Introduction

As per the World Health Organization (WHO) global TB control report 2011, India continues to bear the highest global burden of TB with an estimated 2.3 million incident cases per annum accounting for more than one-fourth of global TB incidence [1]. The Revised National TB Control Programme (RNTCP) is being implemented in the country since 1997 with complete country coverage by March 2006, with TB diagnostic and treatment services integrated throughout the public health infrastructure. Despite this success, India has a very large unregulated private medical sector. Although data are sparse, there could be as many TB patients seeking health care in private sector as there are in the public [2–5]. A recent analysis of drug sales in the country circumstantially supported this interpretation [6]. Effective engagement of the private sector is vital to facilitate national TB control strategies.

There have been significant efforts to engage the private sector with the RNTCP through various Non-Governmental Organization/Private Provider (NGO/PP) schemes [7]. The Indian Medical Association (IMA), the country's largest representative voluntary organization of qualified medical practitioners of modern medicine, is an important partner of the RNTCP and has adopted the International Standards for TB Care (ISTC). These standards describe a widely accepted level of TB care that all health care practitioners, both public and private, should seek to achieve, and the essential public health responsibilities that they must carry out [8]. The ISTC includes 21 standards that cover four broad areas: diagnosis, treatment, addressing HIV and other co-morbid conditions and public health responsibilities. Of the 21

Abstract

Setting: Private medical practitioners in Visakhapatnam district, Andhra Pradesh, India.

Objectives: To evaluate self-reported TB diagnostic and treatment practices amongst private medical practitioners against benchmark practices articulated in the International Standards of Tuberculosis Care (ISTC), and factors associated with compliance with ISTC.

Design: Cross-sectional survey using semi-structured interviews.

Results: Of 296 randomly selected private practitioners, 201 (68%) were assessed for compliance to ISTC diagnostic and treatment standards in TB management. Only 11 (6%) followed a combination of 6 diagnostic standards together and only 1 followed a combination of all seven treatment standards together. There were 28 (14%) private practitioners who complied with a combination of three core ISTC (cough for tuberculosis suspects, sputum smear examination and use of standardized treatment). Higher ISTC compliance was associated with caring for more than 20 TB patients annually, prior sensitization to TB control guidelines, and practice of alternate systems of medicine.

Conclusion: Few private practitioners in Visakhapatnam, India reported TB diagnostic and treatment practices that met ISTC. Better engagement of the private sector is urgently required to improve TB management practices and to prevent diagnostic delay and drug resistance.
standards, six describe diagnostic and seven describe treatment
standards.

Many studies from India have documented that the private sector often deviates from the standard, internationally recommen-
ded, TB management practices [9–12]. Inappropriate diag-
nostic practices may lead to diagnostic delay, perpetuating TB transmission. Inappropriate treatment practices risk amplification of
drug resistance.

Very few prior studies on private TB management practices
have included representative samples of providers or assessed risk
factors for such practices. We conducted a representative survey of
formally qualified private medical providers (PMP) in one district
of Andhra Pradesh, South India to evaluate self-reported TB
diagnostic and treatment practices against the benchmark
practices articulated in the ISTC. We further evaluated factors
associated with compliance with ISTC-recommended practices.

The principles of diagnostic and treatment standards in the
ISTC with their rationale [13–31] are summarized in Box 1
(Figure 1).

Methods

Ethics Approval

Ethics approval was obtained from Ethics Advisory Group of
the International Union against Tuberculosis and Lung Disease
(The Union) and the ethics committee of the National Tubercu-
losis Institute, Bangalore. Administrative approvals were obtained
from the State authorities for conducting this study. A written
informed consent was taken from each participant and confiden-
tiality was assured as data collection formats were maintained
securely by programme staff and electronic databases contained
no personal identifiers.

Study Design

This was a cross sectional survey of Private Medical Practition-
ners (PMP) in Visakhapatnam district, Andhra Pradesh, South
India.

Setting

The district of Visakhapatnam (population 4.6 million) is
located in the State of Andhra Pradesh India with a total
population of ~83 million and 23 administrative districts. The
district has been consistently achieving the RNTCP objectives
with cure rate of more than 90% and new smear positive case
detection rate of more than 80%. Nearly 60% of population is
urban and 40% is rural of which 15% lives in tribal areas. This
district was purposefully chosen because of the large and diverse
target population of PMP’s (~4000), with ~70% practicing in the
urban areas and the long history of efforts to sensitize private
practitioners. The RNTCP was implemented in 1997 and on a
regular basis over the years, district and state health authorities
have conducted outreach and sensitization on TB for private
practitioners. In addition, since 2008 a Global Fund supported
project—implemented by the Indian Medical Association—has
conducted systematic sensitization and training of all qualified
allopathic providers about the RNTCP.

Study Population and Study Period

The study was conducted during December 2010 to July
2011. The study population included all PMPs with a medical
degree from any recognized system of medicine (Modern medicine
(allopathy), Ayurveda, Unani, Siddha and Homeopathy). All
PMPs with private practice irrespective of their association with
the government health services were included in the study. The
‘master list’ of PMPs was generated from a line list of enrolled
doctors from the IMA directory, the list of all PMPs maintained by
the programme and a list of practitioners from the Association
of AYUSH (Ayurveda, Unani, Siddha, and Homeopathy). This
master list was reviewed for duplicates and cleaned of those
practitioners who might not be in current practice (i.e. died,
moved out of district or were not in practice currently).

Sample Size and Sampling

The sample size was calculated as 296 based on the assumptions
of 20% expected frequency of ISTC adherence, with 5% precision
and 20% non-response among eligible participants. The required
number of PMPs was selected by systematic random sampling.
Prior appointment with each PMP was confirmed over the phone,
a participant information sheet was handed over to the PMP and
written consent for her/his participation was obtained before the
interview. If the practitioner was not available during the first visit,
at least two subsequent visits were made at intervals of one week
within a month. If a selected PMP was not available for interview
or a non-responder, the next consecutive PMP from the master list
was included in the sample.

Data Variables

Data collected include the system of medicine practiced by the
PMPs, duration of practice, the type of private practice (exclusive
private practice or combined with public practice), average
number of TB patients seen in a month and history of exposure
to RNTCP sensitization. The key outcome variables were the
number (proportion) of practitioners following the ISTC Stan-
dards of Diagnosis (Standards 1 to 6) and Treatment (Standards 7
to 15).

Data Collection

The semi-structured questionnaire was designed and pilot tested
on ten providers outside the sample population and then the
standardized questionnaire was developed. The questionnaire
consisted of vignettes and multiple choice close ended questions.
The vignettes presented a case history (narrative) to the
practitioner, who then provided his/her responses on diagnostic
treatment choices as the case may be. If the answer met the
expected standard response, it was rated to be correct and if it
deviated from the principles in the standards it was rated as
incorrect. Questions for Standards 3, 4, 5 for evaluation of
diagnostic practices and questions for standards 11, 12 for
evaluation of treatment practices were vignette based. A decision
aid was prepared to assist in clearly sorting out ‘compliant’ and
‘non compliant’ responses to the questions as summarized in Box 2
(Figure 2).

Eight medical officers working for the RNTCP were trained by
the investigators to impart interview skills and administer the semi-
structured questionnaire through personal interviews. These
interviewers underwent robust training at the district TB centre
for one day and it was ensured that the interviewers were well
conversant with all the topics and practiced at least three
interviews on non-study participants. Each interviewer was
assigned a geographical area with a definite number of private
practitioners to be interviewed.

Data Quality Assurance

In order to elicit optimum responses and minimize interviewer
bias, the interviewers were medical practitioners who were not
from the same location or related to the sampled private
practitioners. Interviewers scrutinized each other’s completed
Box 1: Diagnostic and treatment standards in International Standards of Tuberculosis Care

**Standard 1**
Practitioners must evaluate all persons with otherwise unexplained productive cough lasting two-three weeks for TB. Using a threshold of ≥2 increases the number of patients with suspected tuberculosis and maximizes chances of identifying cases [13, 14]

**Standard 2**
Sputum smear microscopy is the basis of diagnosis and two samples must be examined. Evidence shows that 12% of patients who are smear positive will be missed if two sputum samples are not examined.[15]

**Standard 3**
In all patients suspected of extra pulmonary TB the basic principle is to seek bacteriological confirmation of the diagnosis from appropriate specimens

**Standard 4**
Practitioners must subject sputum specimens for microbiological examination in persons with x-ray findings suggestive of TB since chest radiography alone is a sensitive but nonspecific test and results in over diagnosis or missed diagnosis.[16,17,18]

**Standard 5**
The diagnosis of sputum smear-negative pulmonary tuberculosis must follow a systematic approach considering the nonspecific nature of TB symptoms and complications with co morbidities such as HIV. It should be based on: at least two negative sputum smears; chest radiographic findings consistent with TB; and lack of response to a trial of broad-spectrum non fluoroquinolone antimicrobial agents

**Standard 6**
Pediatric TB diagnosis must be based on history, clinical examination, Tuberculin skin testing, bacteriological evaluation or relevant investigations for cervical lymph node TB. These are recommended approaches in Integrated Management of Childhood Illness (IMCI) program of WHO widely used in first-level facilities in low- and middle-income Countries[19]

**Standard 7**
Practitioners must assess treatment adherence of the patient and address poor adherence to ensure rapid and lasting cure since TB treatment is not a matter of individual health alone but is a matter of public health concern.

**Standard 8**
Practitioners must prescribe standardized first-line treatment regimen in appropriate dosages to all previously untreated TB cases using drugs of known bioavailability, as 2 month initial phase [isoniazid (INH), rifampicin (RIF), pyrazinamide (PZA) and ethambutol (EMB)] and 2 month continuation phase( RIF and INH). Fixed dose combinations (FDC) are recommended. [20-22, 23]

**Standard 9**
Practitioners must adopt patient centered approaches such as DOTS or use treatment support systems and enablers to foster adherence. It is well established that incomplete and irregular treatment fuels drug resistance in TB. Interventions other than DOT have also shown promise.[24,25-27]. Individualized treatment support measures to suit unique patient needs must be devised.[24,28,29]

**Standard 10**
Response to treatment must be monitored by sputum smear microscopy or culture in pulmonary TB as radiographic or clinical assessments are unreliable [30]. In extra pulmonary TB and in children however, clinical examination may be appropriate.

**Standard 11**
Practitioners must suspect drug resistance and prescribe drug susceptibility testing (DST) to all previously treated TB patients, contacts of DR TB cases and those who remain sputum positive after 3 months of initial treatment [31]. Early suspicions of resistance and confirmation by DST cut the chain of DR TB transmission.

**Standard 12**
Standardized or individualized treatment regimens for drug resistant TB must be prescribed based on DST results with at least 4 drugs and a minimum duration of 18-24 months beyond culture conversion. Standardized treatment regimens are based on representative drug resistance surveillance data or on the history of drug usage in the country and therefore must be strictly adhered to [31].

**Standard 13**
Practitioners must maintain records of treatment and monitoring of all patients under treatment. This ensures high standard and continuity of care, while allowing for individualized follow up of patients.
questionnaire before data entry. All the data collection forms were checked for completeness and consistency by the principal investigator and corrections were made.

Data Handling and Analysis

Double data entry was done in a pre-designed format of Epi Info Version 3.5.1 independently by two data entry operators. Both the data bases were compared and discrepancies were resolved by referring to the original data collection formats. PMPs were classified into those following ISTC or not based on whether they followed three selected and core ISTC standards (use of cough for 2 weeks for identifying Pulmonary TB suspects; sputum microscopy for diagnosing Pulmonary TB; use of the 6–8 months fixed dose combination (FDC) regimen for treating TB). Any PMP adhering to all three standards was classified as “compliant with ISTC” while those only adhering to 2 or less were classified as “non-compliant”. All questions in the questionnaire were not mandatory considering the varied nature of practices among the PMPs. There was an option of no response in the questionnaire. For the purpose of our analysis a PMP was considered for analysis only for the standards he responded to. All analysis was done using Epi Info analysis software. Proportions were compared using frequency distributions and the chi-squared test. Relative risks and 95% confidence intervals were derived, and a ‘p’ value of less than or equal to 0.05 was considered as statistically significant.

Results

Of a total number of 3,956 PMPs in the district, 296 were randomly selected for the study, of whom 201 (68%) were assessed for diagnostic and treatment practices against ISTC (Figure 3). The mean age of PMPs was 35 years and 154 (75%) were male. Other characteristics of the PMPs were as follows: 84% practiced allopathic medicine and had a bachelor’s degree (MBBS); 82% had been in medical practice for 10 years or longer, with the majority solely in private practice; 81% had treated 20 or fewer TB patients in the previous year, and 43% had been sensitized in RNTCP guidelines. There were 18 PMPs from the Medical colleges. All of them were sensitized in RNTCP; 12 of them were compliant with Standard 1, 10 with Standard 2, 7 followed Standard 8 and only 4 followed all the three standards together (not shown in the table).

Characteristics of responders and non-responders are compared in Table 1. Non responders were similar to responders by age, sex and qualification.

The number and proportion of PMPs following ISTC standards for diagnosis are shown in Table 2. The number of responders considered for analysis against each standard changes based on whether or not a response was recorded against that question. Two thirds of PMPs followed standards for suspecting pulmonary TB based on a cough of 2 weeks or more but fewer than 45% adopted sputum smear examination as the standard diagnostic practice. About 50% of PMPs followed the other ISTC diagnostic standards, with the exception of pediatric diagnostic approaches where the proportion was higher at 77%. Only 11 (6%) of PMPs followed all 6 diagnostic standards together.

The number and proportion of PMPs following ISTC standards for treatment are shown in Table 3. Less than 40% of PMPs prescribed standard TB treatment regimens, practiced directly observed treatment (DOT), prescribed culture and drug susceptibility testing or appropriate treatment for drug-resistant TB. Adoption of methods to ensure treatment adherence and the follow up of cases with sputum smear microscopy was higher at about 85%. Only 27% maintained patient clinical records. Only one PMP followed all 7 treatment standards altogether.

There were 28 (14%) PMPs who were compliant with the 3 selected core ISTC standards. Characteristics related to compliance with each of these standards and all 3 ISTC standards together are shown in Table 4. Higher levels of compliance with all three standards were observed among those practitioners practicing AYUSH, those who saw more than 20 TB patients in the previous year and those who were sensitized to RNTCP guidelines.

Discussion

This is the first study in India on a representative sample of qualified private practitioners which has evaluated diagnostic and treatment practices for tuberculosis, relative to international standards of care. Previous studies on PMPs have been conducted in India [4,9–12] but none of them have assessed adherence to ISTC-recommended professional practices. Compliance to ISTC standards was quite poor overall; only 6% of PMPs followed all 6 diagnostic standards together and only <1% of PMP followed all seven treatment standards together. Even using just the core three standards (i.e. cough for PTB suspects, referral for sputum smear microscopy examination, and treatment with the standard 6-month regimen) less than 15% of PMPs followed the three standards together. These findings suggest that the TB diagnosis and treatment practices uncommonly reach even the most basic standards of TB care.

Our data provided several findings that warrant closer examination. First, doctors with qualification from alternate systems of medicine (i.e. AYUSH doctors) surprisingly performed better than those with basic medical and specialist degrees. We speculate that diagnostic and treatment standards may be more important to providers with less extensive training in tuberculosis, hence adherence was higher. This group constituted 15% of the sample of providers in our survey. Existing interventions to engage the private sector such as the IMA-RNTCP project, systematically neglect AYUSH practitioners; our data thus suggest that AYUSH providers are important.

Second, compliance to the two important standards of diagnosis was only 34%, meaning only few rightly suspected TB and prescribed sputum microscopy for diagnosis of TB as their first choice. Only 47% diagnosed TB based on both sputum microbiological examination and X-ray. This indicates the over reliance on other investigations like ESR and other serological tests in the private sector [32]. It could be due to the tendency of practitioners to adopt investigations that give immediate results and pressure on them to provide faster results to their clients. Vigorous efforts should be made by the district to disseminate information to the practitioners on the availability of newer standard diagnostics to help change their prescribing practices [33,34]. Strategies adopted by private drug or diagnostic companies to influence and market their products like regular visits and attractive incentives to supporting practitioners may work well for the programme and may be piloted in a few districts. Private labs that already offer these facilities can be identified, accredited and encouraged to participate.
### Box 2: Decision aid for analysis

| Standards/Question type | Question | Compliant Response |
|-------------------------|----------|--------------------|
| **Diagnostic Standards** |          |                    |
| Standard 1 / Close ended multiple choice | Duration of cough | More than 2 weeks of cough |
| Standard 2 / Close ended multiple choice | Investigations to diagnose TB | Sputum smear microscopy with two sputum samples as the basis of diagnosis |
| Standard 3 / vignette | Action taken to diagnose a given EP TB case | Bacteriological confirmation of the diagnosis from appropriate specimens |
| Standard 4 / vignette | Course of action to diagnose TB in a given case | Prescribe both sputum microscopy and radiological examination; not radiological examination alone |
| Standard 5 / vignette | Course of action to diagnose TB in a given case | Prescribe sputum microscopy radiological examination and trial antibiotics (non fluoroquinolone) to diagnose smear negative pulmonary TB |
| Standard 6 | Investigations to diagnose TB in a child | Pediatric TB diagnosis based on at least 3 of 5 recommended approaches |
| **Treatment Standards** |          |                    |
| Standard 7 / Close ended multiple choice | Methods to ensure patient follows prescribed treatment | Any method to ensure treatment adherence |
| Standard 8 / Close ended multiple choice | Mention drugs, dosage, IP/CP, duration, intermittent/daily. | Correct drugs, dosage, duration and frequency of INH, RIF, EMB and PZA only (could be FDC, 6 months, IP & CP Phase, daily regimen). No other antimicrobials. |
| Standard 9 / Close ended multiple choice | Methods to oversee drug intake | Follow DOT or other incentives/enablers |
| Standard 10 / Close ended multiple choice | Methods for follow up of patients on treatment | Monitoring by sputum smear microscopy/culture in pulmonary TB and clinical/radiological examination in extra pulmonary TB |
| Standard 11 (vignette) | Course of action in a previously treated TB case | Suspect drug resistance and prescribe DST to previously treated TB cases |
| Standard 12 (vignette) | Treatment regimen in a confirmed drug resistant TB case | Standardized treatment regimen for drug resistant TB case. |
| Standard 13 / Close ended multiple choice | Methods to record details of treatment and follow up | Maintain some records of patients being treated |

**Figure 2. Box 2. Decision aid for analysis.** This is a decision aid for the purpose of analysis of data; the type of question asked in the questionnaire, subject of the question and the responses which should be considered as compliant against each diagnostic and treatment standard are summarized.

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Third, it was noted that the PMPs addressed poor adherence to treatment by methods like ‘intensive counseling’, ‘follow up by phone calls’ and also ‘periodic check ups’. However, in response to question addressing standard 9, very few observed any means of supervised treatment. This is encouraging compared to earlier studies [9] and is a potential area to introduce newer methods of ensuring adherence. Studies have shown that attitude of health care staff is very important in determining treatment adherence [35] and most PMPs would be looking for means to build rapport with their patients. Directly Observed Treatment (DOT) can be advocated as the preferred method; however PMPs who can document and report treatment adherence by other means should also be supported.

Fourth, only one-third prescribed the correct treatment regimen for a new case of Tuberculosis with no previous history of TB treatment. Two third prescribed a large variety of different prescriptions in terms of drugs, dosage and duration. Particularly disturbing was the finding that more than 50% prescribed second line anti TB drugs like fluoroquinolones, as trial antibiotics to initial smear negative cases, a practice specifically recommended against in ISTC and any TB treatment guidelines. These findings are reminiscent of a recent report from Mumbai where a small convenience sample of practitioners reported use of more than 80 different prescriptions [36]. Poor TB treatment practices are well known to increase the risk of the development of anti-TB drug resistance. The high prevalence of PMPs reporting treatment

IMA = Indian Medical Association; RNTCP = Revised National TB Control Programme of India; AYUSH = Ayurveda, Unani, Siddha, Homeopathy; TB = tuberculosis

Figure 3. Selection of Private Practitioners (study participants) in Visakhapatnam, Andhra Pradesh. A master list of 3956 private practitioners was prepared from the year 2010 list of IMA*, RNTCP*** practitioners and AYUSH**. Of these 877 were excluded due to death, 195 relocated out of district, 164 non-practicing status and 486 were duplicate entries. Of the remaining 3079 practitioners, a random sample of 296 was contacted for interview. Of those contacted, 95 (32%) were non-responders, 23 did not consent for the study, 33 not reached after 3 attempts and 39 reported seeing zero TB**** patients in one year. So, Private Practitioners interviewed for compliance with TB diagnostic and treatment practices were N = 201 (68%). IMA* = Indian Medical Association; RNTCP** = Revised National TB Control Programme of India; AYUSH*** = Ayurveda, Unani, Siddha, Homeopathy; TB**** = tuberculosis.

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practices not aligned with the standards of TB treatment warrants considerable alarm.

Very few PMPs maintained any record of the patients they treated consistent with findings from earlier studies [37]. Those that responded favorably could only show some documents recording the date of starting treatment and the follow up investigations advised. Programme must devise easy methods to encourage reporting and recording of these cases. This will provide an estimate of how many cases are actually treated under the private sector.

Practitioners vary in their levels of competence and this also varies between practitioners from public and private sector [38,39]. Measure of competency is a function of their compliance to technical as well as quality of care standards. Evidence from literature reveals that PMPs compared to public sector exhibit serious lapses in complying with prescribed technical standards of health care [40]. On the other hand, there is evidence that elements of quality of care such as geographical accessibility, shorter waiting periods, flexible hours, confidentiality, availability of staff, belief in values of relationships are reasons why patients seek health care from PMPs in preference to public sector [41]. Both technical standards and quality of care aspects are critical for TB control. This study prompts further research to study quality of care issues among PMPs in management of TB cases.

Limitations of the Study
In this cross sectional, questionnaire-based study, only 68% of selected candidates were interviewed and hence a response bias could have been introduced. However, comparison of baseline characteristics among non-responders and responders shows no difference in the two groups by age, sex and qualification. This is reassuring and suggests that effect of response bias on the overall results might have been minimal. Our sampling frame included only qualified providers and hence the findings cannot be generalized to the vast number of non-qualified health care practitioners not aligned with the standards of TB treatment warrants considerable alarm.

Table 1. Characteristics of responders and non-responders among private practitioners in Visakhapatnam, Andhra Pradesh.

| Characteristics | Responders N (%) | Non responders N (%) | Total | P value |
|-----------------|------------------|----------------------|-------|---------|
| Total           | 201              | 95                   | 296   |         |
| Age (years)     |                  |                      |       |         |
| 20–40           | 65 (32.3)        | 28 (29.4)            | 93    |         |
| 41–60           | 91 (45.2)        | 47 (49.4)            | 138   | 0.53    |
| >61             | 45 (22.4)        | 20 (21.1)            | 65    | 0.92    |
| Gender          |                  |                      |       |         |
| Male            | 154 (76.6)       | 69 (72.6)            | 223   |         |
| Female          | 47 (23.4)        | 26 (27.4)            | 73    | 0.46    |
| Total           | 179              | 95                   | 274   |         |
| Qualification   |                  |                      |       |         |
| AYUSH           | 27 (13.4)        | 11 (11.6)            | 38    |         |
| Modern medicine | 152 (86.6)       | 84 (88.4)            | 236   | 0.43    |

Responders = those who were administered the questionnaire, non responders = those who were not administered the questionnaire, AYUSH = Ayurveda, Unani, Siddha, Homeopathy, P value ≤0.05 = significant.
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Table 2. Private Practitioners adhering to ISTC diagnostic practices in Visakhapatnam, Andhra Pradesh.

| Diagnostic Practices | Total number responding to the question | Number (%) adhering to ISTC standards |
|----------------------|----------------------------------------|--------------------------------------|
| Standard 1           | 201                                    | 137 (68)                             |
| Cough of 2–3 weeks to suspect TB |                                         |                                      |
| Standard 2           | 198                                    | 87 (44)                              |
| Two sample Sputum smear examination for diagnosis of Pulmonary TB |                                         |                                      |
| Standard 3           | 176                                    | 93 (53)                              |
| Extra Pulmonary TB diagnosis based on appropriate investigations |                                         |                                      |
| Standard 4           | 182                                    | 85 (47)                              |
| Sputum microbiological examination in those with radiological findings suggestive of TB |                                         |                                      |
| Standard 5           | 155                                    | 75 (48)                              |
| Diagnose sputum smear-negative pulmonary TB based on both sputum microscopy & X-ray |                                         |                                      |
| Use of the right trial antibiotic* | 161                                    | 85 (53)                              |
| Standard 6           | 188                                    | 144 (77)                             |
| Diagnose Pediatric TB based on at least 3 of 5 recommended approaches ** |                                         |                                      |
| Standard 1 and 2 together | 201                                    | 68 (34)                              |
| Standard 3 and 4 together | 192                                    | 42 (22)                              |
| Standard 5 and 6 together | 197                                    | 56 (28)                              |
| Standards 1 to 6 altogether | 201                                    | 11 (6)                               |

*(International Standards of TB Care). TB = tuberculosis.
*Response to what antibiotic was used as trial antibiotic. 85 (53%) used non-fluoroquinolones.
**5 approaches included history, clinical examination, Tuberculin skin testing, bacteriological evaluation or relevant investigations to diagnose e.g. cervical lymph node TB.
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Table 3. Private Practitioners adhering to ISTC* treatment practices in Visakhapatnam, Andhra Pradesh.

| Treatment Practices                                                                 | Total number responding to the question | Number (%) adhering to ISTC standards |
|-------------------------------------------------------------------------------------|----------------------------------------|---------------------------------------|
| **Standard 7**                                                                        |                                        |                                       |
| Adopt methods to ensure adherence to treatment                                        | 188                                    | 159 (85)                              |
| **Standard 8**                                                                        |                                        |                                       |
| Prescribe standard TB treatment regimen 2HRZE and 4RH (daily and thrice weekly) in FDC| 177                                    | 61 (35)                               |
| **Standard 9**                                                                        |                                        |                                       |
| Practice DOT or foster adherence with treatment supporter or other enablers           | 195                                    | 40 (21)                               |
| **Standard 10**                                                                       |                                        |                                       |
| Follow up cases with sputum microscopy                                                | 187                                    | 160 (85)                              |
| **Standard 11**                                                                       |                                        |                                       |
| Prescribe culture and drug susceptibility testing for previously treated TB cases      | 151                                    | 59 (39)                               |
| **Standard 12**                                                                       |                                        |                                       |
| For diagnosed DR TB, prescribe standardized regimen, or individualized TB treatment regimen based on availability of drug susceptibility testing | 97                                     | 37 (38)                               |
| **Maintain the patient clinical record**                                             | 165                                    | 44 (27)                               |
| **Standard 7 and 8**                                                                  |                                        |                                       |
|                                                                                  | 191                                    | 52 (27)                               |
| **Standard 9 and 10**                                                                 |                                        |                                       |
|                                                                                  | 201                                    | 16 (8)                                |
| **Standard 11 and 12**                                                                |                                        |                                       |
|                                                                                  | 200                                    | 23 (12)                               |
| **All treatment standards (7–13)**                                                   |                                        |                                       |
|                                                                                  | 201                                    | 1 (1)                                 |

*International Standards of TB Care). H = INH, R = Rifampicin, Z = Pyrazinamide, E = Ethambutol, FDC = Fixed Drug Combinations, DOT- Directly observed treatment; TB = Tuberculosis; DR TB = Drug resistant TB.
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Table 4. Characteristics of private practitioners in relation to compliance with 3 selected core ISTC* in Visakhapatnam, AP.

| Characteristic                           | Standard 1 | Standard 2 | Standard 8 | Standard 1+2+8 | RR (95% CI) |
|------------------------------------------|------------|------------|------------|----------------|-------------|
| **Gender:**                              |            |            |            |                |             |
| Male (n = 154)                           | 106 (70)   | 67 (45)    | 44 (32)    | 23 (15)        | 1.2 (0.5–3.1)|
| Female (n = 47)                          | 24 (57)    | 17 (41)    | 16 (47)    | 5 (12)         |             |
| **Qualification:**                       |            |            |            |                |             |
| AYUSH (n = 27)                           | 22 (82)    | 18 (69)    | 9 (35)     | 8 (30)         | 2.4 (1.2–4.9)|
| Modern Medicine (n = 152)                | 96 (63)    | 63 (42)    | 47 (35)    | 19 (13)        |             |
| **Years in Practice:**                  |            |            |            |                |             |
| Less than 10 (n = 32)                    | 22 (69)    | 20 (65)    | 13 (46)    | 7 (22)         | 1.9 (0.8–4.3)|
| 10 or more (n = 153)                    | 102 (67)   | 56 (37)    | 44 (33)    | 17 (11)        |             |
| **Type of Practice:**                   |            |            |            |                |             |
| Private and Government (n = 71)          | 46 (65)    | 35 (50)    | 27 (44)    | 14 (20)        | 1.7 (0.8–3.7)|
| Private only (n = 100)                   | 68 (68)    | 37 (38)    | 29 (32)    | 11 (11)        |             |
| **TB patients seen last year:**          |            |            |            |                |             |
| 21 and above (n = 53)                    | 40 (76)    | 31 (56)    | 21 (45)    | 12 (22)        | 2.1 (1.1–4.1)|
| 20 or less (n = 148)                     | 97 (66)    | 56 (39)    | 40 (30)    | 16 (11)        |             |
| **Sensitized to RNTCP guidelines:**     |            |            |            |                |             |
| Sensitized (n = 87)                      | 67 (77)    | 53 (61)    | 36 (43)    | 20 (23)        | 3.2 (1.5–7.0)|
| Not sensitized (n = 113)                 | 69 (61)    | 34 (31)    | 25 (27)    | 8 (7)          |             |

*International Standards of TB Care). Core ISTC Standards: Standard 1 = Using 2–3 weeks cough for identification of Pulmonary TB suspects; Standard 2 = Using sputum smear microscopy examination; and Standard 6 = Treatment with the standard 6-month regimen; TB = Tuberculosis; AYUSH = Ayurveda, Unani, Siddha, Homeopathy; RNTCP = Revised National TB Control Programme; RR = Relative Risk has been calculated for standard 1+2+8; CI = Confidence Interval.
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providers in the district. Most importantly, data on TB diagnostic and treatment practices were as reported by the PMPs and may not be exactly the same as what they actually practice. Assessments in quality of care should seek to include empric data on actual treatment practices, which may differ in important ways from reported practices. Furthermore, other studies have suggested that TB patients shop for effective treatment and sometimes later shift treatment practices on patient outcomes is unknown but is beyond the scope of this study.

Conclusion

Our study found that compliance to internationally recommended standards of TB diagnosis and treatment was uncommon among the PMPs in Visakhapatnam, India. As India plans towards universal access to TB care in the next five year plan (2012–17), programme needs to prioritize the involvement of Private sector to its fullest with unique and innovative strategies.

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Author Contributions

Conceived and designed the experiments: SA JJ SBN AMK PKD. Performed the experiments: SA JJ SKB. Analyzed the data: AMK SA JJ SBN. Contributed reagents/materials/analysis tools: SA JJ AMK SBN ADH SAN. Wrote the paper: SA SBN AK. Provided comments and input to revise manuscript: SBN JJ SRMS AMK SS PKD ADH SAN.

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