive case finding as the case detection strategy [3]. It simply means that the outreach workers should not go in the community on a routine basis and look out for active cases of TB [1]. This should not be confused with contact tracing which refers to the identification of susceptible contacts that may have been exposed to infectious pulmonary TB cases [2]. However, the findings of some of the active case finding survey have been encouraging especially in settings with high case load [8,9]. In-fact, many health professionals and stakeholders do support the active-case finding strategy and is definitely in the pipeline, once the public health care system is strengthened [8].

RNTCP - DIAGNOSTIC ALGORITHM

After identification of a TB suspect, the primary aim is to diagnose TB, as an infectious patient is a potential source of infection to multiple susceptible contacts, if left undiagnosed / untreated [3]. RNTCP has recommended a diagnostic algorithm for adults, children and extra-pulmonary TB patients [2]. These protocols should be strictly adhered to by the physicians as most of the cases of drug-resistant TB results because of non-compliance of medical practitioners to the algorithm [2].

One of the most important key messages under RNTCP diagnostic algorithm is to sensitize the medical practitioners to not to administer Fluoroquinolones / Cephalosporins / other drugs with anti-Mycobacterium tuberculosis properties. Two reasons have been cited to not to advise these drugs – Owing to anti-Mycobacterium tuberculosis properties most of the clinical symptoms subside for a transient period and thus patient ignores the appearance of future symptoms; and as they are expensive, not all patients completes the entire course of treatment. From a public health perspective, most of these patients presents with drug-resistant forms of TB and that too

at an advanced stage of the disease. This is the main aspect as a major proportion of community access private practitioner for their complaints, who have minimal orientation about the same. The program recommends administration of broad spectrum antibiotics like Erythromycin, Cotrimoxazole, etc [2].

For determining the diagnosis of pulmonary TB, sputum microscopy is the recommended laboratory technique [10]. Chest X-rays also deserve a place in the diagnostic algorithm for identification of sputum negative pulmonary TB [1]. In addition, there is a provision under the program to rely on the results of other radiological investigations (viz. CT scans, biopsy, FNAC, etc.) in establishing a diagnosis of extra-pulmonary TB [1]. Finally, RNTCP is the one of the most flexible programs in the country, and there is a provision that if the diagnosis cannot be established on the basis of laboratory / radiological investigations, but the treating physician / clinician still suspects the presence of TB, they can start the Anti-TB treatment after appropriate categorization of patients as described below [2].

TREATMENT OPTIONS FOR DIAGNOSED TB PATIENTS

Treatment guidelines under RNTCP have been extensively revised. Currently, as revealed in Table 1, depending on the type of patients, they are started with either Category I or Category II anti-TB treatment (ATT) [1]. Both of these categories of treatment have been divided into two phases – Intensive phase and Continuation phase [1]. The objective of the intensive phase (IP) is to achieve rapid killing of actively multiplying bacillary population which in turn will eliminate drug resistant mutants and thus prevent the imminent emergence of drug resistant mutants [2]. On the other hand, the continuation phase (CP) ensures elimination of persisters which are responsible for relapses [2].

In the intensive phase, patient has to go to the DOT center / provider thrice a week and consume the drugs in front of the DOT provider [1,2]. However, in the continuation phase, patient is supposed to visit the DOT center / provider only once a week where he / she consumes the first dose in front of the DOT provider, and the remaining blister they can take their home. Once the blister is over, patient has to again come to the DOT center along with the empty blister next week on the same day to take their next blister [2].

Category I treatment last for a period of 6 months including two months of intensive phase and four months of continuation phase. In contrast, Category II treatment comprises of 8 months consisting of three months of intensive phase and five months of continuation phase. Under the RNTCP, there is a provision to assess improvement in the clinical profile (viz. for both extra-pulmonary and pulmonary TB patients) and microbiological profile (for pulmonary TB cases – by assessment of the bacterial load in the stained AFB slides). Generally, three sputum examinations (viz. Category I – 2, 4, and 6 months; Category II – 3, 5, and 8 months) are recommended after the ATT has been initiated [2].

Table 1: Categorization of patients under RNTCP

Treatment category	Type of patients	Drug regimen	Duration of treatment
CATEGORY I	Any patient who never took ATT or taken ATT < 1 Month	$2(H_3R_3E_3Z_3) + 4(H_3R_3)$	2 months + 4 months
CATEGORY II	Patient who has taken treatment previously for > 1 month	$2(S_3H_3R_3E_3Z_3) + 1(H_3R_3E_3Z_3) + 5(H_3R_3E_3)$	2 months + 1 month + 5 months

H – Isoniazid; R – Rifampicin; Z – Pyrazinamide; E – Ethambutol; S – Streptomycin

TB – HIV COLLABORATIVE ACTIVITIES

As already mentioned in Chapter 1, TB-HIV co-infection has been identified as one of the five key priority areas by the WHO owing to the presence of multiple challenges associated with these groups of patients [4]. Anticipating the special needs of these co-infected & vulnerable categories of patients, the National Framework for Joint TB/HIV collaborative activities has been developed in 2007, in India [2]. This National Framework has intensified the TB/HIV package of services across the entire nation, with special attention to those states with higher burden [2]. Program officers of National AIDS Control Program (NACP) and RNTCP are working in close coordination with each other to improve the health indicators of the TB-HIV co-infected patients [11].

In-fact, specific TB-HIV collaborative activities such as strengthening NACP-RNTCP coordination mechanisms at various levels; ensuring joint monitoring and evaluation including standardized reporting between the two programs; conducting training of both program managers and field staff on TB/HIV; expanding coordination of TB and HIV services (viz. offering HIV testing services to all diagnosed TB patients / subjecting symptomatic HIV positive patients for sputum examination / providing antiretroviral treatment or ATT or Cotrimoxazole Prophylactic Treatment (CPT) for HIV-infected TB patients); implementing infection control measures; fostering cooperation with NGOs/Community-based organizations to work for the welfare of infected people; and promoting operational research in different aspects to enhance the impact of TB/HIV collaborative activities; have been planned and implemented across the nation [2,12,13].

CONCLUSION

In conclusion, to counter the enormous magnitude of the disease in India, the government of India has launched Revised National TB Control Program. It is one of the most flexible program of the country and it deals with both diagnostic and treatment aspect of the disease.

SUMMARY

India launched a National TB Program in the year 1962 to counter the rising trends of the disease. However, this initiative was not very much successful in improving the case detection rate or bringing down the treatment relapse rate / default rate. This eventually led to the launch of the Revised National TB Control Program (RNTCP) with an ultimate goal to reduce the morbidity and mortality due to tuberculosis and interrupt the chain of transmission until TB ceases to be a public health problem. The structure of RNTCP comprises of five levels: the National level, State

level, District level, Sub-district level and Peripheral health institution level. Guidelines have been framed under the program to identify TB suspect and then subject the diagnosed patients to appropriate category of anti-TB treatment. One of the most important key messages under RNTCP diagnostic algorithm is to sensitize the medical practitioners to not to administer drugs with anti-Mycobacterium tuberculosis properties. In conclusion, to counter the enormous magnitude of the disease in India, Government of India has launched Revised National TB Control Program. It is one of the most flexible program of the country and it deals with both diagnostic and treatment aspect of the disease.

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