

Original Research Article

Management of pulmonary tuberculosis in private health sector: is it according to revised national tuberculosis control programme guidelines?

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ABSTRACT

Background: As private sector is dominant tuberculosis (TB) care provider in India, to realize the vision of TB free India, it is crucial that public and private sector follow uniform standard of TB care. This can be achieved when private health sector adopts TB management methodology of Revised National Tuberculosis Control Programme (RNTCP) of India. The present study was conducted to estimate whether or not TB management practices of allopathic private practitioners (PPs) conform to RNTCP guidelines by assessment of their knowledge and practice about new pulmonary TB (PTB).

Methods: A cross-sectional study conducted using a semi-structured questionnaire among PPs practicing in urban areas of five of the six districts of Kumaon Division of Uttarakhand State of India between October 2013 to November 2014.

Results: Of 71 PPs included in the study, almost 66% did not suspect pulmonary TB unless cough was associated with other symptoms. For diagnosis and follow up, sputum AFB microscopy alone was used by only 10% and 8.4% PPs respectively. Of the 71 PPs, 67 PPs who prescribed treatment for new PTB, used 20 diverse anti-TB regimens, and 10.5% of them included levofloxacin in the regimen.

Conclusions: Majority PPs didn't follow the RNTCP's TB management guidelines for new PTB.

Keywords: TB, Private sector, India, TB care

INTRODUCTION

The Revised National Tuberculosis Control Programme (RNTCP) of India is the world's largest TB control programme. Encouraged by its achievements, the programme in 12th five year plan (2012-2017) had articulated National Strategic Plan with a vision of TB Free India.¹ Tuberculosis (TB) care in India is provided by both the public and the private health sector.² In order to realize this vision, TB management needs to be uniform between these two sectors. This means that the private health sector needs to adopt the World Health

Organization (WHO) recommended RNTCP's TB management methodology.

However, since the earliest documented report by Uplekar et al in 1991 to a systematic review by Satyanarayana et al on suboptimal TB management in private sector of India, TB care in private health sector has been reported to be substandard and erratic.^{3,4} As almost half of Indian TB patients are managed by the private health sector, the substandard TB care in private sector has the potential to disrupt TB control efforts of RNTCP.⁵⁻⁷ The RNTCP has been aware of this fact

since its inception in 1997, and has been therefore putting in persistent efforts for almost more than a decade to bring in uniformity of TB care between these two health sectors by educating the private TB care providers by means of countrywide workshops, release of quarterly TB/RNTCP newsletters, continuing medical education (CME) programmes and introduction of a specific RNTCP Training Module for Medical Practitioners in year 2010.⁸⁻¹⁰

However, to our knowledge, there was no direct documentation available as to whether or not private health sector manage PTB as per the RNTCP's management methodology in the present study region. This paucity of information prompted us to undertake this cross-sectional study among allopathic private practitioners (PPs) practicing in Kumaon division of Uttarakhand state of North India by assessment of their knowledge and practice about new pulmonary TB (PTB). The results of this study would be helpful in providing important insights for bringing in uniformity of TB management between the public and the private health sector.

METHODS

The research question for this study was whether or not the TB management practices between the private and public health sector in the study settings were uniform. Answer to this was sought by assessing the response of PPs to following inquiry: (i) Number of TB educational/training sessions PPs attended so far, (ii) Presenting symptom which makes PPs suspect PTB, (iii) Test which PPs rely the most for diagnosis of PTB, (iv) Follow-up test which PPs prefer the most to judge efficacy of anti-TB treatment, (v) PPs' perception about completion of full course of treatment by their PTB patients, (vi) Record keeping of PTB patients by PPs, (vii) Retrieval mechanism exercised by PPs for their defaulted PTB patients, (viii) Measures suggested by PPs for patient compliance, (ix) Please write anti-TB treatment prescription to a 60 kg weight new smear positive PTB (NSP-PTB) patient.

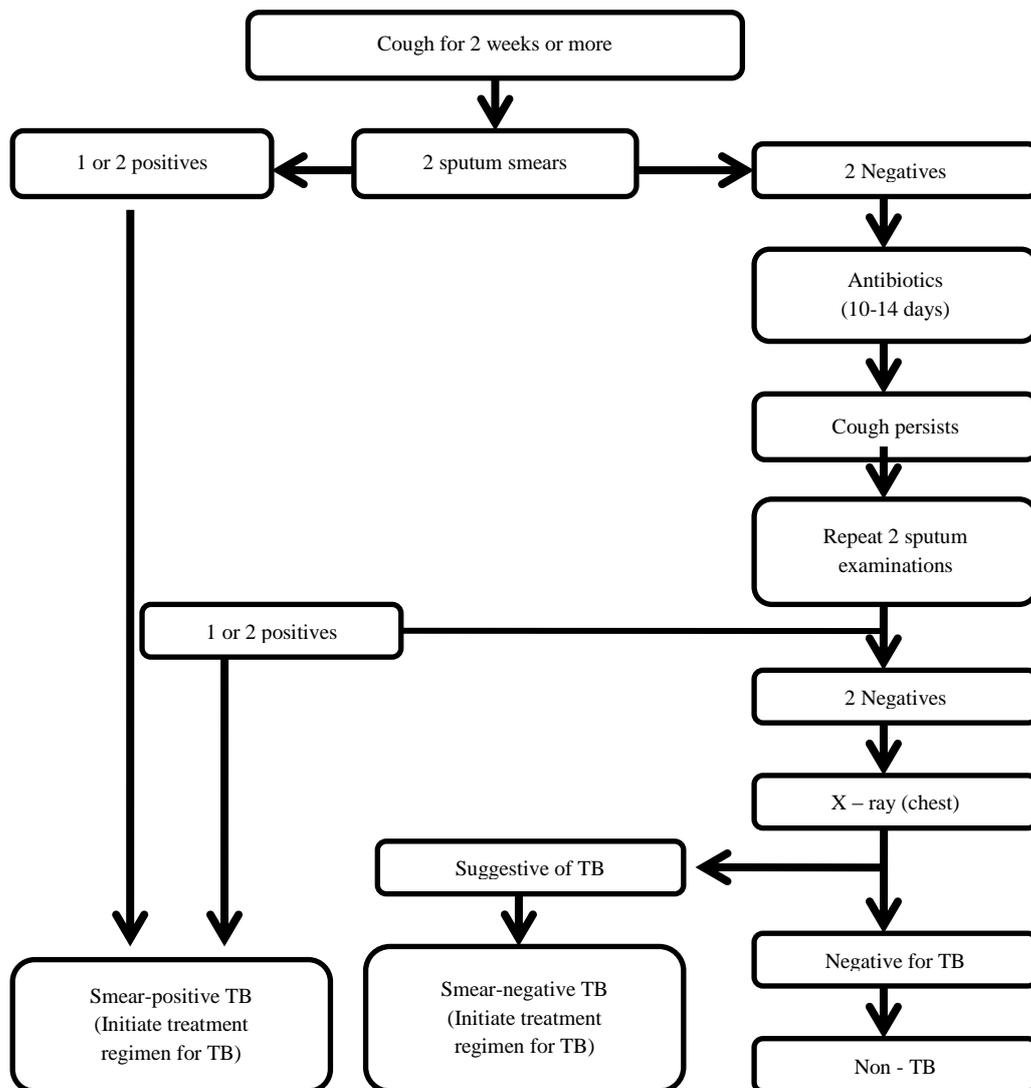


Figure 1: Diagnostic algorithm for adult PTB.¹⁰

Table 1: RNTCP training module (2010) guidelines for medical practitioners.¹⁰

Drug regimen and duration of treatment for adult NSP-PTB	Directly observed thrice weekly intermittent regimen	
	Intensive phase	Continuation phase
	H ₃ R ₃ Z ₃ E ₃ for 2 months	H ₃ R ₃ for 4 months
Follow-up tests to judge efficacy of anti-TB treatment	Sputum Acid Fast Bacillus microscopy	
Record keeping of the patient	Maintain the prescribed TB treatment card	
Action for patients who interrupt treatment	The practitioner should inform the concerned supervisory staff at sub-district level (TB unit)	

H-Isoniazid, R-Rifampicin, Z-Pyrazinamide, E-Ethambutol; the subscript stands for number of doses given per week.

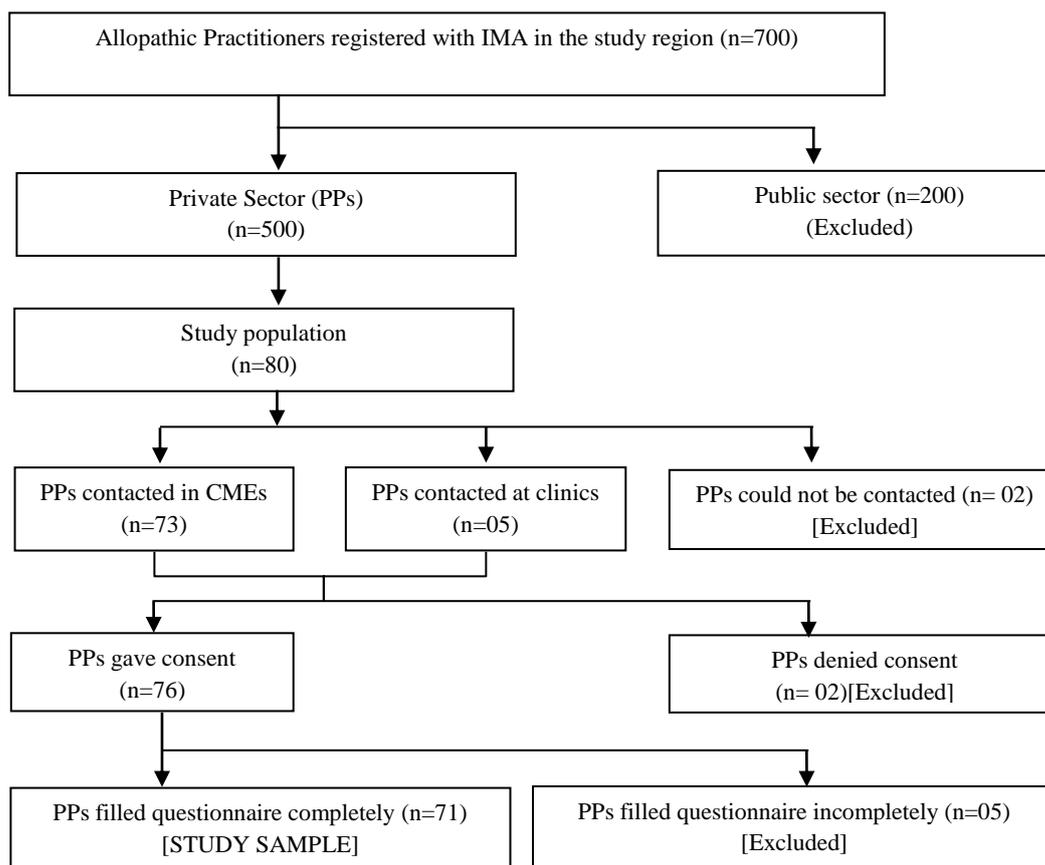


Figure 2: Study sample selection.

As management of PTB in public sector is done as per the RNTCP guidelines, the TB management methodology of RNTCP as outlined in the RNTCP Training Module (2010) for Medical Practitioners was taken as standard for assessment of TB management practices of PPs.¹⁰ The diagnostic algorithm and other aspects of TB management mentioned in the said training module for adult PTB are shown in Figure 1 and Table 1 respectively.

Study design and setting

A cross sectional survey among PPs in 5 of the 6 districts of Kumaon Division of Uttarakhand Province of India, conducted between October 2013 to November 2014.

Study population

There were about 700 allopathic medical practitioners (200 public sector doctors and 500 PPs) registered with Uttarakhand State Indian Medical Association (IMA). The study sample was chosen among 500 PPs.

Sample size calculation

As no such study was undertaken in the region, it was assumed that at least 50% PPs might have adopted the RNTCP guidelines in their clinical practice. We calculated the sample size with formula $(1.96)^2 pq/d^2$ at 95% confidence level and d=10% absolute error. The sample size was thus calculated as 96. Because the sample size exceeded 5% of source population,

correction formula of $n_f = n_i / (1 + n_i / N)$ where n_f =corrected sample size, n_i = uncorrected sample size and N =total source population was applied.¹¹ Thus, finally a sample size of 80 was required for the study.

Sampling technique and study sample

The first author (RGN) of the study who has almost 20 years of experience in management of TB, line listed PPs practicing in the urban settings of Kumaon Division of Uttarakhand and purposively sampled only academically active PPs with rich clinical practice in the region. The idea behind purposive sampling was that the academically active PPs were supposed to be best informed about the RNTCP’s TB management methodology and the public health importance of uniform TB care between public and private health sectors. A semi-structured questionnaire was served to the selected PPs to attempt it in presence of the investigator during various continuing medical education (CME) sessions. PPs missed at the CME sessions were approached at their clinics. Due consent was taken from the participants after explaining them the purpose of the study and ensuring confidentiality and anonymity. Of 80 PPs who formed the study population, 9 were excluded, and a sample of 71 PPs was obtained for final analysis. The sample selection process is shown in Figure 2.

Statistical analysis

Using numbers and percentages, a descriptive analysis of data was done after fetching the data in MS excel. The statistical software R (R Foundation for Statistical Computing, Vienna, Austria; <http://www.R-project.org>) version 3.4.2 (2017-09-28) was used for calculation of 95% confidence interval for proportions.¹²

Ethical consideration

Prior approval of Institute Ethical Committee of Government Medical College Haldwani was taken.

RESULTS

A total of 71 PPs were included in the study for assessment of their PTB management methods.

Table 2 shows that majority (85.9 %) PPs were non-chest specialists, and 14.1% were chest specialists. The average duration of practice of PPs was 17.5 years with a range from 6 months to 50 years, and 36.6% had more than 20 years of practice. About two-third PPs (65%) were seeing one to ten TB patients in a month. One-fourth PPs did not attend any RNTCP training session, while the majority (70%) PPs attended one to five training sessions on TB.

Table 3 highlights the knowledge and practice of PPs regarding PTB. Only one-third (33.8%) PPs suspected

PTB on the basis of cough alone. Majority (66.2%) PPs, however did not suspect PTB unless cough was associated with one or more other symptom/s like haemoptysis, weight loss, loss of appetite, chest pain and fever. Sputum AFB smear examination alone as a reliable test for diagnosis of PTB was considered by only 10% PPs. Almost 17% PPs didn’t consider sputum examination necessary. Majority (73.2%) PPs prescribed chest X-ray along with sputum AFB microscopy for diagnosis of PTB. For judging the efficacy of anti-TB treatment, sputum AFB smear examination alone as follow-up test was preferred by only 8.4% PPs. Almost 27% PPs didn’t consider sputum examination necessary. Majority (64.8%) PPs prescribed chest X-ray along with sputum AFB microscopy for follow up of PTB.

Table 2: Demographic profile of PPs (n=71).

Variables	Number	Percentage (%)
Professional qualification		
Chest specialists	10	14.1
Non- chest specialists	61	85.9
Place of practice		
Nainital	26	36.6
Udham Singh Nagar	32	45.1
Almora	09	12.7
Pithoragarh	03	04.2
Champawat	01	01.4
Duration of practice (years)		
0–5	16	22.5
6–10	13	18.3
11– 20	16	22.5
>20	26	36.6
Number of TB patients seen every month		
01–10	46	64.8
11–30	15	21.1
>30	6	08.5
No response	4	05.6
Number of RNTCP training sessions attended		
Nil	18	25.4
1–5	50	70.4
>5	03	04.2

Table 4 shows that none of the PPs was found to keep treatment records of their PTB patients. While majority (53.5%) perceived that 10-75% of their PTB patients did not complete treatment, 46.5% PPs perceived that more than 90% of their PTB patients completed full course of anti-TB treatment. None of the PPs was using any mechanism for retrieval of their defaulted TB patients.

Table 5 and Figure 3 represent that of 71 PPs, 67 (94.4%) responded to the request to write anti-TB treatment to a 60 Kg weight new PTB patient. None of these 67 PPs prescribed the RNTCP recommended

intermittent regimen. Majority (89.5%) of the 67 PPs prescribed 20 diverse unsupervised daily regimens with first line anti-TB drugs (Isoniazid, Rifampicin,

Pyrazinamide, Ethambutol). Of the 67 PPs, 10.5% added levofloxacin in their prescription.

Table 3: Knowledge and practices of PPs regarding PTB (n=71).

Practices of PPs	Private practitioners		95 % CI
	Number	Percentage (%)	
Presenting symptom which makes PPs suspect PTB			
Cough only	24	33.8	23.3 – 46.1
Cough with one or more other symptoms ^s	47	66.2	53.9 – 76.7
PPs' most relied diagnostic test for PTB			
Sputum AFB only	07	09.9	04.4 – 19.8
Chest x-ray only	12	16.9	09.4 – 28.1
Sputum AFB + chest x-ray	52	73.2	61.2 – 82.7
PPs' most preferred follow-up test for PTB			
Sputum AFB only	06	08.4	03.5 – 18.1
Chest x-ray only	19	26.8	17.3 – 38.8
Sputum AFB + chest x-ray	46	64.8	52.5 – 75.5

^sOther symptoms - Haemoptysis, weight loss, loss of appetite, chest pain, fever; CI – Confidence Interval.

Table 4: PPs' version on record keeping, treatment completion, default retrieval and patient compliance (n=71).

Variables	Private practitioners	
	No.	%
PPs' practice of keeping TB treatment record		
No	71	100.0
Yes	00	00
PPs claim about percentage of patients completing full course of anti-TB treatment		
25-<50%	6	08.5
50-<75%	13	18.3
75-<90%	19	26.8
> 90%	33	46.5
Use of retrieval mechanism by PPs for defaulted TB patients		
No	71	100
Yes	0	0
Measures suggested by PPs for patient compliance		
Registering patient	16	22.5
Telephonic contact	5	07.0
Educating patient	5	07.0
Granting allowance to patient	1	01.4
No Suggestion	29	40.8

Table 5: Drug regimens prescribed by PPs for NSP-PTB.

Type and number of drug regimens prescribed (n=20)	Private practitioners (n=67)*	
	Number	%
Intermittent regimen (n=0)	00	00
First line anti-TB drugs daily regimens (n=20)[#]	67	100.0
Without Levofloxacin (n=14)	60	89.5
With Levofloxacin (n=6)	07	10.5

*4 PPs did not prescribe treatment; #First line anti-TB drugs- Isoniazid, Rifampicin, Pyrazinamide, Ethambutol

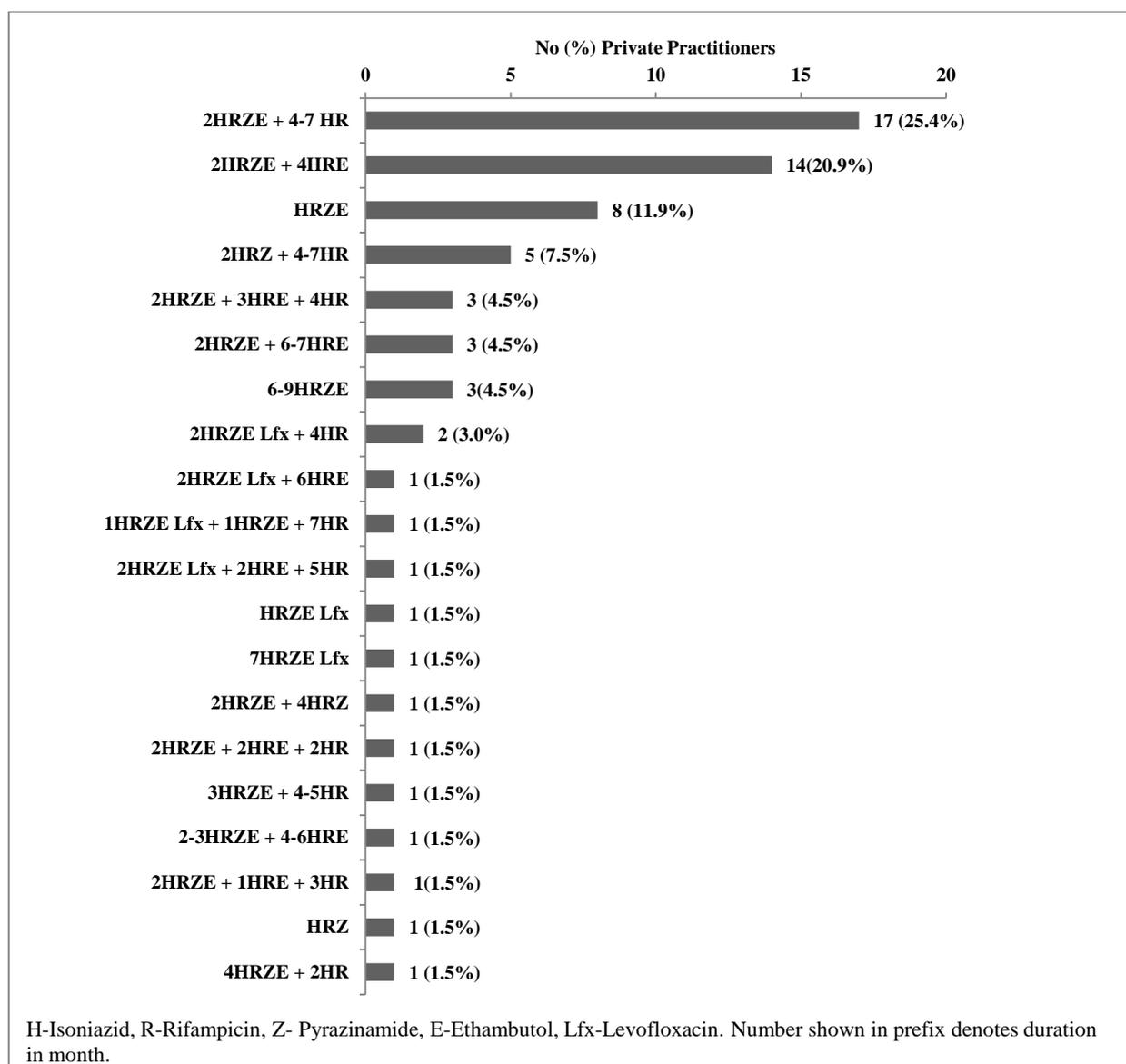


Figure 3: Drug regimens (n=20) prescribed by 67 PPS.

DISCUSSION

This study provides information on whether or not TB care is uniform in public and private health sector.

Our study documents that though the RNTCP’s diagnostic algorithm values cough as the defining symptom for suspecting PTB, almost two-third (66.2%) PPs did not consider cough alone as a qualifying symptom for diagnostic evaluation of PTB, unless it is associated with one or more other symptom like fever, haemoptysis, weight loss, loss of appetite and chest pain. The reason for this undervaluation of specificity of cough for suspicion of PTB may be, that in India cough is a prominent symptom in many other more prevalent respiratory illnesses related to smoking, poor indoor and outdoor air quality, and respiratory infections. However, ignorance of cough for suspecting

PTB by majority PPs may have serious implications— one, a large number of PTB patients may not be subjected to sputum AFB examination and are sent back home with antibiotics and cough syrup; two, consequent diagnostic delay which poses the risk of increased morbidity, mortality, drug resistance and financial loss to the patient; three, risk of prolonged exposure of the community to infection. A systematic review in 2014 by Sreeramareddy et al which included 23 studies from different parts of India, had also reported a significant provider related delay of 55 days in diagnosis and treatment of PTB.¹³ This finding in our study highlights that though RNTCP puts much emphasis on public health importance of cough, majority PPs do not value it more than a symptom of a disease.

It is evident in our study that sputum AFB smear examination alone as a reliable test for diagnosis of

PTB was considered by only 10% PPs. Almost 17% PPs didn't consider sputum examination necessary. Majority (73.2%) PPs prescribed chest x-ray along with sputum AFB microscopy for diagnosis of PTB. This implies that majority PPs considered chest x-ray as an indispensable diagnostic tool for diagnosing PTB. The reasons for this under-reliance on sputum AFB smear examination alone, and indispensable need of chest x-ray by PPs might be—one, the RNTCP could not properly convince PPs the public health importance of sputum AFB smear examination and consequence of over-diagnosis of PTB in up to 37-70% patients by over reliance on chest x-ray; two, the PPs might feel that quality microscopy services were not available to them in the private sector; three, low sensitivity (60-80%) of sputum AFB smear examination; four, PPs' practice experience that if chest x-ray was not done, they might miss the alternative or co-existing diagnosis; five, many new PTB patients usually have dry cough; six, financial incentive associated with the diagnostic work up of the patient.^{10,14-16} Amid this indispensable reliance on chest x-ray by PPs for diagnosis of PTB, it is important to highlight that the RNTCP has also currently approved simultaneous use of chest x-ray along with sputum AFB examination in initial diagnostic evaluation of PTB.¹ This recent change in the RNTCP diagnostic algorithm may appreciably reduce the gap of diagnostic practice between the public and the private health sector. However, under reliance on sputum AFB smear examination by majority PPs clearly emphasizes that a higher sensitivity, universally acceptable and easily available rapid test needs to be researched for initial diagnostic evaluation of early PTB.

On the question of most preferred follow-up test for PTB, it is evident that sputum AFB smear examination alone was preferred by only 8.4% PPs. Almost 27% PPs didn't consider sputum examination necessary. Majority (64.8%) PPs prescribed chest x-ray along with sputum AFB microscopy for follow up of PTB. These findings indicate that for follow-up of a PTB case, majority PPs do not rely on sputum AFB smear examination without chest x-ray. The reasons for this practice of PPs may be—one, RNTCP's efforts were grossly inadequate in convincing the PPs about superiority and public health importance of sputum smear test over chest x-ray for follow up of PTB; two, disappearance of cough and expectoration in most patients after initiation of treatment and other reasons already cited above for under reliance on sputum AFB smear examination for diagnosis of PTB.

This study found that 53.5% PPs perceived that 10-75% of their PTB patients did not complete full course of prescribed treatment. This perception of PPs is in line with the known fact that under the setting of unsupervised anti-TB treatment in India, of every 100 TB patients in the community, 30 are identified, 10 remain under treatment and only 8 are cured, and TB treatment completion rate falls in the range between 5-59% in private sector.¹⁷⁻¹⁹ It is also evident in this study

that though 59.2% PPs were aware of the measures to be taken for ensuring patient compliance, none of the PPs kept treatment record of their PTB patients and no one used any retrieval mechanism for their defaulted PTB patients. This highlights the “know-do” gap in PPs' practice. The possible reasons for this “know-do” gap may be—One, PPs felt record keeping and retrieval of patients as burdensome; Two, they did not think it as an issue enough of public health importance. This highlights that while systematic recording and monitoring of patients is given high importance in RNTCP, PPs do not consider it so.

Our study documents that while the RNTCP had educated the PPs that intermittent thrice weekly treatment regimen was as effective as daily treatment regimen, none of the PPs used the intermittent regimen. Reasons for not using the intermittent regimen were evident in the study by Nautiyal et al, wherein almost 97% PPs did not perceive RNTCP as a successful strategy.²⁰ This suggests that PPs do not realize the scientific basis of intermittent TB treatment. However, the recent shift of RNTCP from intermittent to daily regimen in the State of Uttarakhand in year 2018, may help in establishing uniformity of TB care between the private and public health sector in the region.

It is evident in this study that 67(94.3%) of 71 PPs who responded to our request to write a prescription for a NSP-PTB case, prescribed 20 diverse unsupervised daily anti-TB treatment regimens which in no way conformed to the contemporary directly observed intermittent regimen recommended by the RNTCP. However, it is an interesting finding in this study that among 67 PPs who prescribed these 20 different regimens, 21% were prescribing the RNTCP's currently approved regimen i.e 2HRZE + 4HRE. Perhaps this shift of RNTCP from intermittent regimen to daily regimen with three drugs in continuation phase is a step in right direction to end the discordance and distrust between the RNTCP and PPs. The RNTCP may utilize this opportunity in near future.

A perplexing finding in this study was that Levofloxacin which is in schedule H1 list of government of India, and is an important ingredient of multi drug resistant TB (MDR-TB) regimen, and is one of the fluoroquinolones along with aminoglycosides which define extensively drug resistant TB (XDR-TB) in RNTCP, was prescribed by 07 (10.5%) of the 67 PPs who wrote treatment for NSP-PTB case. Such misuse of levofloxacin may create more XDR-TB cases in the country.^{1,21}

Most of the findings of this study are proximate with the results of a systematic review by Satyanarayan et al which included 47 studies conducted in different parts of India between 2000-2014 on TB care provider's knowledge and practices, wherein only half of the health care providers were aware of the importance of suspecting PTB in persons with cough of 2-3 weeks

duration, and two-thirds knew about using sputum smear examination for persons with presumed PTB, and only one-third of the providers were aware of the correct regimen for patients with early PTB.⁴

CONCLUSION

Majority PPs didn't follow the RNTCP's TB management protocol for new PTB. Hence, this study highlights the need to plan strategies to ensure uniformity of TB care in India across all its health settings.

Recommendations

Introduction of following measures may achieve the desired uniformity of TB care in India: i) Up-scaling countrywide teaching and training in RNTCP to all kinds of TB care providers, ii) Strengthening the public health infrastructure to make it more attractive to patients, iii) Setting up multi-centric operational research using standardized patient to find out barriers which preclude uniformity of TB care between the public and private health sector, iv) Research to develop a higher sensitivity, universally acceptable and accessible rapid test for diagnosis of early PTB.

Limitation

As it was an interview based study, it did not show the actual practice of PPs. Further, it does not highlight the barriers of uniformity of TB management between public and private health sector.

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Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

- Central TB Division, Directorate of Health services, Ministry of Health and Family Welfare, Government of India. Revised National Tuberculosis Control Programme, Technical and operational guidelines for tuberculosis control in India. 2016.
- Lal SS, Sahu S, Wares F, Lonnroth K, Chauhan LS, Uplekar M. Intensified scale-up of public-private mix: a systems approach to tuberculosis care and control in India. *Int J Tuberc Lung Dis*. 2011;15(1):97-104.
- Uplekar MW, Shepard DS. Treatment of tuberculosis by private general practitioners in India. *Tubercle*. 1991;72(4):284-90.
- Satyanarayana S, Subbaraman R, Shete P, Gore G, Das J, Cattamanchi A, et al. Quality of tuberculosis care in India: a systematic review. *Int J Tuberc Lung Dis*. 2015;19:751-63.
- International Institute of Population Sciences (IIPS) and Macro International. 2007. National Family Health Survey (NFHS-3). 2005-06: India: Volume I.
- Suganthi P, Chadha VK, Ahmed J, Umadevi G, Kumar P, Srivastava R, et al. Health seeking and knowledge about tuberculosis among persons with pulmonary symptoms and tuberculosis cases in Bangalore slums. *Int J Tuberc Lung Dis*. 2008; 12(11):1268-73.
- Hazarika I. Role of Private Sector in Providing Tuberculosis Care: Evidence from a population-based Survey in India. *J Glob Infect Dis*. 2011;3(1):19-24.
- Central TB Division, Directorate General of Health Services, Ministry of Health & Family Welfare, New Delhi. Involvement of private practitioners in the Revised National Tuberculosis Control Programme. 2005.
- Central TB Division, Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India, TB India 2011, RNTCP status report.
- Revised National Tuberculosis Control Programme, Training module for medical practitioners, Central TB Division, Directorate of Health services, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi. December 2010.
- Bartlett JE, Kotrlik JW, Higgins CC. Organizational Research: Determining Appropriate Sample Size in Survey Research. *Information Tech Learning, Performance J*. 2001;19(1):43-50.
- R Core Team (2017). R: A language and environment for statistical computing. R Foundation for statistical computing, Vienna, Austria. Available from <http://www.R-project.org/>. Accessed on 18 November 2018.
- Sreeramareddy CT, Qin ZZ, Satyanarayana S, Subbaraman R, Pai M. Delays in diagnosis and treatment of pulmonary tuberculosis in India: a systematic review. *Int J Tuberc Lung Dis*. 2014;18:255-66.
- Nagpaul DR, Vishwanath MK, Dwarakanath G. A socio-epidemiological study of outpatients attending a city tuberculosis clinic in India to judge the place of specialized centres in a tuberculosis control programme. *Bulletin of the World Health Organization*. 1970;43:17-34.
- Nair SS. Significance of patients with X-ray evidence of active tuberculosis not bacteriologically confirmed. *Indian J Tuberc*. 1974;21:3-5.
- Toman K. What are the relative merits of chest x-ray in case finding among new out patients with prolonged chest symptoms? In: Toman K, ed. *Tuberculosis case finding and chemotherapy-questions and answers*. Geneva: World Health Organization, 1979.
- Radhakrishnan S. National Tuberculosis Programme: relative merits of enhancing the operational efficiency of different components of treatment programme. *Indian J Tuberc*. 1993;30:3-8.

18. Ramana GNV, Naidu CSBM, Murthy KJR. Mapping of TB treatment providers at selected sites in Andhra Pradesh State, India. 1997. World Health Organization, Geneva. Available at <http://www.who.int/iris/handle/10665/63692>. Accessed 6 June 2018.
19. Uplekar M, Juvekar S, Morankar S, Rangan s, Nunn P. Tuberculosis patients and practitioners in private clinics in India. *Int J Tuberc Lung Dis*. 1998;2:324-9.
20. Nautiyal RG, Singh RK. Public private mix in tuberculosis control: is it really working in India? *Int J Community Med Public Health*. 2018;5:728-33.
21. Ministry of Health and Family Welfare, Government of India. The drugs and cosmetic rules 1945 (amended up to 15 August 2013).

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