

Revised National Tuberculosis Control Program in India: The Need to Strengthen

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Tuberculosis (TB) is an infectious disease caused by the bacterium *Mycobacterium tuberculosis*. It is spread through the air from people suffering from TB. A single patient can infect ten or more people in one year. TB remains a major public health problem in India, with the country accounting for 26% of all TB cases reported globally.^[1] In 2011, out of the estimated global annual incidence of 8.8 million TB cases, nearly 2.3 million were estimated to have occurred in India.^[2]

In 1992, the Government of India, together with the World Health Organization (WHO) and Swedish International Development Agency (SIDA), reviewed the national tuberculosis program and concluded that it suffered from managerial weaknesses, inadequate funding, over-reliance on x-ray, non-standard treatment regimens, low rates of treatment completion, and lack of systematic information on treatment outcomes. As a result, the Revised National Tuberculosis Control Program (RNTCP), based on the internationally recommended Directly Observed Treatment Short-course (DOTS) strategy, was launched in 1997 and implemented a phased expansion, achieving nationwide program coverage in March 2006. This program now covers more than 1 billion (1164 million) populations across 632 districts in 35 states and union territories. DOTS has initiated more than 12.8 million TB patients on treatment, saving an additional 2.3 million lives.^[2]

All of India is now covered by the RNTCP, making it the second largest such program in the world. The program has developed a strategic vision for TB control for the country up to 2015, under which it aims to achieve and maintain a cure rate of at least 85% in new sputum-positive (NSP) pulmonary TB patients and achieve detection rates of such cases of at least 70%.^[3] Clearly, both good outcomes and high case detection rates are essential. But, it is essential that the system is geared up to reliably cure patients, before any attempts are made at expanding case detection. In fact, experience clearly shows that reliably curing patients result in a “recruitment effect”—wherever effective services are offered, case detection rates steadily increase.

The RNTCP has sustained the objectives (NSP case detection rates of over 70% and treatment success rates of over 85% nationally) since 2007, in line with global targets for TB control.^[2] TB mortality and prevalence in the country has decreased compared with 1990 figures, indicating progress towards achieving TB-related targets of the United Nations Millennium Development Goals (MDGs).^[2]

However, recent evidence has shown the limitations of the RNTCP, and these limitations might make control of TB a difficult task. One study showed the efficacy of DOTS category I and category III in lymph node TB to be around

71%.^[4] There is controversy regarding the efficacy of the 6-month regimen that is recommended under RNTCP in TB meningitis and TB of bones and joints cases compared with the 9–12 month regimen recommended by some experts.^[5,6] Ramachandran *et al.* showed that even after a decade of RNTCP implementation, there is still a lack of awareness among patients about the availability and quality of free diagnostic and treatment facilities locally under RNTCP. These patients use facilities from hospitals, medical colleges or private practitioners.^[7] Considering the current incidence of TB, more than half of the total TB patients bypass RNTCP services and are either treated in private sectors or are untreated.^[8] In India, 75% of doctors (6 million) are based in private practice and only 0.31% are implementing RNTCP.^[1] Most of the private practitioners still have practically no access to information or training programs, which accounts for the surprising disparity in their management strategies. The RNTCP needs to ensure active involvement of the private sector in case detection and notification and provide them with the standard guidelines of TB care. The health system could be strengthened by resolving the issue of the shortage of staff and by creating parallel staff for the private sector. Medical colleges should be actively involved by undertaking activities such as training of health functionaries and performing operational research in the field of TB. There should be active attempts to decentralize the decisions over TB research and other activities at district, state, and medical college levels.

The RNTCP provides free diagnostic and treatment services to benefit the poor and vulnerable groups of the society. However, recent studies shows that people most in need of free services were not accessing or utilizing these services, and that a significant proportion of TB patients who are illiterate and from low-income rural households were being diagnosed and treated outside the DOTS/RNTCP system, and being charged for treatment.^[9] The RNTCP is moving in to the next phase of the program, which includes promoting the concept of ‘universal access to TB care.’ The implementation of this concept is expected to allow all TB patients in the community to have early access to good quality TB diagnosis and treatment services. One of the key challenges

in achieving this objective is to address the reasons behind inter/intra-district disparities in program performances, since problems persist more in the poorer and backward districts (low agricultural productivity, unemployment, and critical gaps in physical and social infrastructure) of the country. Under the RNTCP, there is a need to co-ordinate between policy makers, practitioners, non-governmental organizations and other stakeholders in setting the foundations for development of specific tools, guidelines, and activities that are aimed at increasing access to TB services for the poor.

Information, education, and communication (IEC) is an important component of all public health programs. IEC activities under the RNTCP aim to promote a better understanding of TB and its cure among the masses, improve the quality of care provided to TB patients, and to reduce stigma. There is a definite need to strengthen the existing IEC activities at all levels in order to make services more accessible to the poor and the marginalized.^[10]

The RNTCP has adopted WHO 2010 guidelines of three standard regimens: ^[11]

- New patient regimen containing 6 months of rifampicin: 2HRZE/4HR
- Re-treatment regimen with the first-line drugs 2HRZES/1HRZE/5HRE; and
- Multi-drug resistant (MDR) regimen.

According to WHO, India had an estimated 73,000 cases of notified MDR-TB; of these, fewer than 3000 were detected in 2011, the highest amount in the Southeast Asia region. The estimated burden of MDR-TB cases in India is about 1.05 million (i.e. 2.1% of new cases and 13–17% of re-treatment cases are possibly MDR). Adding to this pool are MDR-TB cases from treatment failures.^[12] The prevalence of MDR-TB among the treatment failures of new cases ranges from 17% to 41%^[13,14] and among re-treatment cases ranges from 32% to 86%.^[15,16] Considering that more than 50% of the new cases are not registered in RNTCP, and by evaluating TB treatment practices in the private sector, the number of MDR estimates is likely to be considerably higher. The RNTCP DOTS-Plus strategy has initiated only around 1600 MDR-TB patients on category-IV treatment. Hence, there is a lot of disease burden to catch up on. There needs to be a scaling up of the DOTS-Plus program to

include all the MDR-TB patients who come to the RNTCP. Given the availability of funding from international financial mechanisms, lack of resources for MDR treatment is no longer an acceptable rationale for providing a re-treatment regimen of first-line drugs (the category II regimen) to patients with a high likelihood of MDR.^[11] There is an urgent need for strengthening of reference laboratories and laboratory networks by equipping them with newer and more rapid techniques for diagnosis of TB and drug resistance and making these techniques available to all the patients who present to the RNTCP. Specimens for culture and drug susceptibility testing (DST) should be obtained from all previously treated TB patients at or before the start of treatment. DST should be performed for at least isoniazid and rifampicin.^[11] In new patients, if the specimen obtained at the end of the intensive phase (i.e. after 2 months) is smear-positive, sputum smear microscopy should be obtained at the end of the third month. In new patients, if the specimen obtained at the end of month 3 is smear-positive, sputum culture and DST should be performed.^[11] TB patients whose treatment has failed or other patient groups with high likelihood of MDR-TB should be started on an empirical MDR regimen.^[17]

After so many years of the RNTCP in India, how has TB still not been brought under control? Treatment of the infectious form of TB has not been validated sufficiently for control.^[18-20] Treatment can be given only to people captured in the diagnostic net, but it does not capture all infectious cases, leading many patients to seek private healthcare, where non-standard treatment is widespread and follow up is poor, contributing to development of drug resistance. The sensitivity of TB diagnosis is inadequate without microbiological diagnostic support. Even those captured in the RNTCP become non-infectious only after they have shed the bacilli for several weeks. Thus, chains of infection continue unabated, and the annual risk of TB infection (ARTI) remains high in all studies.^[21]

Addressing health inequities necessitates multi-sector co-ordination, and makes sustained TB control efforts involving pro-poor approaches with a resulting decline in TB prevalence and advanced welfare among the poor likely. This is possible only when intensified efforts sustained by the RNTCP

are augmented with coordinated and synergistic efforts of concerned departments across diverse sectors dealing with populations that are considered to be poor. Based on experiences at medical colleges and large hospitals that receive patients from large areas, the program will consolidate its existing mechanisms of referral for treatment at the participating centers to create a seamless service so that patients are not inconvenienced when accessing treatment facilities after diagnosis and so that the process is well documented, thereby facilitating follow-up of such cases and to minimize defaulter cases.

The program re-affirms that DOT with standardized short-course chemotherapy regimens is the most appropriate way to treat TB, and will continue to have DOT as the core of treatment delivery system for all types of cases. The program will venture to garner support of adequate staff and volunteers, who are committed and humane, to deliver DOT as per the recommended strategy. The vision is to further foster community participation in the DOT services and to implement it. The program will endeavor to further streamline the patient-wise box distribution systems at sub-district levels. All RNTCP partnerships will be formalized with the agreement that DOT is the adopted modality of treatment by the partner agency. The program will also ensure continued supervision and monitoring of DOT by sub-district supervisors and their assistance to DOT providers in retrieval of patients who are late for their treatment. The program should attempt to reduce delays in treatment initiation, for example by trying to decrease the average distance between a patient's residence and their DOT center as far as it is logistically and programmatically feasible.

In India, the HIV/AIDS epidemic is a potential threat to the future success of the program. The ongoing joint collaborative activities of the RNTCP and the National AIDS Control Program will be strengthened, especially in the advent of free anti-retroviral therapy being offered by the Government of India. The links between Integrated Counseling and Testing Centers (ICTCs) and the RNTCP microscopy services will be strengthened and widened as ICTCs are widely established at the sub-district level. Service delivery mechanisms will be established so that care for both diseases

is delivered at a single site, rather than at multiple sites. The RNTCP will endeavor to further involve non-governmental organizations and the community in the delivery of DOT to TB patients, both those living with HIV/AIDS and those who are HIV-negative. IEC material will be developed to address the issues surrounding TB/HIV and will be widely disseminated.^[22]

The RNTCP must be revamped, deficiencies covered, interfaced effectively with healthcare (public and private sectors), and supported adequately with laboratory facilities. Infection incidence must be regularly monitored in all districts by systematic surveys of Acute Respiratory Tract Infection (ARTI). Pediatric TB infection and disease must be given high priority for detection and treatment. Such strengthening and intensification of the RNTCP will be essential to control TB and reliably document it.^[18-20]

In order to achieve the ultimate goal of TB control in India, the program will have to be sustained for many years to come. Continued decentralization of program management and implementation, ensuring financial support for the RNTCP and mobilization of community participation in TB control efforts would facilitate the process.

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