

# Newer Initiatives under RNTCP

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# Abstract

The Revised National Tuberculosis Control Program (RNTCP) has taken continuous efforts in addressing issues toward TB control in India. It has allowed India to take a huge leap in controlling TB. The program has been actively modifying its strategies according to latest scientific evidence and changing dynamics of the disease. These modifications provide a good ray of hope, if implemented effectively. These innovations will effectively leverage India's endeavor.

Keywords: Tuberculosis, RNTCP.

# Introduction

Tuberculosis has existed in India since the earlier days. In 1500 BC, the Rigveda described the illness as *Rajayakshma*, "King of diseases".<sup>1</sup> The National Tuberculosis Control Program was reviewed in 1992 and Revised National Tuberculosis Control Program (RNTCP) was launched in 1997 with WHO recommended DOTS strategy. The program was expanded in a phased manner and by March 2006 the entire country had been covered under the pogram.<sup>2</sup> In spite of this, tuberculosis continues to be one of the most common infectious causes of mortality and morbidity, thus imposing enormous health and economic burden on India.<sup>3</sup> However, ever since its inception in 1992, the RNTCP has been revised in multiple aspects over the years, in accordance with the availability of new scientific evidence and changing dimensions of the disease to reduce the associated mortality and morbidity.<sup>4</sup> This article highlights the recent newer initiatives under RNTCP with their implementation status.

# **The Problem**

Though India is the second-most populous country in the world, India has more new TB cases than any other country. Out of the 8.6 million TB cases that occurred in the world in 2012, 2-2.4 million were in India, with the best case estimate of 2.2 million cases (176 cases per 100,000 population).<sup>5</sup> As per WHO Global Report 2013, India has contributed to

approximately 25.5% of the total global new cases detected during the year 2012.<sup>6</sup> In India, TB kills one person every two minutes and 750 people every day. According to WHO estimate, the prevalence of Multidrug Resistant Tuberculosis (MDR-TB) among notified TB patients is 5.3%, among new pulmonary TB patients 2.2% and among retreatment pulmonary TB patients 15%. As per WHO, HIV prevalence among incident TB cases is estimated to be 5%.<sup>6</sup>

# **Journey So Far**

In the year 2013, the RNTCP has put 141,601 patients on treatment.<sup>7</sup> The program has consistently maintained the treatment success rate of 85% and national strategic plan case detection of 70% since 2007 after country-wide coverage. Treatment success rates have tripled from 25% in pre-RNTCP era to 88% in 2012. TB prevalence per lakh population has reduced from 465 in 1990 to 230 in 2012. TB incidence per lakh population has reduced from 216 in 1990 to 176 in 2012. TB mortality has reduced from 38 in 1990 to 22 in 2012.<sup>5</sup>

Modifications in the program have been observed in different areas to curb the menace such as adoption of newer diagnostic tools, treatment regimens for DR-TB, notification of disease, standards for TB care in India and other innovative approaches have also been tried upon.<sup>8</sup>

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# Objectives of the Program as proposed in National Strategic Plan<sup>9</sup>

- Early detection and Treatment of at least 90% of estimated TB cases in the community; including drug-resistant and HIV-associated TB.
- Successful treatment of at least 90% of previously treated TB patients.
- Initial screening of all retreatment smear-positive till 2015 and all smear-positive by 2017, for drug-resistant TB and provision of treatment for MDRTB patients.
- Offer of HIV counseling and testing for all TB patients and linking infected TB patients to HIV care and support.
- Extend RNTCP services to patients diagnosed and treated in private sector.

# **Newer Initiatives**

The following is an account of newer initiatives taken under the program.

# **Diagnostic Tools**

- The policy makers have recommended use of only two sputum smear testing in contrast to three samples to establish the diagnosis because of operational constraints, patient-related factors and almost equivalent results.<sup>10,11</sup>
- The Gazette of India MOHFW has notified GRS 432 (E) for prohibiting the import of commercial sero-diagnostic kits for TB and GSR 433 (E) for prohibiting the manufacture, sale, distribution and use of the sero-diagnostic kits for TB on 7th June 2012.<sup>12</sup>
- Introduction of project LIGHT (LED fluorescent microscopy in gaining TB cases in high workload teaching hospitals) introduced in 200 medical colleges where the case load in high (>25 slides per day) to fast track the process of microscopy/reduce the burden on laboratory technicians.<sup>13</sup>
- Adoption of line probe assay for diagnosis of DR TB using culture and DST testing over other conventional methods to avoid the delay in obtaining results.
- Procurement of CBNAAT (cartridge-based nucleic acid amplification test): A portable equipment which delivers result within 2 hrs and enables DTO/DR-TB center committee to put patient on appropriate treatment without unnecessary delay/risk to susceptible members of the

community. The program envisages to procure 1000 such machines under NSP 2012-17.<sup>14-17</sup> Automated NAAT is also under consideration in RNTCP. The program has undertaken feasibility study for implementation of NAAT in terms of infrastructure, HR requirement and EQA procedures involved.<sup>18</sup>

- Establishment of guidelines and fast tracking the process of accreditation and certification of private laboratories in order to establish more number of laboratories that can provide quality assured results.<sup>19,20</sup>
- SOP for transportation of sputum to NRLs has been developed.<sup>21</sup>
- Two additional NRLs have been proposed in Bhopal and Bhubaneswar to reduce the sample load on existing NRLs.<sup>20</sup>

# **Treatment Options**

- On account of poor effectiveness, Cat III regimen has been withdrawn.<sup>4</sup>
- Five new weight bands (<16 kg/16-25 kg/26-45 kg/46-70 kg and >70 kg) have been developed for treatment of adult MDR- TB.<sup>21</sup>
- Six new weight bands (6-8 kg/9-12 kg/13-16 kg/17-20 kg/21-24 kg and 25-30 kg) have been developed for treatment of pediatric age group.<sup>4</sup>
- The dose of INH for chemoprophylaxis has been increased from 5 mg per kg to 10 mg per kg.<sup>4</sup>

# Programmatic Management of DR TB Services (PMDT)

It is the modification of erstwhile DOTS plus for DR TB diagnosis, management and treatment. RNTCP introduced PMDT services in 2007 to address the MDRTB issue in the country. All districts in the country have achieved complete geographical coverage by March 2013 and program is now moving toward universal access to quality treatment of MDR TB patients.<sup>22</sup>

# New Anti-TB Drugs

Bedaquiline has successfully completed phase-3 clinical trials in Africa. It was launched as a pilot project in five cities of Delhi, Mumbai, Chennai, Ahmadabad, and Guwahati as these cities have high load of tuberculosis, while Linezolid is in the final stages of human trials.<sup>37</sup>

#### **Universal Access to TB Care**

Accelerating India's access to universal TB care an innovative scheme to further strengthen it was launched in the National Review Meeting of September 2015, the project seeks to engage with private practitioners in treating tuberculosis patients and providing drugs to patients free of cost. This project has already been implemented in cities like Mumbai in Maharashtra, Patna in Bihar and Mehsana in Gujarat.<sup>35</sup>

#### **99 DOTS**

Yet another novel scheme to strengthen TB treatment care was launched. The research was carried out by NTI, Bangalore in collaboration with St. Johns National Academy of Health sciences, Bangalore and Karma Health Care. It is a fixed-dose combination with daily regimen. Each time a patient takes a dose of medication a hidden number is revealed which is unpredictable to the patient. The revealed number completes a phone number, while the first point of the number is printed on the front side of the envelope. The patient makes a free call to the completed phone number. The call center maintains a large array of phone numbers which are packaged in an unpredictable way to the patient and the only way for a patient to call time correct number is to dispense the pills. Thus with a phone call the official can be confident that the patient has taken their medication for the day. With this, information reminders, incentives, retrieval action and counseling can be provided to patients with low adherence. The project has completed scaled pilots across five urban and rural sites with implementation across public and private sector. Currently, a large-scale clinical trial is in process to improve adherence in HIV-TB co-infected patients. The RNTCP program seeks to implement this strategy across the nation in a phased manner.<sup>35,36</sup>

#### **TB-HIV Collaborative Activities**

The initial 2007 national framework for joint collaboration between RNTCP and NACP promoted selective referral of patients with high risk behavior. The frame work was revised in 2009 including provider initiated model as a part of an intensified package. The package was designed to enhance identification of HIV-infected TB cases, linking to HIV care and support and set the ground for better monitoring and evaluation jointly by the two programs.

The TB-HIV intensified package includes:

- 1. Routine referral of all TB patients for HIV counseling and testing.
- 2. Provision of CPT to all HIV-TB co-infected patients through decentralized delivery under the RNTCP program.
- 3. All HIV-infected TB patients must be provided access to care and support for HIV/AIDS, including antiretroviral therapy.
- 4. Expanded recording and including shared confidentiality of HIV status with TB program.<sup>24</sup>

#### **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.<sup>25</sup> 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 special format.<sup>26</sup>

The rationale behind this decision was to have an accurate estimate of number of TB cases in the community, to help program managers to take evidence-based decisions.<sup>27</sup>

#### Standards for TB Care in India

The Central TB Division has developed standards for TB care in India (STCI) on the basic framework prepared by WHO and 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.<sup>28</sup>

Overall, STCI consists of 26 standards, viz., diagnosis 1-6; treatment 7-11; public health 12-21; social inclusion 22-26.<sup>28</sup>

#### NIKSHAY

The RNTCP database earlier used epi info-based software for reporting with electronic data transmission from district level upwards. The program then shifted toward Windows version in 2007.<sup>29</sup> Later CTD in collaboration with National Informatics Centre developed a case-based web-based online (Cloud) application-Nikshay launched in May, 2102, which has now been scaled nationally. It was honored with National e-governance award (Gold) held at Kochi on 30-31 January, 2014.<sup>5</sup>

# Public-Private Mix

The private sector plays a crucial role in the health sector in Indian scenario as more than 70% of country's population avails healthcare services in the private sector.<sup>30</sup> Thus to build linkages with the private sector and other healthcare establishments, RNTCP has initiated multiple schemes to promote the involvement of private sector.<sup>31</sup> The basic idea behind these schemes is to assist the private partner financially and logistically to improve the quality of work.<sup>31</sup> Sputum collection scheme, DMC scheme; TB ACSM scheme, LT scheme and slum scheme are few of them launched with the private sector. The post of PPM coordinator and TBHV have also been formed for coordinating with private sector under the program.<sup>31</sup>

# **Diabetes Screening**

After a pilot study in 2011, a policy decision was taken in 2012 to screen all TB pts for diabetes in 100 districts where National Program for Prevention and control of Cancer, Diabetes, CVD and stroke (NPCDS) activities is being implemented.<sup>2</sup> The program is looking forward to country-wide scale of this initiative.

#### **Involvement of Medical Colleges**

Under RNTCP, medical colleges play an important role in service delivery advocacy, training and operational research. They also make contributions in RNTCP policy formulation and program implementation. They help RNTCP with additional human resources, logistics for microscopy, funds to conduct sensitization, trainings and research in RNTCP priority areas. Recently, thesis grant has been increased from 20,000 to 30,000 rupees for promoting students to take thesis on TB-related topics.<sup>32</sup> At present, over 330 medical colleges, both public and private, have been involved in TB control in India. They have contributed in a major way in finding more TB cases, especially sputum-negative and extra-pulmonary cases.<sup>5</sup>

# **Future Plans**

- Implementation of airborne infection control guidelines in healthcare institutions.<sup>33</sup>
- Most importantly, devising legal provisions to restrict over the counter sale of anti-TB drugs.<sup>34</sup>
- Involvement of school teachers and students in the ACSM activities.<sup>31</sup>
- Periodic revision in the financial norms under RNTCP.<sup>32</sup>

- Fostering liaisons with Medical Council of India.<sup>32</sup>
- Promoting operational research.

# Conclusion

To sum up, RNTCP has been well-revised and multiple strategies have been planned to keep pace with international standards. Efforts have also been made to make services more patient-friendly. The program must continue and sustain these efforts to make India TB free as global TB control is unattainable without enhanced control of TB in India.

# Conflict of Interest: None

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Date of Submission: 22<sup>nd</sup> Feb. 2016

Date of Acceptance: 06<sup>th</sup> Mar. 2016