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A Review on Tuberculosis Mismanagement in India and Failure of the Current Dots Programme

Srijoni Sarkar[1]*

1. Department of Pharmacology NSHM College of Pharmaceutical Technology, NSHM Knowledge Campus, Kolkata Group of Institutions 124 B.L. Saha Road, Kolkata-700053.

ABSTRACT

Tuberculosis remains a significant public health issue worldwide especially in developing countries. India leads the world in its burden of tuberculosis (TB) due to its neglect as a public health problem, and mismanagement of TB patients in both public and private sectors. The original National Tuberculosis Programme (NTP), launched in 1962, failed because of several reasons. To overcome its shortcomings, the DOTS strategy was introduced in 1992 as an initiative under the Revised National Tuberculosis Control Program (RNTCP). Though the latter has been better funded and better managed, it is yet to address several key issues like lack of adequate and updated infrastructure, unregulation of the private practice sector and the emergence and increase in number of drug-resistant tuberculosis in India.

Keywords: Tuberculosis, DOTS, RNTCP, mismanagement.

*Corresponding Author Email: srijoni24@gmail.com

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INTRODUCTION

Tuberculosis is an infection caused by the rod-shaped, non-spore forming, aerobic bacterium, Mycobacterium. It is transmitted by small air-borne droplets generated by coughing or sneezing of a person affected with pulmonary or extra-pulmonary tuberculosis. The bacteria present in these minute droplets enters the airways of an individual where they get trapped. If it enters a healthy individual, the body's own defense combats it; however, in those subjects who are immune compromised, the bacteria settles inside the airways and wreaks havoc. TB is usually characterized by fatigue, weight loss, night sweats etc[1]. About two billion people (one-third of the world's population) carry latent tuberculosis (TB) infection and more than nine million of them become sick each year with active TB, which can be spread to others[2]. In 2011, 8.7 million people suffered from active tuberculosis with 1.4 million deaths, with over 95% of these deaths occurring in low- and middle-income countries. TB is also a major killer of those co-infected with human immunodeficiency virus (HIV), causing one quarter of all deaths[3]. Poor health systems, limited laboratory capacity for case detection, treatment barriers and complications (unreliable drug supply, patients not completing treatment, or prescribing errors), TB and HIV co-infection, and the emergence of drug resistance make TB a major challenge facing public health programmes, particularly in the 22 countries with the highest TB burden (Figure 1).

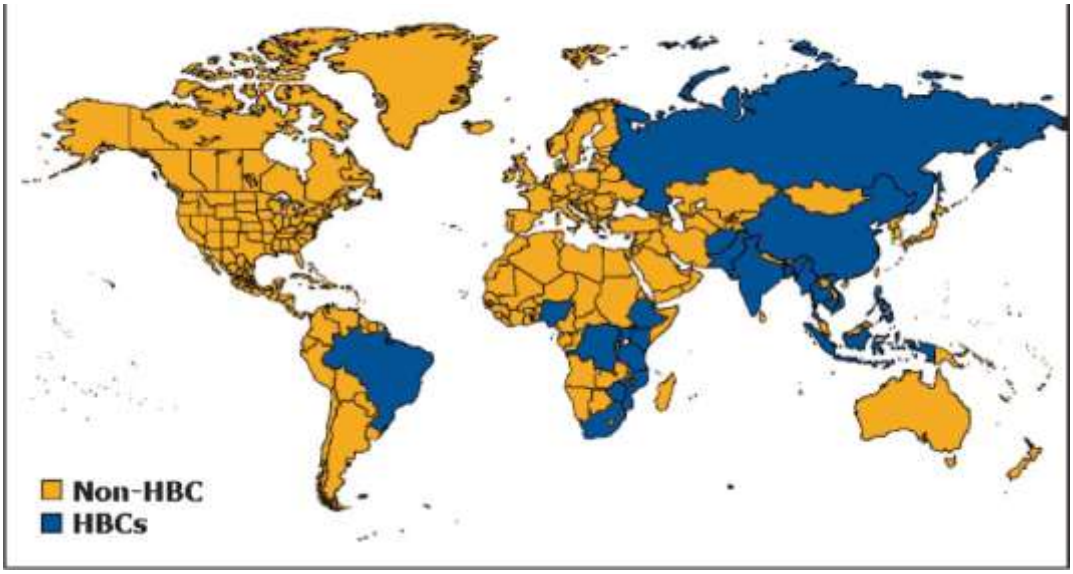

Figure 1: The 22 high burden TB countries in the word (*Source*: Kaiser Family Foundation, *www.GlobalHealthFacts.org*, based on WHO, *Global tuberculosis control* 2010, Slide Date: March 04, 2011; reprinted with permission from the Henry J. Kaiser Family Foundation, California, USA).

Drug resistance to TB arises due to improper use of antibiotics in chemotherapy of drug-susceptible TB patients. India leads the world in its burden of TB, accounting for 20% of its global incidence, due to the neglect of TB as a public health problem, and mismanagement of TB patients in both public and private sectors. India has an even higher share of global incidence of multi–drug resistant (MDR) TB. Thus the success of any global effort to control TB and MDR–TB is critically dependent on the success of such an effort in India.4.

Control of TB in India has come a long way since the initiation of the National TB Programme (NTP) in 1962. The NTP failed because of several reasons- managerial weaknesses, inadequate funding, overreliance on chest radiographs, lack of standardized treatment regimens, low rates of treatment completion, and lack of systematic information on treatment outcomes. This prompted the Government of India, in collaboration with the World Health Organization (WHO) to evolve a revised strategy for the control of tuberculosis in India. Revised National Tuberculosis Control Program (RNTCP), based on the Directly Observed Therapy Short course (DOTS) strategy, began as a pilot project in 1993 and was launched as a national program in 1997 and the entire country was covered under DOTS by 24th March 2006.[5] DOTS is the internationally recommended strategy to ensure cure of tuberculosis; it has become the standard for the diagnosis, treatment and monitoring of tuberculosis worldwide and has been implemented in 182 of 211 countries, covering more than 77% of world's population in response to the growing threat of this disease.

The basic principles of RNTCP are:

1. Political commitment for ensuring adequate funds, staff and other key inputs.
2. Establishment of diagnosis primarily by microscopic examination of specimens obtained from patients presenting to health care facilities.
3. Regular and uninterrupted supply of anti-TB drugs in the form of a patient-specific box that contains the medicines for the entire course of treatment so that no patient is subjected to interruption of treatment for lack of medicines.
4. Direct observation of every dose of treatment in the intensive phase and of at least the first dose in the continuation phase of treatment.
5. Systematic monitoring, supervision and cohort analysis-one Senior Treatment Laboratory Supervisor (STLS) is responsible for organization of uninterrupted treatment and one Senior Tuberculosis Laboratory Supervisor for ensuring quality laboratory service for every 5,00,000 population[6].

Though RNTPC and DOTS have a high success rate and have been able to standardize drug regimens, prevent misuse of drugs and avoid emergence of drug resistance; in light of recent

evidence, several limitations that bind RNTPC and pose a threat to TB management in India have surfaced and should not be overlooked. In this review, the problem of mismanagement of TB in India, in diagnosis as well as treatment, in both the public sector and the private sector, and the challenges that RNTCP will need to address in its next phase (2012 – 2017) will be examined[7].

Mismanagement in Tb- Diagnosis and Treatment

Failure in optimum case diagnosis

Under–utilization of sputum microscopy and over–reliance on chest radiography

Sputum smear microscopy is the most reliable method for diagnosing patients with pulmonary TB, though chest radiography is more sensitive but less specific. In India, 70% of the population resides in the rural areas. Due to lack of expansion of healthcare services in the rural areas with respect to the rise in population during the operational years of NTP, only a very minute fraction of cases were diagnosed with sputum microscopy and chest radiographs became over utilized-virtually, 78% cases were diagnosed using the latter only[8]. This resulted in the unwarranted administration of anti–TB treatment to a large number of patients. The same pattern of under–utilization of sputum microscopy and over–reliance on radiology has been documented in the private sector as well.

Use of suboptimal diagnostics in the private sector

In the private sector, there was widespread abuse of suboptimal diagnostic tests, such as sero-logical (antibody–detection) tests for active TB. A large amount of published literature has shown that serological tests for TB are inaccurate and have no clinical role in the diagnosis of either pulmonary or extra-pulmonary TB. Also, there are no international guidelines supporting their use[9,10]. Despite this, an estimated 1.5 million TB serological tests are done in India alone every year at an expenditure conservatively estimated at US $15 million per year. This has lead not only to inflated healthcare costs, but also delayed or incorrect diagnoses. Thus the fuel to TB endemic just keeps growing.

Diagnostic challenges in the era of drug resistance

With the advent of the RNTCP, facilities for sputum microscopy have improved, both in number as well as quality. But the diagnosis of drug-resistant TB still continues to be a challenge as it requires specialized and updated equipment, which are at par with their global counterparts[11, 12]. Facilities for testing of culture and drug susceptibility testing (DST), along with newer tools like molecular testing, MDR screening are grossly inadequate, mostly even absent.

Failure in optimizing treatment strategies with the shift in demand of public health:

Poor treatment practices in the private sector

The private sector in India is highly unorganized, with a lack of regulation in both prescribing practices as well as the qualifications of practitioners. Practitioners of various alternative forms of medicine often prescribe anti–TB drugs without being qualified to do so[13,14]. These lead to prolonged morbidity and increased mortality from the disease, and emergence and spread of drug–resistant organisms. Studies have shown that private practitioners in a single area of a city or town had described a vast number of different drugs regimens, most of them not even valid and in accordance with the treatment guidelines.

Limited access to treatment regimens for MDR–TB and continued use of retreatment regimens which are not evidence based

In 2006, the RNTCP launched the DOTS– Plus initiative for dealing with the problem of MDR–TB, but even today, less than 1% of the estimated number of MDR–TB patients have access to adequate treatment. The estimated burden of MDR-TB under program conditions is about 1,10,132 cases according to the RNTCP 2008 data (i.e. 3% of fresh cases and 12-17% of retreatment cases are possibly multidrug resistant). Adding to this pool are MDR-TB cases from treatment failures. Prevalence of MDR-TB among the failures of fresh cases ranges from 17 to 41% and among retreatment cases ranges from 32 to 86%. Considering that more than 50% of the new cases are not registered in RNTCP, and evaluating TB treatment practices in the private sector, the number of MDR estimates is likely to be considerably high. RNTCP DOTS-plus strategy has initiated only around 1600 MDR-TB patients on category-IV treatment[15-18]. Unfortunately, retreatment patients in India continue to receive a single standardized regime of 2HRZES/HRZE/5HRE. This leads to a situation where a patient who has failed a first line treatment with HRZE (isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E)) is given a single new drug, streptomycin (S), as part of the retreatment regime[19-22]. This regime violates a basic tenet of TB chemotherapy which is to never add a single drug to a failing regimen. The WHO in its TB treatment guidelines (2010) no longer recommends this regimen, and despite demands for a review of this policy, this suboptimal re–treatment regimen continues to be used for treatment failure patients in RNTCP[23-26]. This can lead both to poor cure rates, and further amplification of the problem of drug resistance in India.

Lack of patient–centered approaches to enhance accessibility to and acceptability of the DOTS programme

A public health program must not discriminate against patients by refusing care; it is not justifiable to refuse available treatment to patients in a control program. No patient should be denied treatment under RNTCP[27-31]. But forced by the circumstances, the implementation of the DOTS strategy is often success driven. It is even claimed by some researchers that DOTS programs

rejected patients who were unlikely to adhere to treatment. Some of the major reasons for patient dropout from the DOTS programme are distance between the patient's home and the DOTS center, failure to adhere to the regimen either because of livelihood or fear of social stigma, lack of adequate patient follow up by practitioners as well as community workers etc[32, 33].

Possible Measures to Tackle the Growing Threat to TB Management in India

Mismanagement of TB is a serious threat for TB control in India[34, 35]. Misdiagnosis and mismanagement can result in only a fraction of TB patients getting correct diagnosis, appropriate therapy, and positive outcomes. Therefore, to improve TB control, TB diagnosis and treatment must be improved so that transmission can be successfully reduced. In addition to addressing the technical and operational issues discussed, there is a need for closer linkages and integration of RNTCP with the general health services on the one hand and with private healthcare providers on the other.

- One of the ways to ensure the success of the TB control programme is to ascertain active involvement of the private sector in case detection and notification and provide them with the standard guideline of TB care[36, 37]. India has the largest private health sector in the world, with a health care market that is worth billions of rupees. Of the 8 million doctors in India, about 6 million are engaged in private practice and only 19,000 private practitioners (0.31%) are implementing RNTCP[1]. Still most of the private physicians have practically no access to information or training programs, which accounts for surprising disparity in their management strategies. Health system strengthening by clearing up of the shortage of staff and creating parallel staff for the private sector is needed. Medical colleges should be actively involved with activities such as training of senior health professionals and other staffs, delivery of services of RNTCP and operational research with involvement of professors of various departments especially those of orthopedics, neurology and gynecology. The procrastination regarding research in TB should end and there should be active attempts to decentralize the decisions over research in TB at medical college level.
- The current RNTCP has been better funded and better managed, although substantial budget increases will be needed to tackle MDR–TB. There needs to be a scaling up of the DOTS-Plus program to include all the MDR-TB patients who come to 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 retreatment regimen of first-line drugs (the "Category II regimen") to patients with a high likelihood of MDR.
- Thorough follow up of relapse cases is crucial for the success of the government programme.

Relapses are not accounted for success of regimen under RNTCP and if disease recurrence is substantial, current end of treatment targets may be too low to bring about the expected declines in incidence. The program should have a provision for a minimum follow up of one year after completion of treatment as 86% of pulmonary relapse occur in first 12 months.

- There is an urgent need for strengthening reference laboratories and laboratory network equipped with newer and rapid techniques for diagnosis of TB and drug resistance available to all the patients who present to RNTCP. Specimen 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. In new patients, if the specimen obtained at the end of the intensive phase (month 2) is smear-positive, sputum smear microscopy should be obtained at the end of the third month.[38, 39] In new patients, if the specimen obtained at the end of month 3 is smear-positive, sputum culture and drug susceptibility testing (DST) should be performed. TB patients whose treatment has failed or other patient groups with high likelihood of multidrug-resistant TB (MDR-TB) should be started on an empirical MDR regimen.
- Rising incidence of smear-negative disease in countries where HIV infection is highly prevalent is a very disturbing current trend. Reflecting this lack of sensitivity, along with deficiencies in case reporting, currently less than 20 percent of the roughly 8 million predicted annual cases of tuberculosis are identified as smear-positive. Diagnosis is more difficult in individuals with TB/HIV co-infection. More than 1.3 lakh TB patients were tested for HIV and more than 20,000 (hardly 2.2% of the 0.9 million total HIV-TB pool) patients are detected to be TB-HIV co-infected. HIV testing for patients with TB should be made mandatory rather than optional. Also, HIV patients should be regularly screened for TB. Daily dosing is now recommended for new patients with pulmonary TB throughout the course of therapy, especially for people with HIV co-infection.

CONCLUSION

In India, already 47% reduction has been achieved in the tuberculosis prevalence rate and 33% reduction in mortality rate in the RNTCP era. Hence, RNTCP continues to be the national and local action and commitment that determines the degree of success in tuberculosis program. The next phase of the RNTCP aims for the provision of universal access to quality diagnosis and treatment for the entire population, and for the detection of at least 90% of all TB patients in the community. RNTCP alone cannot achieve this without scaling up further, and the active

engagement of the private sector and other providers such as the non-profit sector, in the delivery of TB services. Small–scale pilot PPM projects will no longer be sufficient; the Indian private sector must be incentivized and engaged on a scale commensurate with its significant role.[40, 41] This will require socially–oriented, but economically viable business models. It is important to emphasize that PPM initiatives should not be used as an excuse for the government to scale back on its TB control investments, or seen as a way of promoting the private sector without adequately regulating it. Most importantly, the mistakes of NTP and shortcoming of implementation of the current RNTCP should not be forgotten or repeated in order to curb the endemic of tuberculosis in India.

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