

A study to critically analyze Revised National Tuberculosis Control Program norms implementation at a medical college-level facility



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ABSTRACT

Background: Tuberculosis (TB) control activities are implemented in the country for more than 50 years. The countrywide lockdown in 2020 adversely impacted routine health-care services including those for the management of TB. Operational research is needed to know whether Revised National Tuberculosis Control Program (RNTCP) (National Tuberculosis Elimination Program) is heading in the right direction as far as the pace and quality of implementation of the program are concerned. **Aims and Objectives:** The aim of the present study was to investigate the strength, weaknesses, and opportunities of RNTCP. An analysis of RNTCP was done to identify competencies and gaps. **Materials and Methods:** The present retrospective and observational study was carried out at the RNTCP facility of a Government Medical College in the Central India in Madhya Pradesh during the year 2019–20. Samples of 238 patients registered under RNTCP for anti-tubercular treatment were taken in the study. Data were collected using a structured schedule from the RNTCP center and tabulated in a Microsoft Excel sheet, to assess the compliance of RNTCP norms in the management of TB. **Results:** The most commonly affected age was 16–49 years and the male: female ratio was 3:2. The most common basis of diagnosis was microbiological (60.92%). Follow-up sputum testing was done on time in 64.71% of patients. Adherence to anti-tubercular treatment (ATT) was regular in 78.57% of patients. All patients were telephoned while 43.14% of patients were home visited as a default action. After default action, 35.29% of patients return to regular ATT. Out of all registered patients initiated on ATT, 81.09% were treatment success, while 7.14% lost to follow-up, 2.1% became defaulters, and 4.62% patients died. **Conclusion:** We conclude that treatment success of TB unit was near the RNTCP norm of 85% which is below the national 88%. The probable reasons for the higher default rate and loss to follow-up rate during the study period could be the ongoing COVID-19 pandemic.

Key words: RNTCP implementation; Tuberculosis unit; DOTS

INTRODUCTION

Tuberculosis (TB) is a curable and preventable disease caused by *Mycobacterium tuberculosis* that most often affects the lungs but may involve any body part. When a person

develops active TB disease, the symptoms may be mild for many months which can lead to delay in seeking care and results in transmission of the bacteria to others. People with active TB can infect 10–15 other people through close contact over a year.¹

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Globally, about 10 million people developed TB in 2018. The annual TB incidence rate ranged from <5 to 500 with a global average of 130 people/100,000 population. Geographically, in 2018, the TB burden was 44% in the South-east Asia region, with half of the global burden in India – 27%, China – 9%, Indonesia – 8%, Philippines – 6%, and Bangladesh – 4%.^{1,2}

TB control activities are implemented in India for more than 50 years. The National Tuberculosis Program (NTP) was launched by the Government of India (GOI) in 1962. In 1993, the World Health Organization (WHO) developed Directly Observed Treatment Short-course (DOTS) and recommended following it by all countries. In the same year (1993), GOI revitalized the NTP to Revised National Tuberculosis Control Program (RNTCP). During 2006–2011 in its second phase, RNTCP improved the quality and reach of services for case detection and cure rate of TB. After this period, for the achievement of the long-term vision of a “TB FREE INDIA,” our Honorable Prime Minister of India proposed the “NATIONAL STRATEGIC PLAN FOR TB CONTROL 2012–2017” and “NATIONAL STRATEGIC PLAN FOR TB ELIMINATION 2017–2025,” in India, 5 years ahead of the “END TB STRATEGY 2030” by United Nations (WHO).^{3,4} On January 1, 2020, the Central government of India renamed the RNTCP to the National Tuberculosis Elimination Program (NTEP) with the aim of TB elimination by 2025.⁵

The countrywide lockdown in 2020 adversely impacted routine health-care services including those for the management of TB. Patients were unable to access routine health services due to the restrictions imposed as an emergency response measure. Individuals with symptoms of TB were not able to reach doctors/hospitals/diagnostic centers for getting themselves tested.⁵

When RNTCP is moving from one phase to another and with transportation across the country coming to a halt, patient specimens could not be transported to laboratories, and drug supplies were also affected. A much greater impact was felt by the private sector as smaller clinics and health facilities remained closed for much of 2020. In addition, people at the NTEP were also redirected to manage the COVID epidemic.⁵

Considering the glorious long history of the TB programs in India ranging from NTP to RNCTP, and now NTEP, these national health programs had achieved various important goals and created milestones. However, TB being an enormous health problem in India with very large numbers of TB patients and difficult but achievable goal set to eliminate TB from India by 2025, more and

more operational researches are needed to know whether it is heading toward the right direction as far as pace and quality of implementation of the program are concerned.

In the present study, it has been aimed to access and analyze the practical functioning of the RNTCP (now NTEP) at a tertiary-level medical college hospital. The medical colleges are believed to be providing better patient care and expertise, since they have all the various clinical expertise, in the form of all clinical and laboratory departments. Moreover, since it is mandatory to have TB treatment services at the medical colleges, the medical colleges may have TB units (TUs), in addition, all medical colleges should have at least a Designated Microscopy Center. Hence, if the implementation of the health programs per laid down norms is critically analyzed at these facilities reviewing the RNTCP functioning with regards to its resources and following the norms prescribed in national program guidelines, it may show the gaps that may exist. This may be beneficial in the way to take adequate and timely action to overcome these challenges and fill the gaps. This type of research may help to further strengthen the national TB program to achieve its desired goals. Therefore, this study was planned to evaluate RNTCP implementation at the TB center of medical college.

Aims and objectives

The aim of the present study was to investigate the strength, weaknesses, and opportunities of RNTCP. An analysis of RNTCP was done to identify competencies and gaps.

MATERIALS AND METHODS

This retrospective and observational study was carried out at RNTCP facility in School of Excellence in Pulmonary Medicine, Netaji Subhash Chandra Bose Medical College and Hospital, Jabalpur, (M.P) for the duration extending from July 1, 2019, to September 30, 2020, on 238 patients who got enrolled for treatment here. All the patients referred from the various department for registration under RNTCP for anti-tubercular treatment (ATT) were taken in the study to assess the compliance of RNTCP norms in the management of TB. While those patients who were referred from this RNTCP facility to another TU as per their residential address for continuing the ATT, were excluded from the study, since their complete treatment records are then available with their concerned TU and the study investigators do not have access to these records. Data on the patient were collected from patients enrolled Nikshay IDs from their Treatment card available at the study center. All the patients diagnosed and treated with standard RNTCP protocol from July 2019 to September

2020 were considered for the study. Information regarding the testing, gap, treatment, sputum conversion rates, and the outcome of treatment at the end of 1 year such as cure, default, death, completion rate, and failure were analyzed in detail. The lack of any standard logistic facilities and manpower facilities available at the study center were also recorded and compared with the norms prescribed by RNTCP guidelines. Standard RNTCP (now the NTEP) guidelines were used to compare the existing structure.⁵

Data were collected from the understudy RNTCP center of the medical college TU. Data entry and statistical analysis were done using Epi Info version 3.2.2 from CDC, Atlanta, and SPSS data analysis package version 26.0. A comparison of treatment success, death, relapse rates, and risk factors for poor outcomes was done using appropriate statistical tests.

Ethical issues

The study involved no major ethical issues, as there was no direct interaction with the patient and only the case records were reviewed; hence, the consent of the individual patient was waved off. The study was approved by the Institutional Ethics Committee in a meeting on December 17, 2019, letter no. IEC/2021/628.

RESULTS

For evaluation of RNTCP guidelines was done using data of 238 patients on diagnosis and testing, treatment, any delays in the process, regularity, and adherence to the treatment and outcome.

Demographic data

Out of all patients, 61.76% were males with the male: female ratio to be 3:2. The most common age was young adults from 16 to 49 years of age group consisting of 70.59% of patients, where 7.14% of patients were from ≤15 years of age, while >65 years of age group was least common as shown in Figure 1.

Diagnostic data/testing data

Most of the patients reported at the study center were diagnosed based on microbiological tests consisting of 145 (60.92%) patients. After diagnosis, 151 (63.45%) patients were of pulmonary origin while the rest 87 (36.55%) cases were extrapulmonary in nature. Among the samples collected for the diagnosis, sputum was the most common one, with 154 (64.71%) patients, followed by 31 (13.03%) patients where lymph node samples were sent. Cartridge based nucleic acid amplification test (CBNAAT) was the most common testing modality used in 211 (88.66%) patients while Acid Fast Bacilli (AFB) staining was done

in 142 (59.66%) patients. Only in 30 (12.61%) cases did reporting had took more than a week for the results, in the rest all results came back within the duration of 1 week in 208 (87.39%) reports of patients. The evaluation of the basis of diagnosing various types of TB and the gaps in implementing RTNCP norms in this is shown in Table 1.

The TU at the study center has performed 3807 AFB smear microscopy of various samples in the year 2019–2020, out

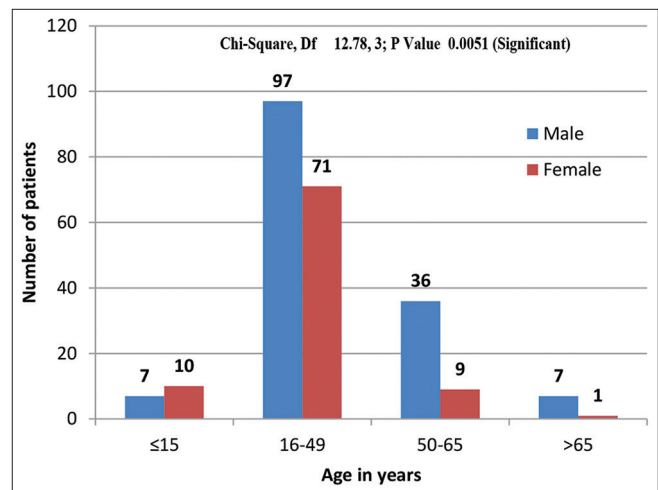


Figure 1: Distribution of patients according to age and gender

Table 1: Distribution of patients according to the basis of diagnostic/testing parameters

Diagnostic Parameters	Number of Patients	Percent
Basis of Diagnosis		
Clinical+Radiological	55	23.11
Microbiological	145	60.92
Cytological/Histopathological	38	15.97
Type of Tuberculosis		
Pulmonary	151	63.45
Extra-pulmonary	87	36.55
Sample for testing		
Sputum	154	64.71
Plural fluid	26	10.92
CSF	0	0.00
Ascites	1	0.42
Lymph node	31	13.03
Bone aspirate	7	2.94
Investigation		
AFB	142	59.66
CBNAAT	211	88.66
ADA	26	10.92
Cytology	38	15.97
Culture	0	0.00
Gap in reporting		
Within 1 week	208	87.39
More than 1 week	30	12.61
Follow-up Sputum		
On time	154	64.71
Late	84	35.29
TOTAL	238	100

CSF: Cerebrospinal fluid, AFB: Acid fast bacilli, CBNAAT: Cartridge based nucleic acid amplification test, ADA: Adenosine deaminase

of which 594 (15.60%) were found positive. During the year 2019–20, 5307 CBNAAT tests were performed at our TU. Out of which 832 (15.68%) *M. tuberculosis* detected and Rifampicin sensitive and 82 (1.55%) *M. tuberculosis* detected and Rifampicin resistant.

Treatment data

The most of the patients (99.58%) were started treatment within a week of reporting to the facility. CBNAAT testing for drug-resistant was done within 1 week of starting anti-tubercular therapy in 206 (86.55%) patients. Follow-up sputum testing was done on time in 154 (64.71%) patients while it was delayed in 84 (35.29%) patients. Adherence to ATT was regular in 187 (78.57%) patients. Of those patients who were irregular with ATT (n=51), 34 (66.67%) were irregular during the intensive phase while the rest 17 (33.33%) patients were irregular in continuation phase of ATT. Among those patients who were irregular, default actions were taken in all 51 (100%) in an attempt to resume treatment, 22 (43.14%) patients were home visited while family counseling was needed in 3 (5.88%) patients as shown in Table 2. After default action taken in 51 patients, 18 (35.29%) patients return to regular ATT while 33 (64.71%) did not returned.

Out of all the 238 patients registered and initiated on ATT, most of the patients had recorded the outcome of treatment completed and 7% were lost to follow-up. The other outcomes noted in the study are shown in Figure 2.

Facility data

The deficiency of one Medical Officer, one pharmacist, and one STS was observed at TU. The rest of the facilities such as sputum testing facilities including laboratory technicians, TB health visitors, and treatment supervisors to impart proper DOTS to patients were found to be adequate as per the norms of RNTCP.

DISCUSSION

Regular monitoring and review of the program interventions are an essential component to control the disease and also in ensuring quality services delivery for achieving the vision of TB-Free India by 2025.⁶

In the present study, 61.76% of TB cases were males. A recent study conducted at Lucknow in 669 patients by Debbarma (2020) reported similar results to this study, 61.58% of TB cases were males.⁷ Similar trend was observed by Bisoi et al., in the Howrah district of West Bengal (64.00% males and 36.00% females) and Masthi et al., in Bangalore, Karnataka (64.77% males and 35.22% females).^{8,9} This might be due to greater exposure of males to the various risk factors of TB.

Table 2: Distribution of patients according to basis of treatment parameters

Diagnostic parameters	Number of patients	Percent
Gap in Report and ATT (n=238)		
Within 2 days	100	42.02
Within 1 week	137	57.56
More than 1 week	1	0.42
Gap between ATT start and CBNAAT (n=238)		
Within 1 week	207	86.97
More than 1 week	31	13.03
ATT Regularity (n=238)		
Regular	187	78.57
Missed dose	51	21.43
ATT Regularity (n=51)		
Intensive	34	66.67
Continuation	17	33.33
Default Action taken (n=76)		
Home visit	22	43.14
Telephone	51	100
Family counseling	3	5.88
Effect of action (n=51)		
Return	18	35.29
Not returned	33	64.71

ATT: Anti-tubercular treatment

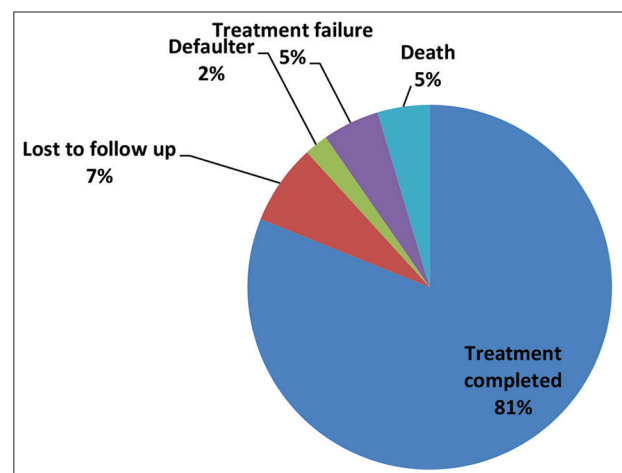


Figure 2: Distribution of patients according to outcome

In a study conducted in Lucknow, the majority (81.00%) of the patients belonged to the age group of 15–44 years.¹⁰ In a study conducted in Kottayam, Kerala by Sukumaran et al., in which they studied 300 patients, where 64.00% of patients were found in the economically productive age group (20–50 years), while in another study, it was found that most (55.00%) of the patients belonged to the age group 20–29 years.^{7,11} These all results were in line with this present study. Young adults are the most productive component of society affected most by TB.

Main diagnostic modalities for PTB as reported by Sunnetcioglu et al., (2015) were sputum/smear analyses (72.7%), clinical-radiological data (21.7%) and biopsy (6.1%); while biopsy (71.5%), sputum/fluid analysis

(18.8%) and clinical-radiological data (4.9%).¹² Those results confirm that microbiological diagnosis was most common.

Sputum smear microscopy is the primary tool that is reliable, inexpensive, easily accessible, and rapid method of diagnosing PTB. Chest X-ray is both a screening and a supportive tool for the diagnosis of smear-negative PTB. Solid (LJ) and liquid culture (MGIT) methodologies while molecular methods such as CBNAAT and Line Probe Assay are available under the program. CBNAAT centers are also established to diagnose Rifampicin resistance among all TB patients (Universal Drug Sensitivity Testing [DST]). The country is in the process of expanding the CBNAAT site network. They also serve to diagnose TB among presumptive TB cases from key population.⁶

The evaluation of the functioning of TU for the implementation of diagnostic services such as performance of sputum smear examination and CBNAAT testing had contributed in a large number of patients, which is recommended as per the RNTCP norms, but due to COVID-19 pandemic, sputum smear testing and CBNAAT testing at the TU have decreased in 2019–2020 compared to the past year.

After diagnosis, 63.45% of patients were of pulmonary origin, while the rest 87 (36.55%) cases were extrapulmonary. Velingker et al., (2018) reported that 30.9% of extrapulmonary TB (EPTB) cases with the most common type of EPTB was TB in the pleural cavity (39.43%).¹³ While a study from Turkey reported a higher prevalence of EPTB where 49.4% were diagnosed with EPTB.¹² These studies had comparable findings to the present study results.

Among the samples collected for the diagnosis, sputum was the most common one, with 154 (64.71%) patients, followed by lymph nodes in 13.03% and pleural fluid in 10.92% of patients. In a study by Prakasha et al., (2013), they also reported lymph node and bone TB samples being most common in the diagnosis of EPTB.¹⁴ These results were comparable to the present findings.

India is the High TB burden country in the world. The WHO TB statistics for India for 2016 give an estimated incidence of 2.79 million cases. The incidence of MDRTB/RR cases is 1,47,000 (11/lakh population) as per the Global TB Report 2017. With the advent of the End TB Strategy, for the rapid diagnosis of Rifampicin Resistance CBNAAT/Genexpert test is used. This helps the patient to be initiated on treatment on the same day thereby reducing the initial loss to follow-up. Patel et al., (2019) undertook that this study to see if CBNAAT is equally sensitive as

LED-Fluorescent Microscopy (LED-FM) to diagnose pulmonary TB; along with its added advantage of upfront drug sensitivity testing (DST) for diagnosed pulmonary TB cases. This may help policy and practice to use only CBNAAT instead of both LED-FM and CBNAAT in routine programmatic settings.¹⁵

Paul et al., (2012) studied 2027 of 3411 patients registered with pulmonary TB who were smear-positive. About 35% of patients had >7 days between diagnosis and treatment and 13% had delays >15 days. The mean duration between TB diagnosis and treatment initiation was 8 days (range=0–128 days). The main factors associated with a delay of >7 days were: Patient reluctance to start a re-treatment regimen, patients seeking second opinions, delay in transportation of drugs to the DOT centers, and delay in initial home visits. To conclude, treatment delay >7 days was associated with several factors that included the history of previous treatment and the absence of TB diagnostic services in the local health facility. Decentralized diagnostic facilities and improved referral procedures may reduce such treatment delays.¹⁶ In a few studies conducted elsewhere the core problem in the delay of diagnosis and treatment seemed to be a vicious cycle of repeated visits at the same health-care level, resulting in nonspecific antibiotic treatment and failure to access specialized TB services.¹⁷ In the present study, the RNCTP center had better time gap management than the above-mentioned studies done in past.

Follow-up sputum testing was done on time in 154 (64.71%) patients in the present study and adherence to ATT was regular in 78.57% of patients. The Revised National Tuberculosis Control Program (RNTCP) of India recommends a follow-up sputum smear examination at 2 months into the continuation phase of treatment.⁶ Owolabi et al., (2020) reported considerable TB diagnostic delay in the Gambia, and this is likely to be worsened by the COVID-19 pandemic.¹⁸ Similar situation can be attributed to the delayed follow-up testing in the year 2019–2020 in this study also.

The prevalence of non-adherence to ATT in the present study was 21.43%. Non-adherence of 78 (50%) to anti-tuberculosis treatment (ATT) was reported by Kulkarni et al., (2013).¹⁹ In another study by Geethalakshmi et al., (2019) reported a non-adherence of 35% in Karnataka.²⁰ The present RNTCP facility center had a better ATT adherence compared to the above-mentioned studies.

After default action is taken 35.29% of patients return to regular ATT. Ratnesh (2020) observed the overall prevalence of defaulters to be 9.35%. The strength of association of default was seen more in the 20–29 years

of age group, sputum smear-negative cases, pulmonary TB cases and patients having a history of the treatment of interruption, and patients belonging to category II in DOTS.²¹

Out of all the 238 patients registered and initiated on ATT, most of the patients had treatment success (Cured+Treatment completed) and constitute 193 (81.09%) patients. While 17 (7.14%) patients lost to follow-up, 5 (2.1%) became defaulters, 12 (5.04%) were treatment failures and 11 (4.62%) patients died. Reports published in India TB care (2020), 96% of patients were initiated once notified.²² In a similar report in the year 2019, treatment success was reported in 83% of notified patients. In the report of 2019, lost to follow-up was reported at 3%, treatment failure was 1%, and deaths were reported to be 4%.²² Apart from lost to follow-up and treatment failure, data on mortality and defaulters were comparable to the present study. Increased numbers in the lost to follow-up and treatment failure could be attributed in the year 2019–2020 to the COVID-19 pandemic where patient follow-up and default actions have been compromised.

In the India TB Report of 2021, state data for Madhya Pradesh had reported a cure rate of 72% along with a 4% lost to follow-up and a 3% death rate. These data are also comparable to the present study except the lost to follow-up percentage was higher in this study compared to state data. The present study site, that is, the medical college had a pivotal role in COVID-19 pandemic management for the year 2019–20 in the Mahakaushal area of the Madhya Pradesh state that includes eight districts around Jabalpur city. All the staff and health-care personnel were overwhelmed with the COVID-19 management workload. A similar fact is evident in the INDIA TB REPORT 2021 where the cure rate was 42% while lost to follow-up and death rates were 11.8% and 2.2%.²² The study TU also lacks on one Medical officer, one Pharmacist, and one STS according to RNTCP Guidelines for TU.⁵ Medical officer under the RNTCP program could have done a better job when all the other healthcare workers focusing on COVID-19 management. At the national level, there is still a deficiency of 26.78% of Medical officer at the medical college level.²³

Limitations of the study

This study was limited in nature, since it took the data only from one TU, If multiple TU gets evaluated in a similar manner, it may provide clearer conclusions. During the planned study period, the COVID-19 pandemic struck, hence, the actual efforts of implementing the NTEP norms properly at every level of care under the national program to reach the goal of TB elimination in post-COVID scenario needs to be studied further.

CONCLUSION

It can be concluded from the study that despite the serious constraints including that of the COVID-19 pandemic faced in the study period the evaluation of RNTCP for infrastructure, resources, diagnosis, treatment, follow-up, and outcome at the TU unit of Medical College revealed that it has performed well despite difficulties and deficiencies mentioned above. The difference in national outcome rates is minimal which could have been easily overcome had there been regular resources as per NTEP norms in place, which may have got hit by the prevailing COVID pandemic during this period.

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RK- Design of the study, reviewed the literature, prepared first draft of manuscript; **SKB**- Concept, Interpreted the results; manuscript preparation; **VP**- Reviewed the literature, coordination, interpretation of results; **AJ**- Statistical Analysis, preparation of manuscript and revision of the manuscript; **BBP**- First draft of manuscript, Manuscript preparation; **BP**- Coordination, Understanding and interpretation of results, Manuscript revisions and submission

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