International Journal of Research in Social Science
Vol. 12 Issue 06, June 2022,
ISSN: 2249-2496 Impact Factor: 7.081
Journal Homepage: http://www.ijmra.us, Email: editorijmie@gmail.com
Double-Blind Peer Reviewed Refereed Open Access International Journal - Included in the International Serial Directories Indexed & Listed at: Ulrich's Periodicals Directory ©, U.S.A., Open J-Gate as well as in Cabell's Directories of Publishing Opportunities, U.S.A

Conceptual changes in the shift from NTP to RNTCP and its implications

Author:

Ashani Dhar

Abstract

Tuberculosis continues to be a public health concern despite the significant efforts to reduce it.

Regarded as a disease that has equally perilous physical and human suffering, it continues to impose major socio-economic burdens on individuals. India alone accounts for the highest TB burden in the world. The national strategies devised to combat TB were designed according to the results obtained from extensive research conducted in the country as against other programs like Malaria Eradication where the program strategy was informed by international decisions. Yet, the way programmatic strategies evolved showcase a conceptual change that necessitate a deeper understanding. The paper intends to highlight the conceptual changes as India moved from NTP to RNTCP and analyse the changes in the strategies thus adopted.

Introduction

Tuberculosis, or TB has been in existence since ancient times. Despite the discovery of the bacteria by Robert Koch in 1882 and subsequent antibiotic treatment strategies, it continues to be the one of the top 10 killers in the country. Out of the total TB cases that occur globally, around 20% of those cases are detected in India although the number of cases that are not diagnosed or notified could range between one to three million cases. India has nearly 2/3rd of the total cases in South-East Asia. In India, 20 lakh new cases are detected every year and 5 lakh cases die annually indicating that it continues to be a fatal disease.

Although more men are affected by TB than women, mortality due to TB is higher in women.

In fact, the number of women dying from TB is much higher than the total number of women dying from causes of pregnancy and child birth.

The treatment for TB was made available with the discovery of antibiotics. Vaccines were extensively used since 1930s and 40s along with anti-TB drugs. TB sanatoriums existed since 1910 in India, and organised efforts in the form of TB programs were instituted since the 1940s. Despite such concerted efforts it continues to be one of the top 10 major killers in the country. The drug-resistance of TB and high chances of co-infection of TB in HIV positive patients is further making matters complicated. It is estimated that about 4.6% of TB patients have HIV infection too.

Pathophysiology of TB

Tuberculosis is an infectious disease and its causative agent of is Mycobacterium tuberculosis. The main reservoir of the bacilli are the humans, however, it is also found in animals like cattle (Bovine TB) which may sometimes be communicated to man through contaminated milk. In recent years, other 'atypical' mycobacterium have been isolated from humans too. It is a droplet infection that can either be transmitted directly from one person to another, or indirectly as micro droplets are released into the air which is inhaled by another individual. The mode of entry could be through the respiratory tract or the gastrointestinal tract. The infection can be a local contiguous spread or distant spread. In case the bacteria affect the lungs it is called pulmonary TB and it is called extra-pulmonary TB in case it affects organs outside the lungs. For example, TB affecting brain is called encephalitis TB. TB can affect every part of the body except hair. It can affect bones, meninges, heart, kidneys, spleen etc. The common clinical manifestations include chronic cough, difficulty in breathing, blood in sputum. In case the brain is effected, seizures, confusions are common. Symptoms depend on the organ affected. Fever, weight loss and loss of appetite are common to all types of TB infection.

Socio-Economic Burden of TB

The study undertaken by Banerjee and Anderson[1] showcased that in addition to the physical suffering that TB caused, it also caused socioeconomic suffering that added to the total TB suffering in the country. The socio-economic burden on the individual

was manifested in terms of loss of livelihood, socio-economic dislocation, loss of social networks etc. At the population level, TB impacts the workdays and money earned by the working population that has far reaching implications for the economy as a whole. Around 170 million workdays are lost due to TB in a year and it is estimated that the economic cost of TB is about Rs. 13,000 crores annually. As per the TCR-Chennai study, TB costs around 300 million USD in direct costs alone, out of which 1/3rd is in the form of debts taken by patients and their family. TB in children is also responsible for high drop-out rates and for women who get rejected from their families and communities due to the stigma attached to TB.

It is believed that about 40% of people in India are infected with the bacilli and 10% of them will develop TB sometime in their lifetime. In case one sputum positive patient goes untreated, it has the potential to infect 13-15 people on an average in a year. Presently, TB is more prevalent in the age group of 20 to 50 years. This age bracket forms the major chunk of the working population. More proportion of the working population getting infected with TB would negatively impact the growth of the country as well.

History of TB Control in India

TB was a major public health concern even in the 1900s and organised efforts to deal with it existed before any national policy was formulated. Though the scope and nature of the organised response was not very extensive, the earliest response can be traced to 1906, when the first TB sanatorium was established near Ajmer. Another sanatorium was established in 1908 in Almora.

These were small-scale institutions that attempted to isolate and treat TB cases.

The first non- missionary sanatorium was set up in Shimla in 1909 and then near Chennai.

[1]Banerji, D. and Andersen, S. (1963): "A Sociological Study of Awareness of Symptoms Suggestive of Pulmonary Tuberculosis", *Bull WHO*, Vol. 29, No 5, pp: 665-683.

The first TB dispensary was set up in Bombay and Madras in 1917 and by 1920 the main strategies were diagnosing, isolating and advising patients to take adequate rest and have a good diet. Till the advent of the chemotherapy, antibiotics in the form of sulphonamides were recommended along with staying in well-ventilated areas.

The availability of X-ray examinations since 1925 improved TB diagnosis. Although, X-ray machines were available at limited sites, radiography was being used to detect TB cases. In 1945, X- ray facilities were expanded by Mass Miniature Radiography (MMR). Mobile MMR units were able to X-ray many people and the results were stored in small films that were later studied and screened for abnormalities.

BCG vaccine, introduced in 1940's was a large-scale effort to combat TB. The vaccine was introduced in India in 1948 for the first time. By 1949, BCG vaccine was being produced in India and its use was expanded to institutions in India, mainly schools, to provide protection against TB at a young age. Anti-TB drugs had been made available in India as well. In 1940's there was Para-Amino Salicylic Acid and Streptomycin and Isonicotinic Acid Hydrazide (a miracle drug created by Koch) and Thioacetazone in the 50's.

The Bhore Committee expected around 20-25 lakh cases to be detected annually along with half a million deaths. A total of 6000 beds were available institutionally. Recognising the constraints of the public health system, the Committee had recommended organised domiciliary services by establishing TB clinics at the district level and mobile TB units at the rural level making use of the MMR units. The establishment of the Central TB division at Directorate General of Health Services indicated that the government was according priority to TB.

Studies had been conducted in the 1950s to study the various aspects of TB. For instance, studies undertaken to ascertain the effect of the context and institutional arrangement in domiciliary application of chemotherapy versus in hospital care. Studies estimated the burden of bacteriologically positive cases to be about 2-8 per 1000 and radiologically positive cases to be about 13-25 per 1000. By 1959, there was a fair estimation of the TB burden in India, and evidence that domiciliary treatment was as effective as treatment delivered at hospitals. In order to develop a sound TB program, the National Tuberculosis Institute (NTI) was set up in Bangalore by GOI to develop a

program that was operationally feasible, applicable to rural and urban areas and economically affordable.

National Tuberculosis Program (1961-1986):

NTI was to formulate a program given the various technological, political, organisational and resource constraints and was faced with some pertinent questions. Should active or passive case detection be used and whether domiciliary treatment should be given. Two studies conducted by ICMR and TRC-Chennai concluded that hospitalisation was not necessary to treat TB and domiciliary treatment was as effective. The second study was conducted by NTI by Anderson and Banerjee to study the symptomatic suffering in the form of level of awareness of the symptoms among the TB patient. It concluded that passive case detection would be effective as 70% of bacteriologically positive cases and 51% of the radiologically positive cases were aware of 1 major symptom and that half of the sputum positive cases and one-third of the radiologically positive cases were going to healthcare to get some relief. This study was important as it dispelled popular belief that people were ignorant and not taking any action. This study proved that atleast 50 % of the bacteriologically positive cases could be treated using passive case detection method.

NTP was devised based on these findings. The aim of the program was not to control TB. It was simply to relive the suffering of those who were visiting a healthcare centre with a felt need. The project was introduced as a pilot in Anantpur district in Andhra Pradesh in 1961. Later, it was launched in the entire country with the aim of reducing the suffering of TB patients by diagnosing and treating them. Thus, efforts were made to control the disease without explicitly aiming to do so.

The core element of NTP was the District TB program. District TB centres were established to carry out monitoring of the program and provide feedback to the states and centre. The District TB Program was to deliver services throughout the district by training a large number of district personnel to implement the program. Application of the findings of the previous studies resulted in the NTP adopting a passive-case detection approach along with symptomatic diagnosis to provide domiciliary treatment.

Because the district had been recognised as the primary unit, the strategy had to be designed accordingly. The study conducted in Anantpur district in 1960 revealed that on an average around 5000 bacteriologically positive cases were expected in each district. Whereas, each district, on average had only 1 TB clinic with a few beds ranging between 20-100. Because of an acute mismatch between the need and the available services and an insufficient budget, very few people were actually diagnosed and an even smaller number was able to complete the treatment that typically lasted from a 1 year to 1.5 years.

On the contrary, every district had around 50 health institutions on average which were managed by an MBBS doctor as the medical officer. This is why it was realised that TB services would be delivered through the general health services based on a felt needs approach. Integrating the program with the general health services would not entail additional costs as long as general health worker would undertake 3 sputum exams daily that could diagnose and treat about 2000 cases per centre. This approach was adopted over the vertical disease program approach because of the understanding of the natural history of TB. Because clinical manifestations of TB may occur after many years, allocating a separate personnel, separate budget and separate organisational structure would have been inefficient. Because the fate of NTP had been linked to the functioning of the general health services, improvements in the general health services would also improve NTP.

Challenges under NTP

Because NTP had been designed based on carefully carried out studies, it was a sound program. Yet, at the operational level, it fell short because of the following reasons:

1. NTP post implementation, was an out rightly neglected program. It did not receive the same priority and attention that other communicable diseases received. For example, 1960's and 70s was the period when other programs for malaria and smallpox eradication were at their zenith. Additionally, unlike malaria, NTP did not specify any clear targets.
2. Despite integration with the general health services, there were no specialised TB workers, microscopes were not used to diagnose suspected cases, the

estimation that 3 sputum exams per day could be fruitful was not happening. The multipurpose general health workers at the PHCs were not taking interest in TB diagnosis and treatment activities. The negative impact was that most of the TB activities were restricted to the district with no notable development at the periphery.

3. Excessive focus on family planning had impacted education and publicity related to TB as well. BCG campaign education and publicity was integrated with the extended education department and most of the publicity activities were for family planning.
4. There was no continued evaluation about the effectiveness of NTP.
5. The functional unit of the program was the district.
6. The treatment lasted for 12-18 months and became a major obstacle in completion
7. Newly diagnosed patients were prioritised over the older patients.

The ICMR expert Committee 1975 identified the following problems with the NTP:

a. Case finding activity was nominal.
b. While the peripheral staff was neglecting TB activities, even the central TB units did not have competent staff to diagnose TB.
c. Inadequate provision for the repair and maintenance of equipment partly due to inadequate budget and partly due to neglect.
d. Inadequate supervision.
e. Lack of machinery to retrieve drug defaulters in peripheral institutions.

The reasons for the failure of the program had also been highlighted by the joint review of the GOI in collaboration with the WHO and Swedish International Development Agency (SIDA) in 1992. The reasons mentioned were:

- Inadequate budgetary allocation for such a serious public health concern
- Inadequate managerial efficiency due to replacement of public health experts by bureaucrats.
- Neglect of the interests of the most vulnerable populations
- Inadequate diagnosis and treatment – only 30% were diagnosed out of whom 30% successfully completed the treatment

- Poor quality of equipment like the microscope
- Excessive use of X-rays to diagnose cases
- Shortage of drugs due to irregular drug supply
- Long duration and multiplicity of the treatment regimen
- Irregular consumption of medicines by the patient
- Poor compliance or non-compliance by the patient
- High default rates
- Non-standardised treatment regimen
- The emergence of HIV led to higher risk of developing TB
- Increased résistance to drugs of the MDR-TB cases
- Lack of systematic information on treatment outcomes

After the shortfalls of the program had been identified, recommendations were made to ensure uninterrupted supply of drugs, improved laboratory services, especially at the periphery and strengthening of the general health services. The idea was to make it a priority by realising that it continued to be a major public health concern.

Based on the recommendations of the Committee of GOI, WHO and SIDA, it was recommended to revise NTP. The revised program was launched as the Revised National Tuberculosis Control Program.

Revised National TB Control Programme (RNTCP):

There were two immediately noticeable changes that were made. The addition of the word

"Revised" and "Control", both leading to conceptual changes in the program. The revision was to be based on financial resources where the program was dependent on aids and loans from various international agencies. From the very inception, RNTCP was not a self-dependent program. For example, World Bank covered a population of 7 million, DANIDA was supporting TB activities in Odisha, WHO was providing technical support at the central, state and district level. The word control referred to the programmatic intent to control the disease.

The organisational structure was one where the District TB Cell was the key institution which was supported by a sub-district level called the TB unit which served as a link between sub-district and the district. The State TB Cell was responsible for monitoring and supervising activities.

Therefore, under the revised program, one more unit – TB unit – had been created with a special cadre of medical officer helped by the Senior TB Supervisor (STS) and the Senior TB Lab Technician.

Under the TB Unit, there were Designated Microscopy Centres which was any health centre with a facility to perform a sputum examination.

The revised program was launched as a pilot program between 1993-1995 in Delhi, Kerala, West Bengal, Maharashtra and Gujarat. 1997 onwards it was expanded throughout the country in a phased manner for which India took a loan of 142 million USD from the World Bank. The first phase was from 1997 to 2005 and the second phase was from 2006-2011.

Two drugs, *Rifampicin* and *Pyrazinamide* were introduced along with the Short Course Chemotherapy. Because the SSC was reducing the treatment duration to 6-8 months as against the 1-

1.5 years, it was believed that more number of people would be able to complete treatment.

Phase 1 of RNTCP:

Started in 1997, the first phase of RNTCP had at the outset set out a goal for the program (something that had not been done in the NTP). The targets were:

1. Achieve atleast 85% cure rate of the newly diagnosed sputum smear positive TB patients.
2. To detect atleast 70% of the new sputum-smear positive patients after the first goal is met

The focus of the RNTCP in the first phase was to expand the DOTS services throughout the country. the DOTS strategy is the – Directly Observed Treatment, Short-course Chemotherapy. By 2006, the entire country had been covered under the DOTS program.

Core Elements of RNTCP

1. Political and Administrative Commitment:

There were about 2 million cases in 1958 and the NTP had not registered any significant decrease in the burden of TB. It continued to be a major killer because the targets had not been identified clearly and other programs got priority over TB. RNTCP recognised that the government will have to give the program due priority and be implemented at the national, state and district level with the same commitment.

2. Good quality diagnosis through microscope:

Good quality microscopes were needed to detect TB patients. Because the goals had also laid emphasis on the bacteriologically confirmed cases, it was important that the quality of the microscopes was improved.

3. Good quality and uninterrupted supply of drugs:

NTP had cited shortage of drugs to be one of the major reasons for its failure. The introduction of rifampicin as an anti-TB drug would lead to better cure rates. But the availability of medicines had to be ensured. A patient-wise box was issued to every registered TB patient to ensure that the said patient would not be forced to interrupt the treatment due to non-availability of drugs. Therefore, once one patient began treatment, there would not be any shortage for the next 6 months ensuring completion of treatment.

4. Supervision

Failure of the NTP had been also credited to non-competition of the treatment regime because it was self-administered with no provision for supervision. Under the RNTCP, the patient-wise boxes were issued to the patient but every dose had to be taken under direct supervision of the health worker or a DOTS provider in the intensive phase. The program explicitly stated that the DOTS provider could not be a family member, though, community members could be DOTS providers. In the continuation phase, the first dose of every week was to be taken at the health centre and the doses for the remaining week could be taken at home. Although, at the next visit in the following week, the patient was supposed to give in the empty strip of the previous week.

5. Systematic monitoring and Accountability:

The responsibility of treating TB was shifted from the patient to the health system by introducing a standard reporting system. Key indicators such as cure rates were observed along with regular performance analysis at every level. Sub-district level mobile supervisory staff had been created as well.

GOI and WHO had jointly review the functioning of the first phase of RNTCP and recognised certain important issues. Some of these issues were that the primary health care infrastructure was ill- equipped to deal with TB appropriately. The government, though recognised that TB was a major killer, had still not prioritised TB. Drug-resistance could slow down the momentum of the program.
HIV associated TB was a major concern, especially for the developed countries which had been able to effectively deal with TB. The review also revealed the low level of participation of the private sector and NGO's with respect to TB-related activities.

Phase 2 of RNTCP

Started in 2006, the second phase of the program had been extended to the entire country, where the main focus was to consolidate the gains so far, along with widening Tb services and access to services. Another loan of 170 million USD was taken from the WB to fund the program. 2006 was also the year when WHO launched the 'Stop Tb Strategy' to achieve a *World without TB.*

The core elements of phase 2 were:

1. Expansion of DOTS

Expansion of DOTS was to be done to include all patients with special focus on poor and the marginalised sections by improving detection and adopting a patient-centric approach.

2. Address the problems of HIV-TB Co-infection and MDR-TB

The DOTS+ regime had been initiated for the MDR-TB as it was resistant to rifampicin and isoniazid.

3. Collaborate with general health services

Because TB program was integrated with the general health services which was already burden with other programs and burdens, it was crucial to strengthen the general health services.

Effective engagement with TB patients

It was essential that needs and problems of the patients were understood and worked into the program strategies, therefore, effective engagement with TB patients had to be made.

4. Enabling and Promoting Research

Improvement of the vaccines, equipment and medicines along with operational research to improve program performance.

To summarise, the second phase of RNTCP focused on improving on the core elements along with diagnostic services through culture sensitivity test, especially in the case of MDR TB. It wanted to expand the scope of the program by reaching out to the most vulnerable populations of the society through advocacy, community involvement and social mobilisation.

Additional improvements in the Second Phase

Efforts were made to improve the quality of diagnosis as well as treatment in the second phase along with ensuring universal access to it. Private sector was also encouraged to undertake TB related activities. The DOTS Plus regime was introduced for MDR-TB along with treatment for XDR- TB. The program design was improved through community involvement, stronger advocacy and social mobilisation. During the second phase, NRHM was a concurrent program and therefore efforts were made to effectively integrate the two. Another improvement was the paediatric patient-wise boxes for children given their requirement of dosage, making India the first country to do so.

By 2009 India had been able to achieve the goals as set out in the RNTCP and that encouraged India to set a target of a ‘TB free India”. Although the natural history of TB clearly indicates that elimination of TB is going to be an extremely challenging task, the idea was to reduce TB burden to a level where it ceases to be a public health

concern. Thus, the objective of 'Universal Access for Quality Diagnosis and Treatment for All TB Patients in the Community' was set out.

The program clearly laid down the importance of including the private sector in the implementation of RNTCP. About 60% of all TB patients are managed by the private sector showcasing its importance in dealing with TB. But, the private sector had often been found guilty of not following proper guidelines for diagnosis and treatment which may lead to drug résistance. Many private hospitals did not notify TB cases. The private sector was costly and unable to supervise the treatment adequately which also leads to irregular medicine intake or patients stop taking the treatment altogether. The heart of the problem lay in the fact that the private sector did not view TB to be a public health concern, instead, it was seen as a standalone problem that could turn into a money minting machine for them. This is why, the government decided in the 12th FYP to deliver free drugs to all patients under private sector as well while directing private providers to improve early case detection and give standardised treatments.

The role of the NGO's has also been given due importance in the RNTP by making them a partner in implementation. NGO's are to play an important role in increasing community participations and in the implementation of the DOTS strategy. Although, after starting treatment, the disease becomes non-communicable in a very short span of time, it continues to be a highly stigmatised disease. For this reason, NGOs have also been entrusted to spread awareness about TB and work towards reducing the social stigma attached to it.

Salient features of RNTCP:

- Supervisory units at the district levels called the TB units were established with dedicated supervisors as against the uninterested general health workers under NTP.
- Budgetary allocation increased majorly due to international funding.
- Decentralisation of diagnostic and treatment services.
- Sputum examination became the primary diagnostic method over X-ray examination.
- Continuation with the passive-case detection technique.
- Categorisation of patients and standardisation of treatment done.
- Drugs were administered under direct supervision.

- Uninterrupted and regular supply of drugs was ensured by introducing the patient-wise boxes.
- Regular follow ups of the patient done through sputum examinations.
- Health workers were evaluating the outcome of the treatment.
- Patients were being educated and made aware about the problem.
- IEC activities, awareness, training of the staff and operational research prioritised under RNTCP

Challenges to RNTCP:

1. Despite achieving the target goals, the diagnosis and treatment was still limited, especially in the private sector.
2. Inadequate staff and equipment.
3. Deficiencies in supervision, monitoring and notifying of the disease.
4. Lack of an enforcement mechanism with respect to prescription and sale of anti-Tb drugs in case of drug-résistance TB.
5. Convergence of RNTCP with general health services was not as effective.
6. Insufficient budget allocation and an interrupted flow of fund.

Important conceptual changes in the shift from NTP to RNTCP

The very first difference between the two comes from the nomenclature of the programs.

NTP acknowledged that TB was a major killer in the country and a significant health problem, but the intent was to reduce human suffering with no outright goals to control it. RNTCP wanted to control the disease to create an epidemiological dent on the burden of the disease by setting out explicitly stated goals.

NTP had been designed and evolved by keeping in mind the Indian context. The design strategy had evolved after undertaking careful empirical studies and was based on the natural history of TB. This is why it was an epidemiologically sound program. RNTCP was designed using a more Western understanding and context adopting a more techno-centric approach. For instance, the study by Banerjee and Anderson recognised that TB entailed human suffering in addition to physical suffering. Studies showed how domiciliary treatment should be undertaken. Following the findings of the study, it was decided to adopt a home-based treatment approach. The

ICMR report had listed certain shortcomings of the NTP to which the foremost response of RNTCP was the introduction of a new drug. While the efficacy of Rifampicin cannot be denied, there were other areas that required immediate attention too. But the introduction of the new drug was in tandem with the interests of the developed countries, and it became the vehicle to introduce positive changes in India as well. Until the late 1980's, TB was a major public health concern in developing countries. The West, which had been able to reduce the TB burden significantly, was not paying it too much attention. It was only with the emergence of the HIV, and increase in the co-infection rates of the HIV positive patients with TB, did the developed countries start paying attention to TB and identified it as a global concern.

The design strategy of NTP had been made on certain assumptions. It was assumed that about 50% of action takers were going to the nearest health facility to relieve their suffering. If the program so designed would work in coordination with these general health facilities then, atleast those 50% of the cases could be diagnosed. NTP had used an epidemiological approach by considering the natural history of the diseases and used it to frame strategies and intervention in the TB program. The studies projected the diseases in a time-dimension and it was realised that the disease was in its declining stage. But, it was still in its endemic stage where it could take a long time (usually decades) to progress from a primary infection to an adult type infection. Therefore, there was no rationale to have a vertical disease program. NTP was integrated with the general health services to provide diagnostic, preventive as well as curative services to the community at the closest possible distance. the belief was that with some minor additional efforts of the general health workers, NTP could be implemented successfully without additional cost to the government. The integration of the NTP with general health services also resulted from the understanding that people were visiting health centres for their felt needs anyway, therefore to catch the patients early, it was more logical to make diagnostic modalities available at these centres rather than wait for the patients to come to specifically designed TB clinics. This integration could result in diagnosis without incurring an additional cost to government and thus the decision to rely on passive-case detection. The treatment could be self- administered at home by giving medicines for a month that were to be taken daily.

The assumptions that shaped RNTCP were different. Although, passive –case detection would continue, it argued against the excessive dependency on X-ray

examinations as sputum exams would be enough. As against the daily regimen, alternate-day regimen was adopted without any significant studies indicating its effectiveness. Supervision of treatment as against self-administration was also a new feature. RNTCP was a vertical program with separate staff and funding made available.

NTP ensured that the technology used was subservient to the needs of the people and not the other way round. Because the socio-economic advantages of treating people at home had been realised, the treatment regime adopted was one that was self-administered at home. There was no requirement to introduce/expand/alter technology to start/continue this program. The program took off from the infrastructure and facilities already available at the general health services. Multi-tier organisation of services based on a referral system were used wherever applicable and necessary, without unnecessary mystification of the disease.

The cost of the program was shared equally by the centre and the state in NTP whereas RNTCP was a 100 percent centrally sponsored program. The funds for NTP were provided by the government whereas RNTCP was funded by WHO and SIDA and other international organisation for programmatic strategies as well as technical support. Because funding for RNTCP was coming from international organisations, the level of autonomy of the government to design and implement a program strategy that they deemed fit was lost. The focus had shifted away from addressing the felt needs of the patients, rather techno-centric solutions had acquired primacy.

The major aim of NTP was to relive human suffering. It had no intentions to set goalposts that had to be achieved. Any reduction in the burden of TB was a welcome consequence of the program measures that had been designed after careful empirical research and analysis. RNTCP, on the other hand, had set targets to “control” TB. There were no explanations given as to how those targets had been devised or what studies had been undertaken to determine the goals.

As far as diagnostic modalities go, both the programs used passive case detection. Any patient with a cough for 3 weeks or more was tested. Under NTP, if 2 out of 3 sputum samples tested positive, the patient was started on anti-Tb drugs. If all the 3 samples were negative but it was a suspected case of TB, a course of anti-biotics was given. The sputum sample was again tested. Under RNTCP, the diagnostic algorithm changed and instead of 3 samples, only 2 samples were taken for testing. NTP had an

overreliance on X-rays whereas the focus in RNTCP was sputum examination.
This was because X-ray examinations are relatively easier to do. Since the district was the basic unit under NTP, X-ray machines had been made available there. However, x-ray exams are only conclusive of some structural abnormality in the lungs, the fact that the abnormality is on account of TB could only be confirmed with a sputum test. Sputum examination requires more labs, more technicians, more equipment and is low on sensitivity but it has high specificity and is a confirmatory test. Therefore, the revision was to switch over to a confirmatory test in the beginning itself without having to rely on unnecessary referrals of patients for radiological examination.

With regards to the treatment, under RNTCP, patients were divided into 3 categories with each category having a specified treatment regime. For example, in category 1, the treatment would last 6 months – 2 months of intensive treatment and 4 months of the continuous phase. Category 2 patients who were relapse, failure or defaulters, the treatment was longer for 8-9 months with 3 months of intensive and 5 months of continuous treatment. Under NTP, there was no standardised treatment protocol and the patient was required to go the health centre daily.

Under NTP the default rates were high because of non-availability of drugs, or because patients left the treatment due to lack of any supervision. The completion of treatment under NTP was low because of the long-duration of the treatment regimen also. Non-completion of treatment or interrupted treatment was leading to development of resistance to the anti-TB drugs making it more difficult to manage the disease. RNTCP acknowledged these shortcomings and attempted to correct this shortcoming by introducing a patient-wise box for every registered patient, including a paediatric patient-box which was not available in NTP, to ensure an interrupted supply of drugs to a person who started the treatment. As a result, the patient did not have to stop the treatment due to logistical problems. RNTCP reduced the treatment time to 6-8 months and followed the intermittent drug regime. To ensure compliance with the treatment, medicine had to be taken under the supervision of the DOTS provider.

To accommodate the new drugs introduced and direct supervision, an alternative day regime was adopted to ensure compliance. Therefore, medicines were at the core of the strategies evolved not the suffering of people as under NTP. Although the drugs were made available free of cost, studies by Muniyandi[2] showed how despite the free drugs, there were opportunity costs involved. By making treatment a supervised

treatment, there were direct and indirect expenses that had to be incurred to take the treatment. Direct costs would be the cost entailed on transport to travel to the health centre and indirect costs would be the loss of wages due to loss of workdays during the treatment. The cost to the government was also higher because of the separate and skilled human resources that were required under RNTCP. About 70% money was spent on the human resources because it was a vertical program, about 25% was spent on the drugs and 5% on the diagnosis. Under NTP, because the treatment was a month long to be administered at home, the direct and indirect costs were lower. Due to integration with an already existing general health services infrastructure, no additional costs were to be undertaken for the program.

Following the evidence from studies carried out specifically to test the efficacy of home-based treatment against institutional treatment, NTP had devised a program strategy of home-based self- administered treatment regimen. This was also recognising that admission in sanatoriums or institutions was leading to change in personal relationships due to prolonged isolation along with loss of livelihood. The program did not require the patient to come to a health centre to take the medicine as the patient was considered responsible and aware enough to take the medicines. RNTCP however, changed this entirely and the dosage was to be taken by the patient at the health centre under direct supervision of the DOTS provider. This change did not take into account the trouble it would entail for a person and his/her caregiver to travel to a health centre every alternate day.

NTP did not have any provisions to involve private practioners or NGO's per say. The reliance was only on the general health services. But, RNTCP thought it prudent to include private practioners, NGOs and the community to ensure the success of the program. For example, teachers, shopkeepers and even cured patients were made DOTS supervisors and were given incentives for ensuring the delivery of the SCC to the patients.

[2] Muniyandi M, R. Rajeswari and R. Balasubramanian (2006): *Estimating provider cost for treating patients with tuberculosis under revised national tuberculosis control programme (RNTCP)*. Indian journal of tuberculosis. Vol 53, pp 12-17

NTP did not have adequate measures for constant monitoring and feedback. This was one reason why there was no reliable data on completion rate, cure rate etc. RNTCP increased peripheral supervision by creating sub-district level TB units where two additional posts of the STS and STLS were created for effective implementation of the program. Therefore, greater decentralisation in terms of supervision was witnessed in RNTCP. The rationale to introduce direct supervision in RNTCP was to ensure that there would be no default by the patient as it affected drug-sensitivity. The focus was on avoiding drug-resistance, and preserving medicines, even if that meant severely inconveniencing the patients. The 'default' under NTP was coming from the shortage of medicines, lack of human resources, insufficient/ malfunctioning equipment. Under RNTCP, it was assumed that the default was happening on account of the patient who was defined as a defaulter if he/she did not comply with the orders of the doctor. The question was to see how much of this default was of epidemiological significance. Studies carried out by Gothi[3] had showed how some patients would recover without any medical intervention and would become negative on their own in 3-6 months. It was only a small proportion of defaulters who were of epidemiological significance as they could spread TB infection. By keeping in mind this small percentage, RNTCP revised its program strategy by forcing all 100 % patients to go to a health centre and take medicine under direct supervision making the treatment process tiresome.

The NTP did not pay much attention to the defaulters and focused solely on relieving the suffering and treating all those who came to seek treatment. RNTCP was designed keeping medicines and technology at the core of the program design. Treatment was only given to those who were willing to comply with the orders and who could be supervised, this included asking patients to sign bonds stating that they will comply with the treatment. Migrants, alcoholics, drug addicts etc. were not given treatment under RNTCP in some states.

NTP made use of the social dimensions of TB. The program was able to identify the felt needs of the TB patients. It recognised that suffering due to TB is a part of the larger human suffering and therefore alleviating human suffering was important. And as felt needs of the people were addressed, more overlaps were noticed between the felt needs and epidemiological needs. The idea was to learn from the experience of the people and integrate those learnings in the programmatic strategies.

Although NTP recognised the human suffering caused by TB, due attention was not

paid to reduction of associated stigma. This was corrected in RNTCP with awareness campaign and IEC campaigns to reduce the stigma associated to TB.

In terms of numbers, the RNTCP had achieved by 2006 its goals of curing 8 out of 10 people, whereas the number was just 3 out of 10 under NTP. By 2009, both the goals set out by RNTCP had been achieved. 2006 onwards, RNTCP made special provisions for TB related activities in the backwards and tribal areas. There were extra TB units and Designated Microscopy Centres set up in tribal areas. Outreach programs were also expanded.

It is interesting to note that the pilot for a revised program was run in 5 of the best possible states in India where the program was successfully implemented. It was able to prove its technical as well as operational feasibility. But, the choice of the 5 best possible states indicates the intent of the government to prove its success without actually testing it. Likewise, the importance of the new drugs that cut down the treatment period to just 6-8 months cannot be ignored, it is pertinent to ask if the mere introduction of a new drug was the need of the hour. ICMR had identified a host of reasons for the failure of the NTP wherein availability of drug and the duration of the treatment regimen were *one* of the reasons. There were other reasons at the institutional levels for which no improvements were made. Therefore, the main question should have been if Rifampicin delivered through the same mechanism could reduce the TB burden significantly or not.

[3] Gothi, G.D. (1978): "Natural History of Tuberculosis", *Indian Journal of Tuberculosis*, Vol. 25, no.2, April, pp: 1-12.

Post RNTCP

The National Strategic Plan for TB control 2012-2017 had been formulated as a part of the 12th FYP for which the following programmatic activities were to be strengthened:

- Adequate funds to be allocated to the implementation of the TB program along with funds for research
- DOTS program to be strengthened and its quality improved
- Better integration of the RNTCP with NHRM
- Better diagnosis of TB at all levels
- Expansion of diagnosis and treatment of MDR-TB and XDR-TB
- Involvement of all health care providers, including private sector to undertake TB related activities
- Urban TB to be controlled more efficiently
- IEC and outreach activities to be improved

WHO came up with the Global Tb strategy to "End TB Strategy" in 2014 that aims to eliminate TB by 2030. Surprisingly, India, a country that accounts for 25% of the global TB burden has taken on an even more ambitious target to eliminate TB by 2025, a task which is impossible given the natural history of TB. RNTCP was renamed as National TB Elimination Program (NTEP) in 2020 to emphasize the aim of GOI to eliminate TB by 2025.

At present, CBNAAT (Cartridge Based Nucleic Acid Amplification Test) is used for rapid and decentralized diagnosis of MDR-TB, TB in HIV positive patients and in pediatric TB cases. One of the drawbacks of the NTP was poor surveillance and reporting of cases. Therefore, NTEP has a web- enabled, case-based patient tracking and management system called NIKSHAY. A mobile application has been developed to not only report but also remind the patient to take their medication to reduce defaults. The problem is in those areas where digital infrastructure is not adequate, staff is not adequately trained in IT and internet connectivity is poor. Health workers often complain of being unable to access the Nikshay portal to enter data related to TB cases.

Conclusion

The achievements of the RNTCP cannot be ignored. However, the conceptual understanding of the natural history of TB under NTP acknowledged that the fight against TB would be a long, and difficult fight. Problems such as overcrowding, malnutrition, poor ventilation in urban slums, and poor living conditions would only exacerbate the problem and therefore controlling TB as envisaged under the RNTCP would not be possible unless noticeable improvements were made in these areas.

The extent of the reach of TB services along with the quality of the services had to be maintained throughout rural as well as urban India. IEC activities had to be scaled up to make people aware not only about TB as a disease, and when to get tested but also to comply with treatment and reduce the social stigma surrounding it. To tackle a disease of this magnitude in a country like India, it is crucial to engage all actors in the society including the private practioners, NGOs etc.

Financial decentralization along with increased community partnership is crucial for TB control. Considering the possibility of developing an HIV-TB coinfection, it is important to integrate the TB program well with the other programs such as the National AIDS control program. Efforts had to be made to reduce resistance to anti-TB drugs and scale up research to be able to deal with the MDR-TB and XDR-TB cases. Training of the health workers was absolutely critical to the success of RNTCP. Despite efforts, RNTCP was unable to reduce the TB burden in India.

References:

Banerji, D. and Andersen, S. (1963): "*A Sociological Study of Awareness of Symptoms Suggestive of Pulmonary Tuberculosis", Bull WHO*, Vol. 29, No 5, pp: 665-683.

Muniyandi M, R. Rajeswari and R. Balasubramanian (2006): *Estimating provider cost for treating patients with tuberculosis under revised national tuberculosis control programme (RNTCP)*. Indian journal of tuberculosis. Vol 53, pp 12-17
http://www.tbcindia.nic.in/

Indian Journal of tuberculosis (1962): Entire issue. Vol. IX, No. 3.