Knowledge of Private Practitioners in Diagnosis and Management of Tuberculosis in Context of National Tuberculosis Elimination Program: A Cross-sectional Study from Gujarat, India

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ABSTRACT

Introduction: According to the World Health Organisation (WHO) global Tuberculosis (TB) report in 2019, 10 million new cases of Tuberculosis were detected worldwide, with India being one of the significant contributors. After achieving some milestones in TB control, the Government of India launched the National Tuberculosis Elimination Program (NTEP) to end TB by 2025. The role of private practitioners in the success of national health programs in India cannot be overemphasised, considering they cater to three times more population than the public sector.

Aim: To understand the knowledge and perceived bottlenecks of private practitioners in achieving the goals of NTEP.

Materials and Methods: A web-based cross-sectional survey was conducted by Community Medicine Department of Pramukhswami Medical College, Bhaikaka University, Karamsad, Anand, Gujarat, India, using a semi-structured questionnaire among randomly selected 110 doctors affiliated with the Indian Medical Association (IMA) from October 2020 to December 2020. The survey questionnaire was prepared by an experienced TB Chest expert and consensually validated. It covered all aspects of the Revised National TB Control Program (RNTCP) training modules. Descriptive statistics (Mean, SD, Frequency (%), etc.,) along with independent t-test and Analysis of Variance (ANOVA) were used to present the profile of the participants as well as associated factors with the knowledge score. A p-value of less than 0.05 was considered statistically significant.

Results: Out of 110 invitations, 97 (88%) doctors responded. Most of the respondents were males 71 (73%), specialists (81, 83.5%), and had been practicing for more than 20 years (66, 68%). The mean (SD) score was 3.31±1.27 out of six for Multiple Choice Questions and 8.05±3.77 out of 15 for True/False questions. Only 37 (38%) participants scored above the passing benchmark of 60%, indicating a substantial knowledge gap. A higher Outpatient Department (OPD) strength (>50 patients per day) and attending a TB training program by the Government were associated with a higher total score (p=0.018).

Conclusion: The knowledge of private practitioners about the diagnosis and management of Tuberculosis was found to be suboptimal. Participants also expressed a few systemic challenges like poor communication and the complexity of the system in the notification of Tuberculosis cases. Innovative training programs, proper communication, and supportive supervision will help in engaging the private practitioners to achieve TB elimination goals.

Keywords: Disease notification, Goals, *Mycobacterium tuberculosis*, Private practice

INTRODUCTION

In 1882, Robert Koch identified *Mycobacterium tuberculosis* as the causative agent for tuberculosis. Over time, several anti-tuberculosis agents were isolated, offering hope for the eradication of tuberculosis. However, new strains of Mycobacterium tuberculosis showed resistance to single and multidrug therapy, making it challenging to achieve the goals of eradication and elimination of tuberculosis [1]. Global declining trends in developed and developing economies created an illusion of the end of tuberculosis. Still, with the emergence of the Human immunodeficiency virus (HIV) - Acquired immunodeficiency syndrome (AIDS) epidemic, coupled with Multidrug-resistant (MDR) strains, tuberculosis rates soared again, prompting the World Health Organisation to declare tuberculosis a global emergency in 1993 [2].

Tuberculosis is a contagious airborne disease that typically affects the lungs, with common symptoms including chest pain, fever, and cough. It remains a significant public health problem, especially in developing countries, and continues to rank among the top 10 causes of death worldwide. In 2019, approximately 10 million people were afflicted with the disease, resulting in about 1.4 million deaths [3]. Regrettably, India leads the world in tuberculosis incidence, mortality, as well as Multiple Drug Resistance (MDR) cases [3]. India's battle against tuberculosis began on a positive note with the establishment of the National Tuberculosis Institute

(NTI) in 1959, followed by the National Tuberculosis Programme in 1962. The work carried out at the NTI was exemplary and globally recognised due to its emphasis on involving the general population in the diagnosis and management of tuberculosis [3,4]. The program was later revamped with the launch of the RNTCP in 1993. It took over a decade for the program to be implemented nationwide. In the Union Budget 2017-18, the Government of India announced an ambitious goal of eliminating TB by 2025, five years ahead of the 2030 deadline [4].

India has achieved many milestones in tuberculosis control through measures such as mandatory notification, integrating the Tuberculosis control program with the National Health Mission, and sufficient budgetary allocations [5,6]. However, the task of eliminating tuberculosis by 2025 requires tremendous efforts from all stakeholders. Dealing effectively with MDR cases, providing access to new technologies across states and increasing budgetary allocations for the tuberculosis control program are recognised as key strategies. Alongside the aforementioned infrastructural and administrative strategies, engaging private practitioners is seen as a crucial step in effective tuberculosis control [4-6]. More than half of the tuberculosis patients are treated at private clinics, and without empowering and involving private practitioners, tuberculosis control may remain a distant dream. Some deficiencies related to notification, diagnosis, and treatment of tuberculosis by private practitioners have been reported. Simultaneously, many barriers hindering the

optimal engagement of the private sector in the tuberculosis control program have been identified [7,8].

Adding insult to injury, the world was struck by a deadly pandemic in the latter part of 2019, namely Coronavirus Disease-2019 (COVID-19). Not only did the economy suffer, but healthcare systems worldwide came to a standstill as the focus shifted to preventing and managing COVID-19. The fight against tuberculosis regressed to square one [9]. India was no exception. Testing and notification of tuberculosis cases significantly decreased after the emergence of COVID-19 in India. Many states experienced a rise in death rates followed by subsequent drops. The restructuring of health systems to address such emergencies in the future and the development of improved surveillance methods might serve as a silver lining during the pandemic for future tuberculosis control programs [10].

In light of the disruption of the health system post COVID-19, it is prudent to revisit the RNTCP program and identify the factors hindering the audacious goal of TB elimination by 2025. Therefore, it is crucial to assess the current knowledge level of private practitioners regarding the diagnosis and management of TB, as well as their perceptions about notifying TB cases. While there have been a few attempts to evaluate the knowledge of private practitioners concerning the diagnosis and management of Tuberculosis patients post-COVID [11,12], these studies, although well-conducted, do not cover all aspects of the RNTCP and issues related to notification. Additionally, there is significant regional variation in testing rates, notification rates, and death rates of TB across India [11]. A similar study conducted in Bhavnagar, Gujarat, reported that 55% of private practitioners had good knowledge of the Standards for Tuberculosis Care [11]. Anand is considered to have slightly better healthcare provisioning due to its close proximity to metro cities like Vadodara and Ahmedabad.

So, to obtain the regional estimates, a cross-sectional survey of private allopathic practitioners in the Anand district of Gujarat was conducted with the aim of assessing their knowledge level regarding the diagnosis and management of Tuberculosis, as well as the challenges they face in TB notification within the context of the NTEP.

MATERIALS AND METHODS
A web-based cross-sectional survey was conducted by Community Medicine Department of Pramukhswami Medical College, Bhaikaka University, Karamsad, Anand, Gujarat, India, among allopathic practitioners Gujarat, from October 2020 to December 2020. A list of doctors registered with the Indian Medical Association (IMA) in Anand was obtained, and this list served as the sampling frame. The institutional Ethics Committee approved the study. (Reference number: IEC/HMPCMCE/2020/Ex. 36/).

Sample size calculation: It was assumed that 60% of private practitioners in Anand would have good knowledge regarding the diagnosis and management of TB. Based on this assumption, a sample size of 93 was deemed necessary to achieve a 95% confidence level, allowing for a 10% error in the estimate. The sample size was increased to 110 to account for a 10-15% non response rate.

Study Procedure
Survey questionnaire: A semi-structured questionnaire was developed by a chest medicine expert, covering all aspects of the RNTCP training modules (Modules 1-4) [13], questions related to the TB notification process, and important socio-demographic details. The questionnaire was then distributed to three chest specialists for evaluating face and content validity. Based on the feedback received from the specialists, the questionnaire was modified. The revised questionnaire was further reviewed in a meeting attended by the developer and the three chest specialists. The final version of the questionnaire was collectively validated in the meeting. The knowledge level was assessed through six multiple-choice questions and 15 true/false questions. Questions with only one correct option were designed using radio buttons, while questions with multiple correct options were created using checkboxes. The questionnaire was pretested on 11 practitioners (who were not part of the study) to ensure its clarity for potential survey participants.

Survey administration: From the list provided by IMA, Anand, a random sample of 110 allopathic practitioners was selected using a computer program (WINPEPI). A Google form containing the questionnaire was created [https://docs.google.com/forms/d/e/1FAIpQLScj3wEwih7S7dmLNeiMbzq-bSI_n9rs-DoQqWlYJrVKCpxGJg/viewform?usp=sf_link]. Prior to the survey questions, a paragraph outlining the purpose of the study was included. Participants were assured of the confidentiality and anonymity of their responses. They were then asked to provide their consent to participate in the survey by clicking an on-screen button that read "I Agree to participate." Upon obtaining participants' consent, the screen displaying the survey questions appeared. A link to the Google form was shared with all selected practitioners, requesting them to complete it within one week. Non respondents received two reminders about the form, spaced two weeks apart.

Assessment: The participants' knowledge level was evaluated through 21 questions (6 multiple-choice and 15 true/false questions). One point was given for each correct answer. In multiple-choice questions with more than one correct option, a point was awarded only if all correct options were selected using checkboxes. The total score was determined by summing the scores (either 0 or 1) for each of the 21 questions. As knowledge was assessed in relation to the TB elimination goal, a slightly stringent benchmark of 60% (13 or more out of 21) was established as the passing score [14].

STATISTICAL ANALYSIS
The data was extracted as a Microsoft Excel file and converted to a Stata file for analysis. The analysis was conducted using software, namely Stata (version 14.2). Descriptive statistics {Mean (SD), Frequency (%)} were utilised to present the profile of the study participants and to assess their knowledge related to the diagnosis and management of TB. The independent sample t-test and ANOVA were employed to evaluate the association of participants' profiles with their knowledge score. A p-value less than 0.05 was considered statistically significant.

RESULTS
Out of a total of 110 invitations, 97 (88.2%) responded. The majority of the respondents were males {71 (73.2%)}, specialists {81 (83.5%)}, and had over 20 years of experience {66 (68%)}. Most of them consulted fewer than 50 patients per day {82 (84.5%)}. While the majority of the respondents reported having seen fewer than 20 suspected/confirmed TB patients {65 (67%)}, about a quarter of the respondents stated that they had not seen any TB patients in the last six months. Only 37 (38.1%) had attended a TB program conducted by the Government, with the majority attending in the last six months {16 (44.4%)} [Table/Fig-1].

Most participants {71 (73.3%)} were aware of NI-KSHAY-(Ni=End, Kshay=TB) as a web-based system for notifying TB cases in both the public and private health sectors. The majority of the respondents {70 (72.2%)} reported TB cases to Government officials, with most doing so during visits by TB department staff to their clinic {45 (64.29%)}. Stigma associated with TB, poor coordination from the Government, and difficulties in the notification process were reported as major obstacles. Surprisingly, 5 (5.2%) respondents were unaware that TB notification is mandatory [Table/Fig-2].

Variables	Categories	Frequency (%)
Age (in years)	20-40	13 (13.4)
	40-60	68 (70.1)
	>60	16 (16.5)
Gender	Female	26 (26.8)
	Male	71 (73.2)
Qualification	MBBS	16 (16.5)
	Specialist (MD/MS)	81 (83.5)
Number of years of passing Bachelor in Medicine, Bachelor in Science (MBBS)	<10	8 (8.2)
	10-20	23 (23.7)
	>20	66 (68)
Clinical experience		
How many patients you see daily in OPD	<20	42 (43.3)
	20-50	40 (41.2)
	>50	15 (15.5)
Attended TB training programme by government	Yes	37 (38.1)
If yes, when in last year	Last 6 months	16 (44.4)
	between 6 months to 1 Year	14 (38.9)
	Do not remember	7 (18.91)
How many TB patients (suspected or confirmed) have you seen in last six months at your clinic?	Nil	25 (25.8)
	1-10	43 (44.4)
	10-20	22 (22.7)
	>20	7 (7.2)

[Table/Fig-1]: Demographic and clinical profile of respondents.

Variables	Categories	Frequency (%)
NI-KSHAY is a case base web-based TB notification system for notification	From both public and private sector	71 (73.3)
	From public sector	11 (11.3)
	From private sector	7 (7.2)
	None of the above	8 (8.2)
Notify TB cases to Government	Yes	70 (72.2)
How do you notify?	Email	9 (12.85)
	Any Other	16 (22.86)
	Staff from TB department comes to your clinic	45 (64.29)
What are the Hurdles in notification of Tuberculosis at the Government centre? (All participants irrespective of whether they notify the TB cases or not answered the question.)	Stigma of TB	14 (14.4)
	Poor coordination from department	15 (15.5)
	Unaware of the enforcement (Mandatory notification)	5 (5.2)
	Difficulty in notification process	8 (8.2)
	Other reasons	13 (13.4)
	No hurdles	42 (43.3)
Your suggestion to improve notification (if you feel it needs to be implemented).*	Should be easy	26 (26.8)
	Periodic checks/Inquiries by government with private practitioners	30 (30.9)
	Supportive supervision	30 (30.9)
	No suggestion	23 (23.7)
	Any other	1 (1)

[Table/Fig-2]: Notification of TB cases.
*The question was populated using a checklist so that the participants can select more than one option. Hence, the total number of responses can be more than number of participants.

The mean (SD) knowledge score on multiple-choice questions was 3.31±1.27 out of six, while the mean (SD) knowledge score on true/false questions was 8.05±3.77 out of 15. The mean (SD) total knowledge score was 11.37±4.28 out of 21. Only 37 (38%) participants scored above the passing benchmark of 60% (13 or more out of 21), indicating a substantial knowledge gap. The domains with very poor knowledge levels mainly included Chest X-ray as a screening and supportive tool for the diagnosis of TB. The interpretation of the Mantoux test, the meaning of MDR TB, and the availability of free diagnostic and treatment facilities for TB patients were domains where the knowledge level was very good. The majority of respondents correctly identified sputum smear as a primary diagnostic test, but they were unable to confirm its reliability and validity [Table/Fig-3].

Univariate analysis revealed that the number of OPD consultations per day (p=0.006) and attending a TB training program (p=0.018) are positively associated with the total knowledge score [Table/Fig-4].

DISCUSSION

The study findings revealed that the knowledge of the respondents was suboptimal in certain domains, specifically in the diagnosis of TB and newer anti-tuberculosis drugs. While the respondents showed a positive attitude towards the elimination of TB, they also highlighted a few challenges in working in sync with the Government system. Attending a training program emerged as the single modifiable factor associated with better knowledge.

The findings are neither new nor surprising. Many studies have been conducted assessing the knowledge, attitude, and practices of private practitioners in the diagnosis and management of TB in India, even after RNTCP coverage has reached pan-India status. All these studies in the last decade used different assessment tools based on the aims and objectives of the study. However, all the studies unanimously pointed out the need to engage private practitioners in the management of TB. Furthermore, these studies also highlighted the positive attitude of private practitioners to be part of the TB control mission [15-18]. Unfortunately, all these studies noted a knowledge gap in various domains of TB care, such as identification, diagnosis, treatment, and processes.

Specific to Gujarat, there is a scarcity of evidence related to the knowledge, attitude, and practices of private practitioners in holistic TB care. A study from Bhavnagar reported a good knowledge level in 55% of private practitioners, with about 69% being aware of mandatory notification. Lack of awareness, complexity of the process, time constraints, and infrequent visits by government health workers were identified as the main hurdles in the notification process [11]. These findings corroborate with the findings of the current study. Another study covering five districts and two corporations in the Bhavnagar region reported a poor knowledge level among Medical Officers (MOs) working at Primary Health Centres. About a quarter of the MOs had poor knowledge, with good knowledge regarding TB diagnosis and treatment but poor knowledge regarding program-related actions [14]. Although these findings are similar to the current study, it is surprising to note that MOs working in the system had poor knowledge of program-related actions.

A recent study from the border districts of Kerala and Karnataka indicated an encouraging trend. Private practitioners engaged through the Private Public Partnership (PPP) model showed good standards of TB care [18]. This study reemphasised the need for training, engagement, and support for private practitioners in achieving the goals of the NTEP. To integrate such sporadic models in a standardised manner, the System for TB Elimination in the Private Sector (STEPS) was recently rolled out [19]. Being a patient-centric model, it gives primacy to people and also bridges the gaps in the quality of care for patients visiting private practitioners. The model also helps establish a good surveillance system for real-time monitoring at the top level to help policymakers make informed decisions. A recent evaluation of the STEPS model revealed favourable results, indicating scalability and self-sustainability of the model [20]. The STEPS and other models are successful but still appear as vertical programs with a hint of horizontal integration. Endemics and pandemics like

Variables	Categories	Frequency (%)
Multiple choice questions (Correct answer/s are indicated in italics)		
Presumptive pulmonary TB signs and symptoms	*Cough for 2 weeks or more*	92 (94.8)
	Chest pain	1 (1)
	Fever for 2 weeks or more	66 (68)
	Chronic headache	6 (6.2)
	Significant weight loss	85 (87.6)
	Haemoptysis	61 (62.9)
	Enlarged lymphadenopathy	75 (77.3)
How many sputum samples are collected from suspected TB patients according to the National TB elimination Program?	1 *2* 3 4	04 (4.1) 45 (46.4) 47 (48.5) 1 (1)
Which is the primary diagnostic test?	Chest X-ray MT *Sputum smear microscopy/culture* Blood culture	22 (22.7) 13 (13.4) 61 (62.9) 1 (1)
Intensive phase (IP) consists of 8 weeks (56 doses) of	*Isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E) under direct observation in daily dosages.*	75 (77.3)
	Isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E) given in thrice a week.	13 (13.4)
	Isoniazid (H), rifampicin (R) and pyrazinamide (Z) given under direct observation in daily dosages.	8 (8.3)
	Isoniazid (H), rifampicin (R) and pyrazinamide given in thrice a week.	1 (1)
Continuation phase (CP), consists of 16 weeks (112 doses)	*Of isoniazid, rifampicin and ethambutol in daily dosages*	66 (68)
	Of isoniazid, rifampicin and ethambutol and pyrazinamide in daily dosages	9 (9.3)
	Of isoniazid, rifampicin and ethambutol twice a week	22 (22.7)
National TB Elimination Programme (NTEP) Government of India has committed to end TB by	*2025* 2030 2035 2040	75 (77.3) 16 (16.5) 6 (6.2) 0
True/false questions		Frequency (%) Correct answers
Mantoux Test positive means patient has TB and needs treatment.		92 (94.8)
BCG ensure 100% protection with TB		86 (88.7)
Sputum Smear microscopy- The primary tool which is reliable, inexpensive, easily accessible and rapid method of diagnosing PTB		8 (8.2)
Chest X-ray is both a screening a supportive tool for the diagnosis of smear negative PTB		8 (8.2)
Solid (LJ) and Liquid Culture (MGIT) methodologies and molecular based diagnostic technologies including Nucleic Acid Amplification Test (Cartilage Based Nucleic Acid Amplification Test, CBNAAT/Truenat), Line Probe Assay etc., are available under the programme.		53 (54.6)
CBNAAT diagnoses Rifampicin resistance among all TB patients.		55 (56.7)
Patients belonging to extra pulmonary TB, HIV and Paediatrics (after X-ray screening in case of children) can be directly referred for CBNAAT		46 (47.4)
Supportive tools for the clinical diagnosis of TB are chest X-ray and other radiological tests,		35 (36.1)
Tuberculin Skin Test (TST) and Interferon Gamma Release Assay (IGRA).		35 (36.1)
Diagnosis of TB by any microbiological tools and treatment for TB are available free of cost at all health facilities under RNTCP		68 (70.1)
All presumptive TB patients should be offered HIV testing.		63 (64.9)
Fixed Dose Combinations (FDCs) refer to products containing two or more active ingredients in fixed doses. In TB program, for adults- 4-FDC (given in Intensive phase) consists of HRZE and 3-FDC (given in Continuous Phase)		57 (58.8)
Diagnosis of TB by any microbiological tools and treatment for TB are available free of cost at all health facilities under TB cell.		66 (68)
Multi Drug Resistant (MDR) TB means a patient whose biological specimen is resistant to both isoniazid and rifampicin with or without resistance to other first line drugs, based on the results from a quality assured laboratory.		70 (72.2)
Newer anti-TB drugs after almost five decades of discovery of Rifampicin is Bedaquiline		39 (40.2)
Mean(SD) score of 6 MCQs		**3.31 (1.27)**
Mean(SD) score of 15 T/F question		**8.05 (3.77)**
Total Mean(SD) score of 15+6= 21		**11.37 (4.28)**

[Table/Fig-3]: Knowledge about TB diagnosis and management.

COVID-19 can disrupt the progress of such models to a great extent. A more holistic approach should be developed that can withstand economic and political instability as well as new threats to mankind like the recent pandemic. Furin J and Pai M suggested one such model (Swiss Cheese Model for Ending TB) that is an artful amalgamation of imperfect strategies to build a successful model [21]. Furin J and Pai M further elaborate on how multi-sectoral collaborations can enhance NTEP objectives by applying wisdom from the COVID-19 pandemic [22].

Limitation(s)

The study was conducted in a town in central Gujarat, and therefore, generalisability is limited. The participants were selected (allopathic private practitioners) as per the list provided by the Indian Medical Association, Anand. Therefore, it is not possible to comment on the knowledge level and perceptions about TB notification of private practitioners trained in Homeopathy, Ayurveda, and other branches like Unani, etc.

Variables	Category	N	Knowledge score Mean (SD)	p-value
Age (in years)	20-40	13	10.30 (4.57)	0.84
	40-60	68	10.80 (4.29)	
	>60	16	11.25 (3.95)	
Gender	Female	26	10.73 (4.58)	0.90
	Male	71	10.84 (4.16)	
Qualification	MBBS	16	11.40 (5.30)	0.52
	Specialist (MD/MS)	81	10.64 (4.03)	
Number of years of passing MBBS	<10	8	12.62 (4.98)	0.38
	10-20	23	11.08 (4.55)	
	>20	66	10.50 (4.04)	
How many patients you see daily in OPD	<20	42	11.90 (4.38)	0.006
	20-50	40	9.20 (3.60)	
	>50	15	12.06 (4.28)	
Attended TB training programmed by government	Yes	37	12.10 (4.27)	0.018
	No	60	10.01 (4.05)	
When in last year	Before 6 months	16	11.68 (3.19)	0.19
	Before 1 year	14	11.28 (4.47)	
	Don't remember	7	14.71 (5.52)	
How many TB patients (suspected or confirmed) have you seen in last six months at your clinic?	Nil	25	9.88 (4.34)	0.51
	1-10	43	11.18 (4.34)	
	10-20	22	11 (4.22)	
	>20	7	11.28 (3.63)	

[Table/Fig-4]: Univariate analysis of factors affecting the total knowledge score.
The mean knowledge score was compared across groups using Analysis of Variance (ANOVA) and independent sample t-test. A p-value of less than 0.05 was considered statistically significant.

CONCLUSION(S)

The knowledge level of private practitioners was suboptimal in certain domains of the diagnosis and management of TB. Private practitioners also face challenges in the notification process. Training programs via digital platforms, unflagging communication, and supportive supervision will help engage private practitioners to their fullest potential to achieve TB elimination goals. An artful, contextual, and culturally acceptable combination of the STEPS and Swiss Cheese Model may be tested in the near future.

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