# Is the Revised National Tuberculosis Control Programme achieving early initiation of treatment post two decades of its operation?: A cross-sectional study from Uttarakhand, India

# Ram Gopal Nautiyal<sup>1</sup>, Rajesh Kumar Singh<sup>2</sup>, Sneha Mittal<sup>3</sup>, Sadhana Awasthi<sup>4</sup>

<sup>1</sup>Professor, Department of Respiratory Medicine, Government Medical College, Haldwani, Nainital, Uttarakhand, India; <sup>2</sup>Associate Professor, Department of Community Medicine, Government Medical College, Haldwani, Nainital, Uttarakhand, India; <sup>3</sup>PG Resident, Department of Community Medicine, Government Medical College, Haldwani, Nainital, Uttarakhand, India; <sup>4</sup>Associate Professor, Department of Community Medicine, Government Medical College, Haldwani, Nainital, Uttarakhand, India.

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# **Corresponding Author**

Corresponding Author: Dr Rajesh Kumar Singh, Department of Community Medicine, Govt. Medical College, Haldwani, Nainital, Uttarakhand, India - 263139

E Mail ID: dr\_rajeshsingh@rediffmail.com



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### **Abstract**

Background: Early case finding and prompt initiation of treatment of pulmonary Tuberculosis (PTB) is the most effective strategy to achieve successful TB control. In order to achieve early initiation of treatment, the Revised National TB Control Programme (RNTCP) since its launch in 1997 has been using advocacy, communication and social mobilization (ACSM) strategy targeted at health care providers (HCP) and other stake holders by large scale utilization of electronic and print media. Objective: To study whether RNTCP is really achieving early initiation of TB treatment among infectious PTB patients. **Methods**: A cross- sectional study among new smear positive PTB patients at Haldwani block of Nainital district of Uttarakhand State of North India. Data was analyzed using the software Epi Info version 7.2.0.1. **Results**: Of the 85 infectious PTB patients included in the study, the median time consumed between onset of cough and contact with the first HCP, between first HCP contact to confirmation of diagnosis, and between confirmation of diagnosis to initiation of treatment were 6 days, 43 days and 6 days respectively. Overall, median time consumed between onset of cough to initiation of treatment was 61 days. HCPs working in the public health settings fared no better than those in the private health sector in this regard. **Conclusions**: Although majority patients sought medical care timely, a considerably unacceptable long time was consumed by HCPs in initiation of treatment of PTB.

### **Keywords**

Tuberculosis; Cough; Health care providers; India

### Introduction

Early case finding and prompt initiation of treatment of Pulmonary Tuberculosis (PTB) is the most effective

strategy to achieve successful TB control. In India, the responsibility of TB control lies with the Revised National TB Control Programme (RNTCP) which is

implemented through public health sector and has been in operation since 1997. Though RNTCP services are universally accessible free of cost throughout the country since March 2006, (1) majority Indian TB patients prefer the private health sector. (2,3,4) There is ample evidence available that in India, usually a significant time is consumed between onset of symptoms to initiation of treatment of PTB. A systematic review by Sreerama Reddy et al in 2014 which included studies from 2000 to 2013 has shown that in India, the median total time consumed from the onset of symptoms to initiation of TB treatment was 55.3 days (46.5 – 61.5 days). (5) This significant time consumption in initiation of treatment of PTB has the potential to disrupt the success of RNTCP in India.

The RNTCP has been aware of this phenomenon, and hence since its launch, has been using its advocacy, communication and social mobilization (ACSM) strategy targeted at health care providers (HCP) and other stake holders by large scale utilization of electronic and print media to achieve early case detection and treatment of TB. (1) However, there was no documented information available on the effectiveness of RNTCP's such educational activities in achieving early case detection and prompt initiation of treatment of infectious PTB across diverse health settings in India.

# Aims & Objectives

- 1. To estimate the time consumed from onset of symptoms of PTB to initiation of TB treatment.
- 2. To determine factors associated with the time consumed in initiation of TB treatment

### **Material & Methods**

**Study design**: A descriptive cross-sectional hospital-based study conducted between July 2018 to October 2018.

Study settings: The study was conducted in Haldwani Block of district Nainital in Uttarakhand State of North India. Nainital is one of six districts in Kumaon region of Uttarakhand State and has eight Blocks, of which, Haldwani block caters the largest population of 2.27 lakh people with one of the eight Tuberculosis units (TU) of the district. There are two Designated Microscopic Centres (DMCs) under the Haldwani TU - One under Department of Respiratory Medicine of Government Medical College Haldwani, and the other under District TB Centre Base hospital, Haldwani. Both these DMCs were selected as study settings.

**Study population:** Sputum Acid Fast Bacillus (AFB) smear positive new PTB patients aged ≥ 18 years, who attended the study setting.

**Sample size**: The sample size for estimating time consumed in initiation of TB treatment was calculated using the formula  $Z_{1-\alpha/2}{}^2SD^2/d^2$  with 95% confidence level, where precision (d) was taken as 5 days and based on the study by Purty et al. (6) the standard deviation (SD) was considered as 25 days. The required sample size for the study was calculated to be 96, and it was decided to include 50 participants from each study setting.

Sampling technique and study sample: A consecutive sampling technique was used for interviewing a total of 100 PTB patients for possible inclusion in the study. The purpose of the study, confidentiality, and anonymity were explained to participants before taking their due consent. Out of 100 patients approached, fifteen (15) patients were excluded as nine (09) did not consent and six (06) provided ambiguous information. Thus, a total of 85 patients formed the study sample for final analysis (Figure 1).

**Data collection**: A trainee junior resident (SM) interviewed the study participants using a pretested questionnaire to seek information on care seeking pathway adopted by the patients. The patients were interviewed within first seven days of initiation of treatment to minimize the recall bias. Attempts were made to audit the available prescriptions with the patients for verification of information given by the patients during interview.

**Definitions:** For the purpose of description, the total time consumed from appearance of symptom of cough to initiation of treatment was divided into following phases of health seeking: Phase 1- time from onset of symptom to contact with first health care provider (HCP), Phase 2 - time from first HCP consultation to confirmation of diagnosis, and Phase 3 - time from confirmation of diagnosis to initiation of treatment.

A health care provider (HCP) was defined as any person irrespective of his/her qualification from whom the patient sought care for the symptom of cough.

**Statistical analysis:** The statistical analysis was done using the software EpiInfo version 7.2.0.1. Descriptive variables were summarized as mean, median, standard deviation, inter-quartile range and 95% confidence interval. To test the differences between medians, the non-parametric test such as

Mann Whitney-U test and Kruskal Wallis test were used. A P value <0.05 was considered statistically significant. Box-plot was generated to estimate the time consumed in initiation of treatment using R software. (7)

**Ethics approval**: Ethical clearance for the study was obtained from the Institute Ethics Committee of Government Medical College Haldwani.

#### Results

### Socio-demographic characteristics of patients:

A total of 85 PTB patients were included in the study. The mean age of study participants was 36.3 years (standard deviation of 16.7 years) with almost half (51.8%) between age group 18-30 years. Majority (57.6%) were male, most (94.1%) had income of more than rupees 3000 per month. Majority were literate (78.8%), Hindu by religion (68.2%) and 44% were employed. More than one-third (37.6%) were current smokers. (Table 1)

### **Health seeking by patients:**

For symptom of cough, about one-third (31.8%) patients first reported to government health sector, while majority (68.2%) first consulted private health setting (31.8% allopathic, 36.4% traditional practitioners/chemists). Almost one-third (31.6%) patients visited three or more than three HCPs before attending the study setting. (Table 2)

### Time consumed in different phases:

- (i). Phase 1: Time from onset of cough to first HCP contact- Majority (81.2%) patients sought first consultation from any HCP within 2 weeks of onset of cough. The median duration between onset of cough and contact with the first HCP was 6 days. (Table 2) and (Figure 2)
- (ii) Phase 2: Time from first HCP consultation to confirmation of diagnosis Majority (61.2%) patients were diagnosed after a time of more than one month from onset of symptom of cough. The median duration between first HCP consultation to confirmation of diagnosis was 43 days. (Table 2) and (Figure 2)
- (iii). Phase 3: Time from confirmation of diagnosis to initiation of treatment—While majority (64.7%) patients were initiated on treatment within one week of diagnosis, in almost one-third (35.3%), it took more than one week. However, the median duration between confirmation of diagnosis to initiation of treatment was 6 days. (Table 2) and (Figure 2)

# Total time from onset of cough to initiation of treatment:

Overall, the median duration between onset of cough to initiation of treatment was 61 days. (<u>Table</u> 2) and (Figure 2)

# Factors associated with time consumed in initiation of treatment:

The total time consumed between onset of cough to initiation of anti-TB treatment was found to be significantly higher among illiterates, income of less than rupees 3000 per month, smokers and consultation with multiple HCPs.

Age, gender, employment status and type of health setting first consulted by the patient did not show any significant association. (<u>Table 3</u>)

### Discussion

Early case finding and prompt initiation of treatment of infectious cases of TB is utmost critical to achieve the best individual and public health outcome. The RNTCP of India currently relies on passive case finding. This passive case finding approach of RNTCP means the first initiative in the pathway of health seeking has to be taken by the patient, for which the patient has to have knowledge of when to suspect PTB, where to find the best TB care and what is the consequence of delayed consultation. Any lapse of such knowledge might leave the patient with no option but to shop for multiple inappropriate health settings with a consequent delay in diagnosis and initiation of treatment. In order to achieve early reporting by the patient and to publicize the RNTCP as the best TB care option available, the RNTCP has been utilizing the electronic and print media for almost two decades to educate the community at large. In addition, to ensure early diagnosis and treatment, the RNTCP has been educating the HCPs in private and public sector by various means since its inception. This research paper is to examine whether RNTCP's such educational interventions directed at community and HCPs could really achieve the early case finding and prompt initiation of treatment of PTB in India.

Our study documents that almost two-third (68.2%) patients preferred to first consult the HCPs in private setting (31.8% to private allopathic and 36.4% to traditional practitioners/chemists) without much inquiry into the educational background of HCPs, and almost one-third patients visited three or more HCPs before attending us. This highlights that despite

decades long existence, wide publicity and in built provision of free of cost treatment, so far, RNTCP could not establish itself as a preferred TB care option available to Indian TB patients. This finding in our study is in agreement with the observations of the National Family Health Survey- 3 (NFHS-3) (8) and other studies from India, wherein 60-88 % of Indian patients preferred to seek care from private sector. (2,3,4) This implies that a large number of patients who seek TB care exclusively from private health setting, do not find place in the recording and reporting system of RNTCP, and as a result, RNTCP do not have any account of the time consumed from onset of symptom to initiation of treatment in these patients. Although TB notification regulation 2012 is in force in the country, (9) it does not keep account of time consumed between onset of cough to initiation of TB treatment - a very important public health aspect in TB control.

An interesting finding in the study was that majority (81.2%) patients consulted the first HCP within the RNTCP recommended time of two weeks of onset of cough with the median time of 6 days. This observation in our study is in discordance with the systematic review by Sreeramareddy et al. and study by Mistry et al. where average patient presenting time were 18.4 days and 23 days respectively. (5, 10) The reason for this difference may be due to urban setting of our study where access to HCPs was relatively better. However, in our observations it was disheartening to note that despite majority patients presented to the first HCP quite early, time from first HCP consultation to confirmation of diagnosis in majority (61.2%) patients was more than one month (median 43 days). This finding in our study is in agreement with systematic Sreeramareddy et al. and observation made by Mistry et al. wherein the median time consumed was 31 and 43 days respectively. (5,10) The reason for not suspecting PTB by HCPs in majority of our patients for such a long time might be due to their experience that cough used to be a common symptom in many other illnesses like bronchial asthma, chronic obstructive pulmonary disease and bacterial and viral respiratory tract infections which are more prevalent than PTB in their day to day clinical practice. This practice of HCPs highlights that RNTCP's educational interventions proved inadequate in convincing them the public health importance of suspecting PTB.

This study documents that though RNTCP recommends initiation of treatment in all diagnosed TB patients within 7 days of diagnosis, (11) almost one-third (35.3%) of our patients were not initiated on treatment within 7 days of diagnosis., Paul et al. from West Bengal and Andhra Pradesh, and Mistry et al. from Mumbai, Kant et al. in 2017 from Haryana had also reported that their 48%, 17%, and 42.3% patients respectively were not initiated on treatment within 7 days of diagnosis. (10,12,13)

In our study it is perplexing to note that the median time consumption between onset of cough and initiation of treatment was 61 days which was largely due to time consumed by HCPs in making diagnosis. A systematic review by Sreeramareddy et al. and study by Mistry et al. had also shown the median total time consumed to be 55.3 and 65 days respectively. (5,10) Due to this significant time consumption, these patients continue to transmit the infection in the community for a long time and hence have the public health implications. Another disadvantage of such practice of HCPs is compromised probability of cure in these patients. These observations indicate that the RNTCP's educational efforts directed at the HCPs were grossly deficient in convincing them the public health importance of early case finding and prompt initiation of treatment.

An interesting finding in this study was that there was no significant association between the type of health setting first contacted by the patients and the time consumed by the health setting in initiation of treatment. HCPs working in the public health settings through which RNTCP is implemented were supposed to provide early diagnosis and prompt initiation of treatment, but they fared no better than the HCPs in the private health sector. This indicates the indifference of public health sector HCPs to RNTCP.

Further, it was also evident in this study that the higher median time consumed between onset of cough to initiation of treatment had significant association with patient related factors such as illiteracy, monthly income less than rupees 3000, current smoking status and multiple HCP contacts. This highlights that the measures to improve the socio-economic development and promotion of general health awareness in the country have the potential to help RNTCP achieve successful TB control in India.

### Conclusion

We found that although majority patients sought medical care timely, a considerably unacceptable longtime was consumed by HCPs in initiation of treatment of infectious cases of PTB. This highlights that RNTCP's ACSM interventions are grossly inadequate in convincing the HCPs the public health importance of early case finding and prompt initiation of treatment. The RNTCP needs to review its ACSM interventions and may think upon the need of community level active case finding to ensure its success.

### Recommendation

As early initiation of treatment is important for control of TB in India, the RNTCP needs to review its ACSM interventions and needs to focus aggressively on community level active case finding.

# Limitation of the study

As it is an interview-based study, it may have a recall bias. However, to minimize the bias, patients were interviewed within first week of their presentation to the study setting. Further, as this is not a multi centric study, the results may not be generalized.

# Relevance of the study

This study highlights the importance of early initiation of treatment in PTB cases which is critical for success of RNTCP and control of TB in India.

### **Authors Contribution**

All the authors have contributed in planning and designing study, data analysis, writing and reviewing of the manuscript. SM interviewed the study participants and collected the data.

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# **Tables**

### TABLE 1 SOCIO-DEMOGRAPHIC PROFILE OF STUDY PARTICIPANTS

Variables	Categories	No. (%)			
Age (Years)	< 30	44 (51.8)			
	> 30	41 (48.2)			
	Mean (SD) - 36.3 (16.7) years				
Gender	Female	36 (42.4)			

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	Male	49 (57.6)
Religion	Hindu	58 (68.2)
	Muslim	27 (31.8)
Literacy status	Illiterate	18 (21.2)
	Literate	67 (78.8)
Occupation	Unemployed	48 (56.5)
	Employed for cash	37 (43.5)
Monthly income (Rupees)	<u>&lt;</u> 3000	05 (05.8)
	> 3000	80 (94.2)
History of smoking	No	57 (67.1)
	Yes	28 (32.9)

# TABLE 2 HEALTH SEEKING AND PTB MANAGEMENT

Variables	Categories	Number (%)	95% CI*				
Health seeking by patients							
Type of health care providers first	Government health sector	27 (31.8)	22.1 – 42.7				
	Private allopathic health sector	27 (31.8)	22.1 – 42.7				
	Traditional practitioners /chemists	31 (36.4)	26.3 – 47.6				
Number of health care providers	< 3	59 (69.4)	58.5 – 78.9				
contacted	<u>≥</u> 3	26 (30.6)	21.1 – 41.5				
PTB management pathway and time consumed							
Phase 1: Time from onset of cough to	2 weeks	69 (81.2)	71.2 – 88.8				
first HCP contact	> 2 weeks	16 (18.8)	11.2 – 28.8				
Phase 2: Time from first HCP contact	≤1 month	33 (38.8)	28.4 – 50.0				
to confirmation of diagnosis	> 1 month	52 (61.2)	49.9 – 71.6				
Phase 3: Time from diagnosis to	<u>≤</u> 1 week	55 (64.7)	53.6 – 74.7				
initiation of TB treatment	> 1 week	30 (35.3)	25.2 – 46.4				
Total time :Time from onset of cough	≤ 2 months	42 (49.4)	38.4 – 60.5				
to initiation of TB treatment	> 2 months	43 (50.6)	39.5 – 61.6				
*CI – Confidence Interval; HCP – Health Care Provider							

TABLE 3 ASSOCIATION OF STUDY VARIABLES & TIME CONSUMED IN INITIATION OF TREATMENT

Variables	Categories	No. (%)	Time consumed (Days)*	P-value		
Age	< 30	44 (51.8)	54.0 (36.5 – 82.0)	0.186#		
	> 30	41 (48.2)	65.0 (37.0 – 97.0)			
Gender	Female	36 (42.3)	57.5 (35.0 – 93.0)	0.732#		
	Male	49 (57.7)	63.0 (37.0 – 92.0)			
Religion	Hindu	58 (68.2)	60.0 (37.0 – 92.0)	0.784#		
	Muslim	27 (31.8)	61.0 (40.0 – 93.0)			
Literacy status	Illiterate	18 (21.2)	91.0 (58.0 – 97.0)	0.015#		
	Literate	67 (78.8)	54.0 (33.0 – 86.0)			
<b>Employment status</b>	Unemployed	48 (56.5)	57.5 (37.0 – 90.0)	0.632#		
	Employed	37 (43.5)	64.0 (37.0 – 92.0)			
Monthly income	< 3000	05 (05.9)	97.0 (94.0 – 98.0)	0.008#		
(Rupees)	> 3000	80 (94.1)	57.5 (36.5 – 88.5)			
Smoking	Non- smoker	57 (67.1)	55.0 (33.0 – 78.0)	0.024#		
	Smoker	28 (32.9)	81.5 (45.5 – 97.5)			
Health care provider first	Government	27 (31.8)	55.0 (31.0 – 97.0)	0.407\$		
	Private allopathic	27 (31.8)	53.0 (32.0 – 78.0)			
contacted	Traditional /chemists	31 (36.4)	64.0 (41.0 – 90.0)			
Number of HCP	< 3	59 (69.4)	53.0 (33.0 – 89.0)	0.029#		
visited	<u>&gt;</u> 3	26 (30.6)	71.0 (59.0 – 98.0)			
*Median (IQR); #Mann-Whitney U test; <sup>\$</sup> Kruskal Wallis – H test						

# **Figures**

### FIGURE 1 STUDY SAMPLE SELECTION

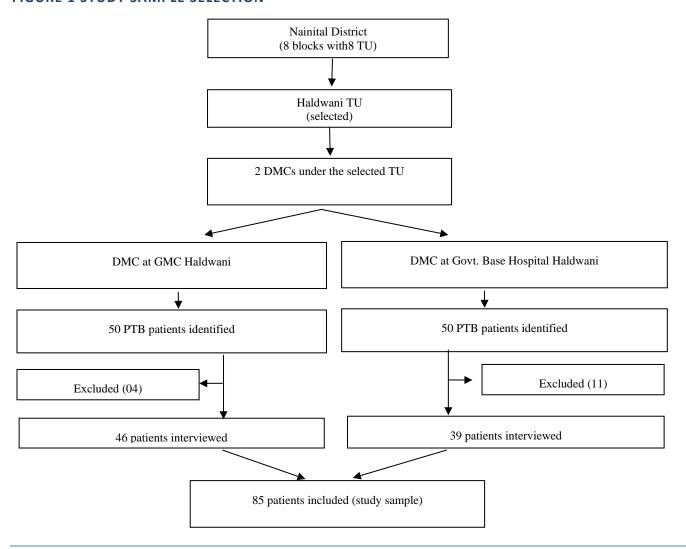
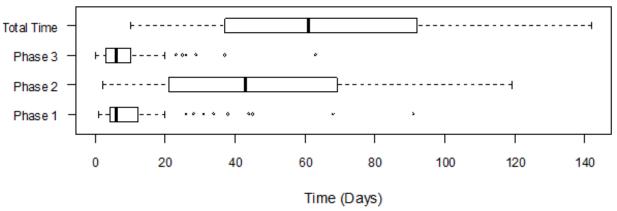


FIGURE 2 TIME CONSUMED IN VARIOUS PHASES OF TB MANAGEMENT



Phase 1: Time from onset of cough to first Health Care Provider (HCP) contact

Phase 2: Time from first HCP contact to confirmation of diagnosis

Phase 3: Time from diagnosis to initiation of TB treatment

Total Time: Time from onset of cough to initiation of TB treatment