Quality of tuberculosis care in India:
Assessing diagnostic and treatment practices of health care providers

Srinath Satyanarayana, MD

Department of Epidemiology, Biostatistics, and Occupational Health,

Faculty of Medicine

McGill University, Montreal,

Quebec, Canada

August, 2016

A thesis to be submitted to McGill University in partial fulfillment of the requirements of the degree of Doctor of Philosophy (PhD)

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Abstract

Introduction

Globally, an estimated 9.6 million people get tuberculosis (TB) disease every year. Nearly 80% of TB cases occur in 22 high burden countries. India, with an estimated annual incidence of 2.2 million cases and 0.25 million deaths, is the highest TB burden country in the world. The current TB control strategy mainly focuses on early diagnosis and appropriate treatment in the public health sector. The Indian health care system is quite complex, poorly regulated, and with a diversity of care providers (qualified, unqualified, pharmacies etc.,) providing medical care to the patients. The overall goal of my PhD thesis is to describe using suitable methods what health care providers 'do' when faced with persons with TB symptoms or disease in routine practice and how that might impact TB control in India. 'Quality' in the context of my PhD thesis is defined as adherence to International Standards of TB Care (ISTC) or Standards of TB Care in India (STCI) by health care providers. My thesis is manuscript-based and includes the following three studies (two of which are published):

Manuscript 1: Quality of TB care in India: a systematic review (Satyanarayana S et al. Int J Tuberc Lung Dis 2015)

We have systematically reviewed studies that provided information on health care providers' knowledge and practices related to TB diagnosis and treatment and benchmarked them against 2nd edition of International Standards of Tuberculosis Care. Studies may have included one or more types of health care providers—qualified, unqualified, those working in public, private sectors, etc., In addition, we also described the strengths and limitations of these studies.

A total of 47 articles met inclusion criteria; 35 were questionnaire surveys and 12 used chart abstraction. None assessed actual practice using standardized patients (SPs) and heterogeneity in the findings precluded meta-analysis. Ten of 22 studies evaluating provider knowledge about using a sputum smear for diagnosis found that less than half of providers had correct knowledge; 3 of 4 studies assessing self-reported practices by providers found that less than one-fourth reported ordering smears for chest symptomatics. In 11 of 14 studies that assessed treatment, less than one-third of providers knew the standard treatment regimen for drug-susceptible TB. Adherence to standards in practice was generally lower than correct knowledge of those standards. Eleven studies

that included both public and private sector providers found relatively higher levels of appropriate knowledge or practice in the public sector.

We concluded that available studies provided a reasonable picture of provider knowledge (i.e., what they know) and, to some extent, providers' self-reported behaviour (i.e., what they say they do). However, these studies did not provide any information about the behaviour of providers in real-life (i.e., 'what they actually do'). We therefore recommended developing study methods that help in capturing practices in real life situations and monitor trends over time as these directly affect patient outcomes.

Therefore, in line with the recommendations of the systematic review, for the next two studies, we used data from an on-going project in Delhi, Mumbai and Patna cities of India in which SPs are being used to assess quality of TB care by private health care providers. In general, SPs are normal (non-diseased) persons who are trained to act as though they have the medical condition (e.g, TB disease) and after training, they present themselves to health care providers unannounced and seek medical care. After the clinical interaction, they are debriefed using a standard questionnaire (within an hour) regarding what care they received from the health care providers. The SP methodology thus helps in controlling/adjusting for the case mix (spectrum of patients based on their disease characteristics), and patient mix (spectrum of patients based on their demographic and other socio-economic characteristics) enabling researchers to obtain a measure of practice in the real world conditions that is uncontaminated by Hawthorne effects or recall bias, and a measure of care that can be comparable across all health care providers.

Manuscript 2: Use of standardised patients to assess antibiotic dispensing for tuberculosis by pharmacies in urban India: a cross-sectional study (Satyanarayana S et al. Lancet Infect Dis 2016)

In India, private retail pharmacies are an important source of medical care and it was hypothesized that these pharmacies dispense medicines (including antibiotics and steroids) without prescriptions, leading to delays in TB diagnosis and treatment. In a cross-sectional study, we assessed how pharmacies managed SPs presenting with classic symptoms of pulmonary tuberculosis (Case 1) and presenting with confirmed TB with a positive sputum smear report (Case 2). In Delhi, Mumbai and Patna, 622 pharmacies were sampled. SPs presented each case once to every pharmacy between

April 2014 and November 2015. 'Ideal management' for both cases was defined a priori as referral to a health care provider without dispensing antibiotics and/or steroids.

The results showed that 'ideal management' was seen in 13% [95% CI: 11–16] of the Case 1 and 62% [95% CI: 58–66] of the Case 2 interactions. Antibiotic use was significantly lower in Case 2 [16%; 95% CI: 13–19] than in Case 1 [37%; 95% CI: 33–41]. Anti-TB drugs were never dispensed in any city. The differences in antibiotic and/or steroid use and number of medicines dispensed between Case 1 and Case 2 were almost entirely attributable to the difference in referral behavior. We concluded that a minority of urban Indian pharmacies correctly managed patients with presumed TB, but a majority correctly managed a case of confirmed TB and lack of a confirmed diagnosis was a key driver of antibiotic misuse and could inform antimicrobial stewardship interventions.

Manuscript 3: Gender differences in the quality of tuberculosis care in India: a standardized patient study

In India, the ratio of female to male TB patients notified is 1:2 and female TB patients are more likely to be diagnosed late when compared to male patients. We hypothesized that health care providers do not contribute to these observed gender differences in notification rates and delays in diagnosis (i.e., there are no differences in how health care providers managed male versus female TB patients). Therefore, in this study, we assessed the gender differences in diagnostic and treatment practices of health care providers for SPs presenting with pulmonary TB symptoms and disease.

Male and female SPs depicting four different TB case scenarios visited a representative sample of 1346 health care providers in the private sector (allopathic, AYUSH providers and un-qualified providers) in Delhi, Mumbai and Patna. The correctness of case management was assessed using the Standards of TB care in India as a benchmark and we used mixed effects regression methods to estimate gender differences. On an average, each health care provider was visited by two standardized patients of either sex depicting two of the four case scenarios. The SPs completed 3007 visits to providers in 1346 health facilities in the three cities; 836 (28%) visits were by female SPs.

Overall, across all sites, providers, and cases, 35% [95% CI: 33-38] of the male SPs and 39% [95% CI: 35-42] of the female SPs were correctly managed. There was no statistically significant

difference in the odds of correct management between male SPs and female SPs after adjusting for the four types of cases, provider qualification, three cities, and accounting for individual provider effects [adj OR 1.08 (95% CI: 0.87-1.34)]. Allopathic (MBBS) providers were more likely to manage cases correctly [52% (95% CI; 49-56)], when compared to providers of alternative systems of medicine [18%; 95% CI: 16-20)]. However, allopathic (MBBS) providers were more likely to correctly manage male SPs than female SPs [adj OR 1.51 times; 95% CI: 1.08-2.07]. With the exception of this finding, stratified analysis across the three cities and across the four types of cases did not show any statistically significant gender differences in quality of care for male versus female standardized patients. We concluded that low levels of correct management for both male and female SPs should be a cause for major concern, and the study results do not indicate major gender differences by health care providers.

In conclusion, in this thesis, I highlighted that the quality TB care in India is sub-optimal. I describe the strengths and limitations of the methods that have been used previously to study health care providers TB management practices in India, how standardized patients can be used to overcome these limitations, strengths and weakness of the standardized patient methodology, as well as described some key aspects on how to analyse and interpret the data from SP studies. Finally, I have made some suggestions on how to use this method to improve quality of TB care in India.

Résumé

Introduction

On estime que 9,6 millions de personnes contractent la tuberculose (TB) chaque année dans le monde. Près de 80% des cas de TB se retrouvent dans 22 pays à forte prévalence. Avec une incidence annuelle de 2.2 millions de cas et 0.25 million de morts, l'Inde est le pays dont la prévalence de TB est la plus élevée dans le monde. Dans le secteur de la santé publique, la stratégie de contrôle actuelle de la TB se concentre principalement sur un diagnostic précoce et un traitement adéquat. Le système de santé indien est très complexe, peu réglementé, et inclut un large éventail de fournisseurs (publiques et privés, ainsi que qualifiés et non qualifiés) offrant les soins médicaux aux patients. L'objectif principal de ma thèse de doctorat est de décrire, en utilisant les méthodes appropriées, ce que les fournisseurs de soins de santé « font » lorsqu'ils rencontrent des patients atteints de la tuberculose dans leur pratique normale, et comment cela pourrait avoir un impact sur le contrôle de la TB en Inde. Dans le contexte de ma thèse de doctorat, la « qualité » est définie comme l'adhérence par les fournisseurs de soins de santé aux normes internationales pour la TB ISTC (*International Standards of TB Care*), ou aux normes indiennes pour la TB STCI (*Standards of TB Care in India*). Ma thèse par articles comprend trois études (dont deux sont publiées):

Article 1: Qualité des soins pour la TB en Inde: une revue systématique [Satyanarayana S et al. Int J Tuberc Lung Dis 2015]

Nous avons complété une revue systématique des études qui fournissaient des informations sur le niveau de connaissances et les pratiques de fournisseurs de soins de santé, en lien avec le diagnostic et le traitement de la TB, en utilisant la 2^{ième} édition des normes internationales pour la TB (ISTC) comme point de référence. Nous avons aussi détaillé les forces et faiblesses de ces études.

Un total de 47 articles respectaient les critères d'inclusion; 35 étaient des sondages par questionnaire et 12 étaient basés sur l'extraction de données de dossiers médicaux. Aucun n'évaluait la pratique réelle à l'aide de patients standardisés (PSs), et l'hétérogénéité des résultats a empêché d'effectuer une méta-analyse. Dix des 22 études qui évaluaient les connaissances des

fournisseurs de soins de santé par rapport à l'utilisation de frottis de crachats pour diagnostiquer la TB ont révélé que moins de la moitié des fournisseurs possédaient les connaissances adéquates; 3 études sur 4 qui évaluaient les pratiques auto-déclarées des fournisseurs ont révélé que moins du quart avaient demandé des frottis pour les patients présentant des symptômes dans la région thoracique. Dans 11 des 14 études évaluant le traitement, moins du tiers des fournisseurs de soins de santé connaissaient le programme thérapeutique de base pour la TB pharmacosensible. Le respect des normes de pratique était généralement plus faible que le niveau de connaissance de ces normes. Onze études qui comprenaient des fournisseurs de soins de santé des secteurs public et privé ont révélé des niveaux de pratiques ou de connaissances appropriées relativement plus élevés dans le secteur public.

Nous avons conclu que les études disponibles offraient une représentation adéquate des connaissances des fournisseurs de soins de santé (i.e. ce qu'ils savaient) et, jusqu'à un certain point, de leur pratiques auto-déclarées (i.e. ce qu'ils disent faire). Toutefois, ces études n'offraient aucune information sur les pratiques des fournisseurs dans la vraie vie (i.e. ce qu'ils font réellement). Nous avons donc recommandé le développement de méthodes qui aideraient à évaluer les pratiques réelles, et à surveiller leur évolution dans le temps, étant donné leur impact direct sur les résultats pour les patients.

Étant donné les recommandations de cette revue systématique, pour les deux études suivantes, nous avons utilisé des données d'un projet en cours à Delhi, Mumbai et Patna en Inde, dans lesquelles des PSs étaient utilisés pour évaluer la qualité des soins pour la TB offerts par des fournisseurs de soins de santé privés. En général, les PSs sont des personnes normales (en santé) qui sont formées pour imiter une personne ayant une condition médicale spécifique (e.g. la TB). Après la formation, elles se présentent chez des fournisseurs, sans s'annoncer, afin de recevoir des soins médicaux. Après l'interaction clinique, elles effectuent un rapport de leur entretien à l'aide d'un questionnaire standardisé (dans l'heure suivant l'interaction) qui fait état des soins qu'elles ont reçus. La méthodologie à l'aide de PSs aide ainsi à contrôler/ajuster pour la variété de cas (éventail de patients selon les caractéristiques de leur maladie), et de patients (éventail de patients selon leurs caractéristiques démographiques et socioéconomiques), et permet aux chercheurs d'évaluer les pratiques dans le monde réel, non contaminée par les effets Hawthorne ou le biais de rappel, ainsi que les soins de façon comparable entre les différents fournisseurs.

Article 2: Utilisation de patients standardisés pour évaluer la prescription d'antibiotiques pour la tuberculose par des pharmacies en région urbaine de l'Inde: une étude de prévalence [Satyanarayana S et al. Lancet Infect Dis 2016]

En Inde, les pharmacies privées représentent une importante source de soins médicaux, et il a été suggéré que ces pharmacies vendaient des médicaments (incluant des antibiotiques et stéroïdes) sans prescription, menant à des délais dans le diagnostic et le traitement de la TB. Dans une étude de prévalence, nous avons évalué comment les pharmacies géraient les PSs ayant des symptômes classiques de TB pulmonaire (Cas 1) et une TB confirmée par un rapport de frottis de crachat positif (Cas 2). À Delhi, Mumbai et Patna, 622 pharmacies ont été échantillonnées. Les PSs ont présenté chaque cas, une fois à chaque pharmacie, entre avril 2014 et novembre 2015. La « gestion thérapeutique idéale » pour chaque cas a été défini a priori comme la référence du patient à un fournisseur de soins de santé sans offrir d'antibiotiques et/ou de stéroïdes.
Les résultats démontrent que la « gestion thérapeutique idéale » a été observée dans 13% [95% CI: 11–16] des interactions pour le Cas 1, et 62% [95% CI: 58–66] pour le Cas 2. L'utilisation d'antibiotiques était beaucoup moins élevée pour le Cas 2 [16%; 95% CI: 13–19] que pour le cas 1 [37%; 95% CI: 33–41]. Aucun médicament contre la TB n'a été fourni dans aucune des villes. Les différences entre l'utilisation et le nombre d'antibiotiques et/ou stéroïdes fournis entre les Cas 1 et 2 étaient presque totalement attribuables aux différences entre la référence, ou non, du patient à un fournisseur de soins de santé. Nous avons conclu qu'une minorité de pharmacies en région urbaine de l'Inde géraient correctement les patients avec une TB présumée, mais qu'une majorité géraient correctement ceux ayant une TB confirmée, et que l'absence d'un diagnostic confirmé était un élément clé de l'utilisation inapproprié d'antibiotiques et pouvait éclairer les interventions en gestion d'antimicrobiens.

Article 3: Différences entre les sexes dans la qualité des soins de santé en TB en Inde: une étude avec patients standardisés

En Inde, le ratio entre les cas de TB déclarés pour les femmes vs. hommes est de 1:2, et les femmes atteintes de la TB sont plus susceptibles d'être diagnostiquées tard de le processus, par rapport aux hommes. Nous avons formulé l'hypothèse que les fournisseurs de soins de santé ne contribuaient pas à ces différences entre les sexes, au niveau des taux de déclaration et des délais diagnostiques (i.e. il n'y a pas de différences entre la façon dont les fournisseurs gèrent leurs patients, hommes ou femmes). Ainsi, dans cette étude, nous avons évalué les différences de pratique entre les sexes au

niveau du diagnostic et du traitement chez les fournisseurs de soins de santé, à l'aide PSs présentant des symptômes de TB pulmonaire, ou la maladie elle-même.

Des PSs hommes et femmes présentant quatre scénarios de TB ont visité 1,346 fournisseurs de soins de santé à Delhi, Mumbai et Patna. L'exactitude de la gestion thérapeutique a été évaluée en utilisant comme référence les normes indiennes (STCI), et nous avons utilisé des méthodes de régression avec effets contrastés pour estimer les différences entre les sexes. En moyenne, chaque fournisseur de soins de santé a reçu la visite de 2 PSs (homme et/ou femme), présentant deux des quatre scénarios. Les PSs ont complété 3,007 visites chez 1,346 fournisseurs de soins de santé dans 3 villes; 836 (28%) visites ont été effectuées par des PSs femmes.

En général, parmi toues les sites, fournisseurs et cas, 35% [95% CI: 33-38] des PSs hommes et 39% [95% CI: 35-42] des PSs femmes ont été gérés correctement. Aucune différence statistiquement significative dans le taux de gestion thérapeutique adéquate entre les PSs hommes et femmes après ajustement pour les quatre scénarios, les qualifications des fournisseurs, les trois villes, et les effets individuels des fournisseurs [OR ajusté 1.08 (95% CI: 0.87-1.34)]. Il était plus probable que les fournisseurs allopathiques (MBBS) gèrent adéquatement les cas [52% (95% CI; 49-56)], par rapport aux fournisseurs de soins de santé alternatifs [18%; 95% CI: 16-20)]. Toutefois, il était plus probable que les fournisseurs allopathiques (MBBS) gèrent adéquatement les PSs homme que femmes [OR ajusté 1.51 fois; 95% CI: 1.08-2.07]. À l'exception de ce résultat, une analyse stratifiée à travers les trois villes et les quatre scénarios n'a pas démontrée de différence statistiquement significative entre la gestion thérapeutique des PSs de sexes différents, en termes de qualité de soins. Nous avons conclu que les faibles taux de gestion thérapeutique appropriée pour les PSs hommes et femmes étaient préoccupants, et que les résultats de l'étude n'indiquaient pas de différences majeures entre les sexes au niveau des fournisseurs de soins de santé.

En conlusion, dans cette thèse, j'ai mis en lumière les limitations des méthodes qui avaient été utilisées précédemment pour évaluer les pratiques des fournisseurs de soins de santé en matière de gestion de la TB en Inde, comment les patients standardisés pouvaient être utilisés pour surmonter ces limitations, les forces et faiblesses de la méthodologie utilisant les PSs. J'ai aussi décrit quelques aspects majeurs de l'analyse et l'interprétation de données issues d'une étude par PSs et finalement, j'ai effectué des recommandations sur la façon d'utiliser cette méthode afin d'améliorer la qualité des soins de TB en Inde.

Acknowledgements

In general, a journey through a Doctor of Philosophy (PhD) programme is arduous and exhausting. But my journey was interesting, inspiring and relatively effortless due to the timely support and guidance that I received from a lot of people. I take this opportunity to express my gratitude to each of them. First and foremost, I want to thank Dr Madhukar Pai, Dr Anthony D Harries, Dr Puneet Dewan and Dr Nevin Wilson for inspiring and encouraging me to get enrolled into the PhD programme at McGill.

After getting enrolled, Dr Madhu has been an exceptional supervisor and mentor for the last three years. Right on day-1, he gave me a clear idea about the path ahead, the milestones that I had to achieve, the challenges that I had to surmount to complete all the course work and dissertation. And throughout the last three years, his constant support and guidance helped me complete my journey as per the plan, on time and without any uncertainties.

I would like to thank both Dr Madhu and Dr Jishnu Das for providing me critical and constructive inputs that helped me develop a deeper understanding of the complexities involved in my thesis. I am also grateful to my other PhD supervisory committee members - Dr Paramita Saha Chaudhuri, Dr Dick Menzies and Dr Anthony D Harries - for sharing their expertise and insights on my thesis studies without which, it would not have been possible for me to have a comprehensive understanding of the fundamentals of this area of research.

Next, I want to extend my gratitude to my colleagues Ramnath Subbaraman, Ada Kwan and Ben Daniels for helping me in data collection, analysis, interpretation and preparation of the drafts of the manuscripts of my studies. I am also thankful to all the co-authors of the manuscripts of my thesis whose comments and inputs strengthened the content & clarity of the thoughts and ideas expressed in my thesis.

My special thanks to Caroline Vadnais for copy-editing some sections of my thesis, for the French translation of my thesis abstract and also for helping me deal with all the administrative & financial aspects/scholarships related to my PhD study in Canada. I also extend my thanks to all my teachers and classmates at McGill for insightful discussions which improved my understanding of principles of modern epidemiology. Further, I also want express my gratitude to all my teachers, friends, and colleagues in various schools, colleges and places of work over

the last 35 years, who taught me all that I know and made me what I am today. I thank Canadian Thoracic Society for the studentship and Center for Operational Research (The Union, Paris, France) for the fellowship support during my PhD programme.

Last but not the least, I am indebted to my family - wife Roopa, lovely daughters - Medhini and Nabha (who was born during the course of PhD), parents, sister & her family, and parents in-law for their unconditional love and patience. They inspired and motivated me to travel all the way across to Canada to pursue my dream of studying in one of the most prestigious universities of the world.

Thank you one and all.

Contribution of authors

As first author of all the manuscripts included in this thesis, I, along with my supervisor Dr. Madhukar Pai, my PhD supervisory committee and other co-authors are collectively responsible for developing the specific research questions addressed in each study, for identifying the study designs, methods and analytical techniques. My personal contributions to the studies described in my thesis are as follows:

Study 1: I have been involved in all stages starting from identifying the research questions, designing the study, collecting and analyzing the data, interpreting the results and writing the manuscript.

Studies 2 & 3: I have been involved in drafting the medical component of the SP case presentations, finalising the SP case scripts & exit questionnaires. I was involved in identifying the research questions, coding, analyzing, interpreting and drafting both the manuscripts. I have not been involved in operational planning and overseeing the implementation of these studies in the field (such as standardized patient recruitment, their training, scheduling their visits).

The individual author contribution for each manuscript of my thesis has been stated at the end of each manuscript.

Statement of originality

The three manuscripts that form the core of my thesis all include original scholarship and provide contributions to knowledge. **Study-1**: is a systematic review that provides an overview of the quality of TB care in India from studies on health providers' knowledge and practices. We have benchmarked their knowledge and practices against International standards of TB care. As such, this is the first such study to do so and provides a template that other high TB burden countries can follow. **Study-2:** It is the first study, to use standardized patients to assess how pharmacies manage patients with TB symptoms and TB disease in a low income high TB burden country. The unique methodological contributions of this study are a) the study design in which each pharmacy received two SPs –this helped us to show that the management of patients by pharmacies is dependent on the information that patients present, b) our description of the strengths and limitations of using SPs to study pharmacy practice and c) our recommendations on the potential uses of this method in public health. **Study-3:** This is the first study, to use SPs to provide an insight into whether health care providers differentially manage male and female patients with pulmonary TB. The uniqueness of this study was its design in which we used four different TB case scenarios of both genders to assess the differences in the quality of care by health care providers of different qualifications in three cities. We assessed gender differences in quality of care across multiple clinical aspects such as elicitation of essential clinical history, laboratory investigations, prescription of medicines such as antibiotics and steroids, assessed for unmeasured confounding and found that the quality of care was low irrespective of the SP gender. We feel that our methodology and results are an important contribution to the scientific and public health literature.

Manuscript of the study-1 has been published in the International Journal of TB and Lung Diseases and the manuscript of study-2 will be published in the Lancet Infectious Diseases (expected date: 24th Aug, 2016). We will be submitting third manuscript to an international peer reviewed journal shortly.

List of key abbreviations

adj OR	Adjusted Odds Ratio
AFB	Acid Fast Bacillus
AMR	Anti-microbial resistance
AYUSH	**Ay**urveda, **U**nani, **S**iddha and **H**omeopathy
DOT	Directly Observed Treatment
DR-TB	Drug Resistance Tuberculosis
FQ	Fluoroquinolone
HCF	Health care facilities
HCP	Health care providers
HIV	Human Immunodeficiency Virus
ISTC	International Standards of Tuberculosis Care
MBBS	Bachelor of Medicine, Bachelor of Surgery
MDR-TB	Multidrug Resistant TB
OR	Odds ratios
PTB	Pulmonary TB
RNTCP	Revised National Tuberculosis Control Programme
SE	Standard Error
SP	Standardized patients
STCI	Standards of Tuberculosis Care in India
TB	Tuberculosis
WHO	World Health Organisation
X-Ray	Radiograph

Chapter 1: Introduction

1.1 Background

Tuberculosis (TB) is an infectious bacterial disease caused by *Mycobacterium tuberculosis* which can affect any part of the body, but commonly affects the lungs (pulmonary TB). The disease spreads predominantly through airborne route when people with pulmonary TB expel bacteria by either coughing or sneezing. Once infected, the life time risk of developing the disease is 10-15%, and is higher in those with immune deficiencies; in others who do not develop the disease, the bacteria is either killed by the host's immune system or the infection remains quiescent, as latent TB infection.[1]

Worldwide, annually, an estimated 9.6 million people get TB disease and 1.5 million die from it. Twenty two low and middle income countries located predominantly in Asia and Sub-Saharan Africa, bear more than 80% of the global TB burden (Figure 1, page 17).[2,3] TB along with HIV is one of the leading causes of deaths worldwide.[4]

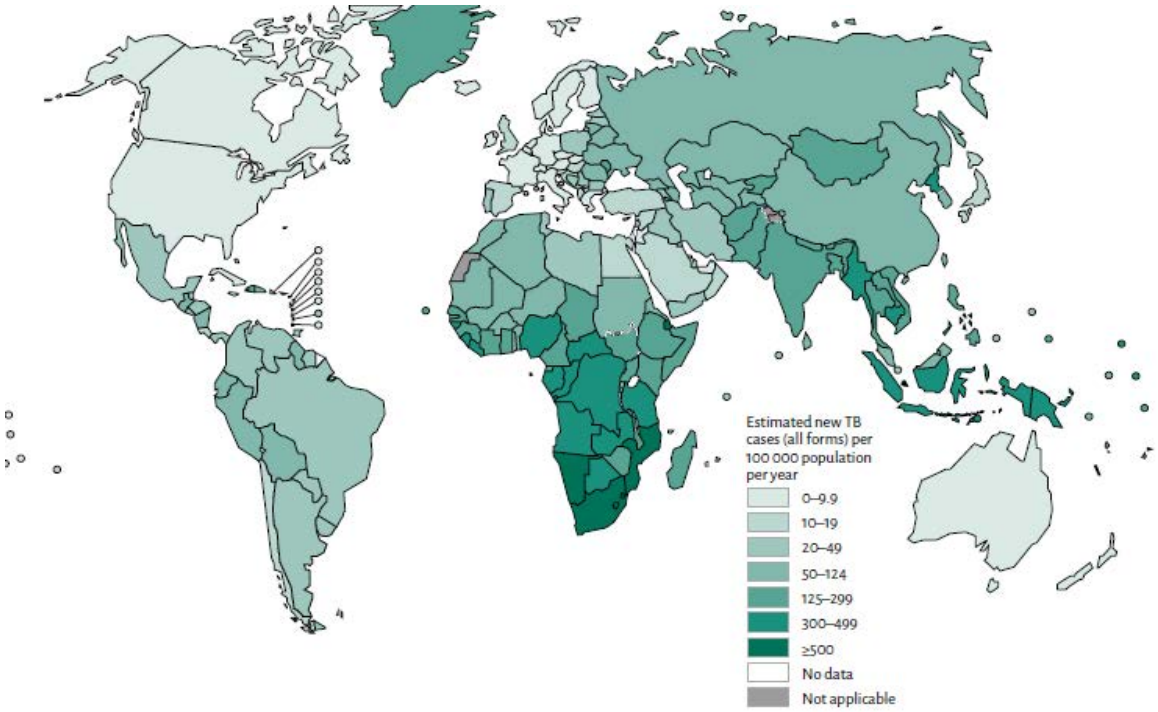

Figure 1: Estimated TB incidence rates (2014) [Source: Global TB Report, WHO, 2015]

Widespread adoption and implementation by the Governments of high TB burden countries of the World Health Organization (WHO) recommended Directly Observed Treatment Short-course (DOTS) strategy since early 1990s and later, the Stop TB strategy since 2006, has cured TB disease in millions of patients.[5] The global TB incidence rate since 2000 has declined by about 1.5% per year. Relative to 1990 levels, the global TB prevalence rate has declined by about 42% in 2014 and the mortality rate by 47% (Figure 2, page 18).[2] The TB related Millennium Development Goal target "to halt and begin to reverse the incidence of tuberculosis by 2015" has been achieved.[6] But the impact of these strategies on reducing TB transmission and incidence has been less than predicted [7] and the gains achieved so far are threatened by rising levels of drug resistant TB, largely due to inappropriate management of TB cases.[8] Given the enormity of the TB burden and based upon the lessons learnt in implementing the DOTS and the Stop TB strategies, the WHO has developed the new End TB strategy,[6] with the goal of ending the global TB epidemic by 2035.

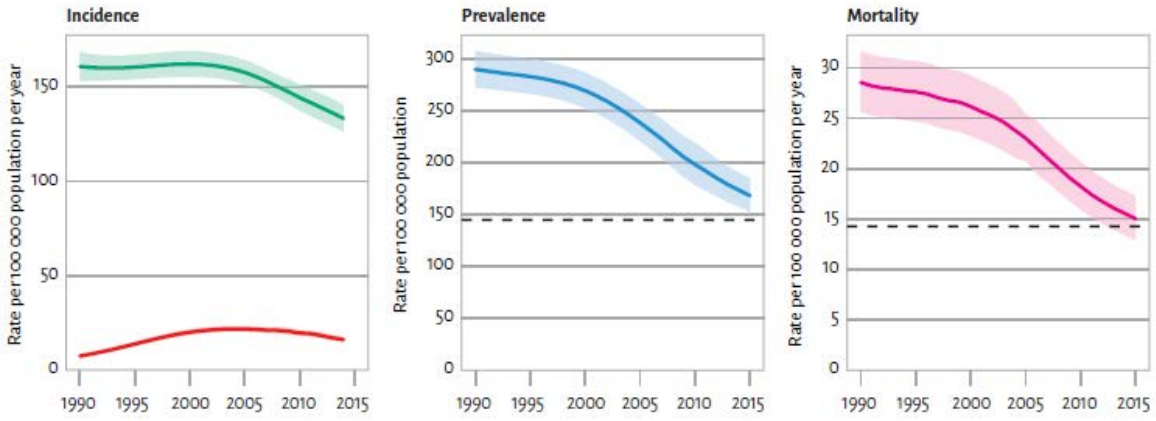

Figure 2: Global trends in estimated rates of TB incidence (1990-2014), and prevalence and mortality rates (1990–2015) [Source: Global TB Report, WHO, 2015]

Several social determinants and risk factors are impediments to TB control in high burden countries. The most common are: poverty, malnutrition, HIV, smoking, diabetes mellitus, alcoholism, indoor air pollution, the presence of large numbers of undiagnosed or poorly treated infectious pulmonary TB diseased persons in the community, overcrowding and weak health systems.[9] However, TB control efforts are primarily based on early diagnosis and treatment of patients with pulmonary TB disease. Chronic, productive cough is one of the cardinal symptoms of pulmonary TB disease, and therefore it is recommended that all individuals who have a productive cough of two weeks or more in high burden countries be evaluated for TB.[1,10]

Pulmonary TB is diagnosed based on clinical symptoms, microbiological tests on sputum specimens and chest radiology. Patients are categorised into various treatment groups based on the disease and drug resistance pattern, and are treated with drug regimens recommended by the WHO and the International Standards for TB Care (ISTC). In those without drug resistance, the treatment lasts 6-8 months and in those with drug resistance, the treatment duration can go up to 24 months.[1,10] Health care providers play a very important role in TB control by facilitating early diagnosis and optimal care to TB patients. Creating systems for integrated patient centred care is one of the key pillars of the global End-TB strategy.

Tuberculosis and India

With an estimated annual incidence of 2.2 million cases and 0.25 million deaths in the year 2014, India continues to be the highest TB burden country in the world. For controlling TB, the Government of India has been implementing the Revised National TB Control Programme (RNTCP) since 1997, by initially adopting the WHO recommended DOTS strategy and later the STOP-TB strategy. More than 13,000 microscopy centres for sputum smear examination, and more than 800,000 TB treatment centres (DOT centres) have been established across the country and thousands of health care providers have been trained on TB diagnostic and treatment guidelines. It was assumed that diagnosing 70% of the estimated incident cases in the country and curing 85% of them successfully would lead to a reduction in TB incidence. Accordingly, about 1.5 million TB cases are being diagnosed and treated under this programme every year since 2007.[3] However, TB incidence has not declined as much as expected (Figure 3, page 20), indicating that transmission of TB continues to be high, either because cases are not detected early and/or because they are not being treated properly. Moreover, rising levels of drug resistant TB, including extensively drug resistant TB, are reported from some urban pockets of the country[11] threatening the gains that have been made so far.

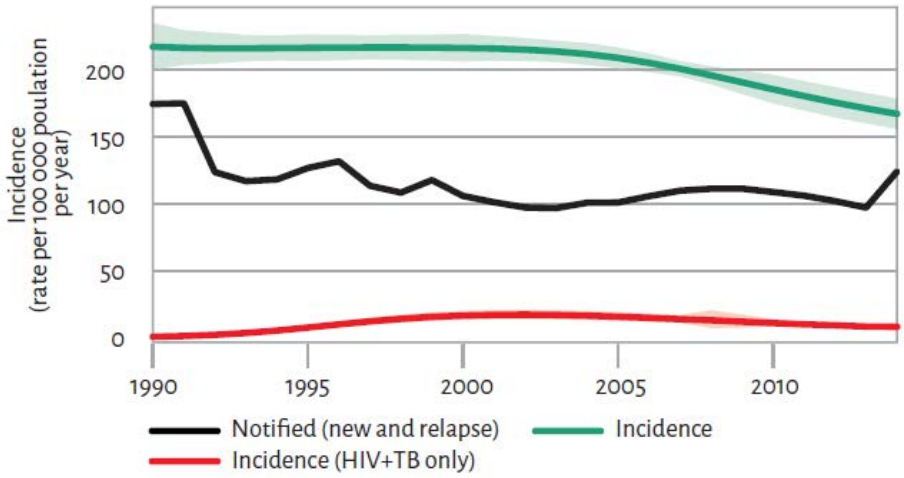

Figure 3: Trends in the incidence (total and HIV+) and notification rates in India [Source: Global TB report, WHO]

In 2012, the Indian Government revised the TB control targets (from 70% case detection and 85% cure) to universal access to quality assured TB diagnosis and treatment for all TB patients in the country.[12,13] To achieve this, establishing mechanisms for linking TB patients to optimal TB care was essential. As a first step, the Government of India issued guidelines for mandatory notification (or reporting) of TB cases diagnosed and treated anywhere in the country to the local public health authorities. Following this, in consultation with various stakeholders, the Indian Government formulated 'Standards of TB Care in India' (STCI).[14] These standards are consistent with those recommended by WHO and the ISTC (3rd Edition) and outline the minimum standard of care that patients should receive. Elaborate plans have been made to procure and make available latest diagnostic technologies such as Xpert MTB/RIF in almost all the districts of the country. However, ensuring care to TB patients as per these standards has been a challenge due to the complexity of the health care delivery system.

Health care system in India

Broadly, there are two relatively parallel sectors that deliver health care to the population, namely the public (government) and the private sectors.[15] The public sector consists of: a) health facilities (primary, secondary and tertiary) manned by medical and paramedical personnel, b) medical colleges and paraprofessional institutions to train the needed manpower and provide the required academic input, c) programme managers to oversee ongoing programmes at the central, state and district levels, and d) health management information system consisting of systems of

data collection, compilation, analysis and response.[16] The TB diagnostic and treatment services of the RNTCP are provided through the public health system and are free for patients.

The private sector is highly diverse and fragmented and consists of health facilities ranging from single standalone clinics to state-of-the-art multispecialty hospitals. While the public sector is made up of predominantly qualified allopathic medical practitioners, the qualification of health care providers in the private sector is highly diverse. The providers range from unqualified (i.e., not having any formal medical degree) to qualified providers (with a formal degree in either allopathic medicine (MBBS) or in alternative traditions, such as Ayurveda, Unani, Siddha, and homeopathy (AYUSH)).[17,18] Their numbers are quite variable and depend on geographic location. For example, in 100 villages in rural Madhya Pradesh (one of the largest states in the country) among primary care providers who were considered as "doctors", 65% did not have any formal medical training, while 25% had AYUSH degrees, and only 10% reported having an MBBS (formal allopathic medicine) degree. In addition, retail pharmacy/chemist shops (those which are permitted to procure, stock and sell medicines) are also involved in providing medical care to minor ailments. The quality of medical care was highly variable and found to be deficient on many levels.[19,20] In India, several efforts have been made to engage the private sector in TB control. But these are far and few, with varying levels of success. The experience has been similar to what has been seen elsewhere in the world. [21-23]

On the ground, evidence shows that most of the patients with pulmonary TB symptoms initially seek medical care in the private sector from pharmacists and unqualified practitioners (due to low cost involved in seeking care from them, proximity, and convenient hours of functioning etc.,) then seek care from qualified practitioners, and eventually may or may not end up in the public sector for free treatment.[24] A recent systematic review showed that on an average, there is a delay of nearly two months before TB patients are diagnosed and initiated on treatment after the onset of symptoms. Patients visited on average three different health care providers before being diagnosed with TB.[25] These studies have indicated that there could be considerable deficiencies in the health care providers' knowledge and practices related to TB diagnosis and treatment. Two small drug prescription analyses conducted 10 years apart shows that irrational and inappropriate anti-TB drug regimens continue to be quite common.[26] Overall, available evidence strongly suggests that quality of TB care in India is likely to be suboptimal, and this partly explains the

reasons for delayed diagnosis, inappropriate treatment, continued TB transmission, high mortality, and emergence of drug-resistance in TB.[27,28]

In countries like India, there is a large gap between the knowledge that health care providers have and their practices. This gap is also known as the 'know-do' gap. Previous work in Delhi, India, showed that although public sector providers were more knowledgeable, their level of effort was lower, leading to worse quality of care than their knowledge alone would predict.[29] Hence, assessing knowledge or attitudes, which represents the bulk of the published research on quality of care in TB,[26,30,31] appears to be less informative and therefore understanding actual clinical practice using appropriate methods is crucial for designing and implementing quality improvement programmes.

1.2 Definition of 'quality' in the context of my thesis

In general, the term 'quality' refers to a value judgement based on several aspects or dimensions of medical care. Judging 'quality' becomes easier if standards are available.[32] Fortunately for TB diagnosis and treatment, two established standards are available: ISTC and STCI. Both these standards are similar as far as TB diagnosis and treatment is concerned [Thesis Appendix 1, Table, pages 161-162]. Therefore, in the context of this PhD thesis, 'quality' is defined as adherence to ISTC or STCI and my focus is on assessing adherence to these standards by private health care providers who are usually the first point of medical care in India.

1.3 An overview of the methods to assess health care providers' practices

A variety of different methods (Table below, from Das J et al, personal communication) are available to measure quality of medical care.

Measure of Quality	Measures Knowledge	Measures Practice	Accounts for Case-Mix*	Accounts for Patient-Mix**	Hawthorne Effects (i.e. behaviour is modified because of observer)	Illnesses Covered and Other Remarks
Vignettes	Yes	No	Yes	Yes	Yes	All
Clinical Observation	No	Yes	No	No	Yes	Limited. First, "serious" illnesses like unstable angina will show up on a sporadic basis. Second, the observer never knows what the patient actually has, and doctors frequently make incorrect diagnoses.
Chart Abstraction (health records)	No	Yes	No	No	No	Similar to clinical observation, but providers rarely keep patient charts. Also, charts tend to be incomplete and don't accurately reflect patient-provider interactions.
Standardised Patients	No	Yes	Yes	Yes	No	Limited to (A) adults with non-critical illness only, (B) diseases that don't have any obvious findings on physical exam (which cannot be mimicked) and (C) conditions that don't require invasive exams. Initial costs are high.

*Case mix indicates disease/illness spectrum and **patient mix indicates different sociodemographic characteristics.

While questionnaires and vignettes provide insight into specific components of the knowledge of health care providers, these methods do not accurately reflect clinical practice.[33,34]

Direct clinical observation can provide information about practice, but this method also has its limitations. First, the presence of an observer may change the health care providers' behaviour

(i.e. the “Hawthorne effect”). Second, observed differences in practice may be confounded with differences in patients and illnesses presented. Third, it is likely that several days of observation may be required before a person with TB symptoms presents himself/herself to the provider. Lastly, when using this method, it is difficult to assess what illness patients presented with and whether the management was indeed correct.

Patient interviews are known to provide a relatively more accurate assessment of care, if suitable patients exiting from the health care providers’ clinics can be identified and interviewed. However, confounding by variations in patient’s characteristics, severity of illness and other morbidities make it difficult to compare ‘practices’ across different health care providers.

The standardised patients (simulated patients or mystery clients) approach [20] is considered a relatively more accurate method for assessing provider practices. Standardised patients (SPs) are normal (non-diseased) persons from the local community who are trained to visit health care providers unannounced; they act as though they have symptoms (without the health care providers being aware that these people are actors) and seek medical care. These clients then come back and narrate/debrief within a very short time regarding what advice/care they received from the health care providers. The SP methodology thus helps in controlling/adjusting for the case mix (spectrum of patients based on their disease characteristics), and patient mix (spectrum of patients based on their demographic and other socioeconomic characteristics) enabling the researchers to obtain a measure of practice in real world conditions that is uncontaminated by Hawthorne effects, recall bias and a measure of care that can be comparable across all health care providers.

However, SP studies also have their limitations. Due to ethical concerns, children cannot be used. In addition, any kind of invasive examination or treatment (e.g. injections) can result in a health risk to the SP and, only diseases with no clear and highly visible clinical signs at the time of clinical interaction can be used. Fortunately in the case of TB, adults can be used as SPs, they can be trained to avoid any invasive procedures and the symptoms of early pulmonary TB (cough and/or mild fever) and physical signs need not necessarily be noticeable at the time of clinical visit to suspect TB.

Standardised patient study in Delhi, Mumbai and Patna

Delhi is the capital city of India. It has a population of about 16 million (2015) people and is located in the northern part of the country. Mumbai is considered the commercial capital of India. It is the capital city for the state of Maharashtra, has a population of about14 million (2015) people and is located in the western part of the country. Patna is located in the eastern part of India and is the capital city of the state of Bihar. The district of Patna has a population of 6 million people (2015).

In these cities, there are a large number of private health care facilities. The private health providers (both qualified and unqualified) are usually the first point of contact for health care. Many of these providers are not associated with the National TB control programme and therefore the number of TB patients and treatment outcomes of the TB patients diagnosed and treated by them is unknown. The Government of India chose Mumbai and Patna purposively as 'model' sites for testing interventions to improve the quality of TB care in the private sector with technical and funding support from Bill and Melinda Gates Foundation. These interventions include training private health care providers on STCI, subsidising TB investigations and drugs for patients seeking care from these private health care providers, incentivising these providers for notifying (or reporting) cases to the public health authorities, creating referral networks between various providers, laboratories and pharmacies for providing co-ordinated care. All these interventions are implemented through an intermediary agency called the 'Public Private Interface Agency'.

I am a member of the team that is conducting a project for assessing the quality of TB care in Mumbai and Patna cities of India, funded by the Bill & Melinda Gates Foundation (Principal Investigators: Madhukar Pai and Jishnu Das). As part of this large project, our team developed and validated the SP methodology for assessing quality of TB care in Delhi, published recently in *Lancet Infectious Diseases*.[35] The validation included four tracer TB medical conditions: a) a patient with classical symptoms of TB, b) a patient with classical TB symptoms + a chest radiography report suggestive of TB, c) a patient with classical TB symptoms + a sputum smear examination report positive for acid fast bacillus, and d) a patient with classical TB symptoms + history of previous TB. A standard script and structured debriefing questionnaire were developed for each case (an example of the standard script and debriefing questionnaire are given in Thesis

Appendix 2, pages 163-177). Thereafter, suitable normal non-diseased persons from the community were identified and trained (in-house) extensively as SPs on both the script as well the debriefing questionnaire. After the training, these SPs made 250 visits to 100 consenting private health care providers in Delhi, and after the visit, they were debriefed with the standard questionnaire within one hour of each visit. The validation involved assessing accuracy of recall by standardised patients, detection as 'fake' patients by health care providers, assessing harm to the standardised patients and the health care providers, and assessing whether the collected data would allow us to describe the practices of health care providers. The methodology was found to be satisfactory on all these measures. The proportion of SPs detected as 'fake' patients was low (11 [5%] detected out of 232 interactions), and SP recall correlated highly with audio recordings (r=0·63 [95% CI 0·53–0·79]), with no safety concerns reported. Among 250 interactions, only 52 (21% [16–26]) were determined to be correctly managed (a major albeit preliminary finding).

Based on this pilot in Delhi, our team is now using the SP approach to assess the change in the quality of TB care by pharmacists and private health care providers in three cities (Delhi, Mumbai and Patna). I am using a part of the data from the baseline (or first round of surveys) in my thesis.

1.4 Thesis aims and objectives

The overall aim of my thesis is to describe the quality of TB care in India by assessing the practices of health care providers for persons with TB.

My manuscript-based thesis includes 3 studies with the following objectives:

Study 1: Quality of TB care in India: a systematic review
Objective: To systematically review studies that provide information on health care providers' knowledge and practices related to TB diagnosis and treatment when compared with the 2nd edition (2009 version) of the ISTC.

Study 2: Use of standardised patients to assess antibiotic dispensing for tuberculosis by pharmacies in urban India: a cross-sectional study
Objective: To assess medical advice and drug dispensing practices of pharmacists for standardized patients presenting with symptoms of pulmonary TB disease in three cities (Delhi, Mumbai and Patna) of India.

Study 3: Gender differences in the quality of tuberculosis care in India: a standardized patient study
Objective: To assess the gender differences in diagnostic and treatment practices of health care providers for male and female standardized patients presenting with TB disease in three cities (Delhi, Mumbai and Patna) of India.

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Chapter 2: Literature review

2.1 Preface

India has the highest TB burden country in the world. TB control depends on early diagnosis of infectious pulmonary TB cases and their correct treatment. Health care providers play a very important role in controlling TB. International and national guidelines are available to guide health care providers on when to suspect TB in a patient, what diagnostic investigations to perform, when to conclude whether the patient has TB or not, what treatment regimens to use & its duration, and how to assess a patient's response to treatment. If providers do not feel competent in dealing with these issues, then they must be able to identify and refer their patients' with TB symptoms to health care providers or facilities that have the competence to manage such patients. Government of India has established mechanisms for optimum management of TB through its Revised National Tuberculosis Control Programme (RNTCP).

However, the health care system in India is complicated with many types of providers. These providers can be stratified by three different ways. First, based on educational background, they can be classified as being unqualified providers (i.e., not having any formal medical degree) or qualified providers who have a formal degree in either allopathic medicine or in alternative traditions, such as Ayurveda, Unani, Siddha, and Homeopathy (AYUSH). Second, providers can be classified based on their level of training, either as paramedical staff, physicians-in-training (i.e., medical students and interns), generalists (i.e., not specializing in TB), or specialists in TB (usually "chest physicians" in the Indian context). Third, providers can be classified based on whether they deliver care in the public health care delivery system or in the private health care system. The reach of RNTCP services is limited to the public health system in the country. Studies suggest that 80% of the first-contact medical care is in the private sector which is dominated by informal/unqualified providers.

In the published literature, several studies have investigated different aspects of health care providers' knowledge and/or practices related to TB diagnosis and treatment in India. However, there is no systematic condensation of this information to inform policy or further investigation. Therefore, as part of my dissertation, I did a systematic review of quality of TB care in India which was published in International Journal of Tuberculosis and Lung Disease. 2015;19(7):751-63.

2.2 Manuscript-1 Quality of tuberculosis care in India: a systematic review

Srinath Satyanarayana, MD[1,2], Ramnath Subbaraman, MD[3,4], Priya Shete, MD[5], Genevieve Gore, MLS[6], Jishnu Das, PhD[7], Adithya Cattamanchi[5], MD, Kenneth Mayer[8], MD, Dick Menzies, MD[9], Anthony D Harries, MD[2,10], Philip Hopewell, MD[5], Madhukar Pai, MD[1]

[1]Department of Epidemiology, Biostatistics and Occupational Health, and McGill International TB Centre, McGill University, Montreal, Canada

[2]Center for Operations Research, International Union Against Tuberculosis and Lung Disease, Paris, France

[3]Division of Infectious Diseases, Brigham and Women's Hospital and Harvard Medical School, Boston, USA

[4]Partners for Urban Knowledge, Action and Research (PUKAR), Mumbai, India

[5]Curry International Tuberculosis Center, University of California San Francisco, San Francisco, USA

[6]Life Sciences Library, McGill University, Montreal, Canada

[7]Development Economics Research Group (DECRG), World Bank, Washington DC, USA

[8]The Fenway Institute and Beth Israel Deaconess Medical Center, Boston, USA

[9]Respiratory Epidemiology and Clinical Research Unit, Montreal Chest Institute, McGill University, Montreal, Canada

[10] London School of Hygiene and Tropical Medicine, London, United Kingdom.

Word Count: Abstract (250), Main-text (3615)

Number of tables: 4

Number of figures: 8

Number of references: 67

Number of Appendix: 2

Short running title: A systematic review on TB management in India

[Reference: Satyanarayana S, Subbaraman R, Shete P, Gore G, Das J, Cattamanchi A, et al. Quality of tuberculosis care in India: a systematic review. The international journal of tuberculosis and lung disease : the official journal of the International Union against Tuberculosis and Lung Disease. 2015;19(7):751-63].

2.2.1 Abstract

Background

Globally, India accounts for a quarter of all new TB cases. Nearly 50% of patients in India seek care in the private sector. While several studies have assessed care providers' knowledge and practices, these data have not been synthesized.

Methods

We searched multiple sources to identify articles (2000 to 2014) on health providers' knowledge and practices. We used the International Standards for TB Care (ISTC) to benchmark knowledge and practice, and generated forest plots for standards with data from ≥5 studies.

Results

A total of 47 articles met inclusion criteria; 35 were questionnaire surveys and 12 used chart abstraction. None assessed actual practice using standardized patients. Heterogeneity in the findings precluded meta-analysis. Ten of 22 studies evaluating provider knowledge about using a sputum smear for diagnosis found that less than half of providers had correct knowledge; 3 of 4 studies assessing self-reported practices by providers found that less than one-fourth reported ordering smears for chest symptomatics. In 11 of 14 studies that assessed treatment, less than one-third of providers knew the standard treatment regimen for drug-susceptible TB. Adherence to standards in practice was generally lower than correct knowledge of those standards. Eleven studies that included both public and private sector providers found relatively higher levels of appropriate knowledge or practice in the public sector.

Conclusions

Available evidence suggests sub-optimal quality of TB care, particularly in the private sector. Measurement and improvement of quality of care should be a central component of India's new goal of universal access to quality TB care.

Key words: Tuberculosis, India, Quality of Care, International Standards for TB Care

2.2.2 Introduction

India, with an estimated annual incidence of 2.0 to 2.3 million tuberculosis (TB) cases and about 150,000 to 350,000 deaths per year, has the highest TB burden in the world.[1] Control of TB depends on early diagnosis of pulmonary TB cases and their treatment with a full course of anti-TB drugs.[2] For early diagnosis of TB, all persons with cough of two weeks or more should be referred for TB evaluation.[3] Correct treatment requires the use of standardized drug regimens recommended by the WHO[2], the International Standards for TB Care (ISTC), and the Standards for TB Care in India (STCI).[2-4]

A recent systematic review showed that in India there is a delay of nearly two months in making a diagnosis of TB; on average, patients are seen by three different providers before a diagnosis is made.[5] Drug prescription analyses have shown that irrational and inappropriate anti-TB drug regimens are widely used.[6] These studies suggest that quality of TB in India is concerning.[7]

The Indian healthcare delivery landscape is complex and fragmented, with many types of care providers in public and private sectors.[8] Studies suggest that 80% of the first-contact health care and nearly 50% of TB care occurs in the private sector. [9] The private sector is further fragmented. There are unqualified (i.e., not having any formal medical degree) and qualified providers (with a formal degree in either allopathic medicine or in alternative traditions, such as Ayurveda, Unani, Siddha, and Homeopathy (AYUSH)).[10,11] A recent study of 100 villages in rural Madhya Pradesh found that, among primary care providers identifying themselves as "doctors", 65% report having no formal medical training, while 25% have AYUSH degrees, and only 10% report having an MBBS (formal allopathic medicine) degree. The quality of medical care was highly variable and found to be deficient on many levels.[12,13]

While several studies in India have investigated different aspects of health care providers' knowledge and practices related to TB diagnosis and treatment, this literature has not been systematically reviewed, or benchmarked against international standards.

2.2.3 Methods

Objectives

We systematically reviewed studies that provided information on health care providers' knowledge and practices in both the public and private sectors related to TB diagnosis and treatment compared with the 2nd edition (2009 version) of the ISTC.[14] ISTC was used as the benchmark for three reasons. First, the standards that make up the ISTC were developed by a team of international experts from public and private sectors and are recognized as defining a widely-accepted level of care to which all providers should adhere; second, the current national guidelines of India's Revised National Tuberculosis Control Programme (RNTCP) and the recent Standards for TB Care in India (STCI)[4] are largely concordant with the second edition of the ISTC [Table 1, pages 53-54]; third, adherence to most of the 21 standards in the ISTC can be measured using quality indicators. While a 3rd edition of the ISTC has recently been published,[3] we used the second edition, as the 3rd edition emphasizes the use of new diagnostic modalities such as Xpert MTB/RIF that were not available in India until recently.

Search Strategy

A medical librarian searched PubMed, Embase and Web of Science for studies published between January 2000 and Sept 2014, without any language restrictions, using search terms for "tuberculosis", "knowledge", "practice", "healthcare providers", and "India" [Appendix 1, pages 69-70 provides the full search strategy].

In addition, we carried out electronic searches of several Indian journals to increase the yield of relevant studies, especially from non-indexed journals, including Journal of the Indian Medical Association, Indian Journal of Tuberculosis, Indian Journal of Community Medicine, Indian Journal of Public Health, Indian Journal of Medical Research, Lung India, Indian Journal of Chest Diseases and Allied Sciences and National Medical Journal of India. Additional studies were identified by searching the reference lists of primary studies. Official reports, such as the RNTCP's Annual Status Reports or the World Health Organization's (WHO) Joint Monitoring Mission Reports, are not included in the review, as they do not provide quantitative information on the knowledge, attitudes, and practices of healthcare providers. In addition, the Joint Monitoring Mission reports are not available in the public domain.

Types of study designs, inclusion and exclusion criteria

All study designs (cross-sectional, descriptive studies, case control studies, cohort studies, and interventional studies) that used any method to assess knowledge, attitudes, or practices such as questionnaire surveys, prescription audits, vignette-based questionnaires, clinical observation, chart abstraction, or mystery client/standardised patients were included. Purely qualitative studies, case reports, and studies of very low quality (explained later) were excluded.

Quality Assessment

We assessed quality of each study based on three criteria: methodology, sampling strategy, and survey response rate [Table 2 & 3, pages 55-56]. These criteria were adapted from the literature on various approaches to assessing quality of medical care.[13,15,16] In addition, we assessed the provider mix in each study, since studies that narrowly focus on one subset of providers (e.g., only allopathic doctors) may inadequately reflect the complexity of India's health system. Studies that had a participation/response rate of less than 50% or that included fewer than 20 providers were considered to be very low quality and were excluded from the analysis.

Study selection

Citations identified by the search were independently assessed by two review authors (SS and RS) for their eligibility. Disagreements between the two reviewers were resolved by discussion or by consulting a third reviewer (PS).

Data extraction and analysis

Three reviewers (SS, RS, and PS) independently extracted the data from each included study on a structured data extraction form. Disagreements were resolved through discussion and or by consulting a fourth reviewer (MP). Data extracted from each of the studies included study characteristics (design, location, urban/rural setting, sample size), and type of health care providers included. For data on the ISTC standards, we first extracted information on the specific ISTC standard(s) that each study addressed, and then quantitative data (proportions, along with 95% confidence intervals) on the knowledge or practice pertaining to each of the standards that were reported in each study. In studies where 95% confidence intervals were not reported, we calculated it from the data provided in the manuscript.

Studies were broadly classified into those measuring knowledge and those measuring practice based on the methodology employed. Studies that had administered questionnaires and vignettes were considered to be measuring knowledge while studies that used patient interviews, chart abstraction, clinical observation, or standardized patients were considered to be measuring practice.

We tabulated the main characteristics of the included studies. Forest plots were generated for each ISTC standard for which data were available from at least 5 studies. A forest plot graphically displays the relative magnitude of the parameter of interest from multiple studies. Each dot represents the proportion of providers adhering to a guideline from a particular study (ranging between 0 and 1) and the lines around each dot represent the confidence interval. Considerable heterogeneity in study methodologies precluded meta-analysis. Instead, we narratively synthesized key findings, highlighting general trends in the findings and critical deficiencies in the current literature and methodologies used.

2.2.4 Results

As shown in Figure 1 [page.63], the literature search from all sources yielded 929 citations. Of these, 47 articles were included in the analysis. Three studies were excluded on the basis of very low quality. A list of excluded studies can be obtained from the authors.

Characteristics and quality of included studies

Table 4 [pages 57-62] shows the characteristics of the 47 included studies. Except for two studies,[17,18] fieldwork for all studies was conducted within two years prior to their actual publication. Studies were conducted in 13 of 37 states in India. Urban locations were more heavily represented, with 25 studies conducted exclusively in urban areas, 19 studies in both urban and rural areas, and three studies exclusively in rural areas; in one study this information was not available. Most studies that evaluated care in both urban and rural sites did not disaggregate data by location, precluding assessment of urban versus rural differences in quality of care.

Forty-six of the 47 studies were cross-sectional and one[19] was an interventional study that provided information on change in the knowledge of the health care providers pre- and post- intervention. In this review, we have used only the pre-intervention (baseline) information from this study.

Thirty-five studies used questionnaires to collect data, and three studies audited medical records or reviewed prescriptions. The remaining nine studies used multiple methods (a combination of questionnaire, vignette, chart abstraction and/or focus group discussions) to collect data. Twenty-eight studies collected data by interviewing health care providers; thirteen studies by interviewing patients on the care that they had received; three studies by reviewing patients' medical records or prescriptions; and three studies by a combination of provider interview and a review of medical records or prescriptions.

Of the 47 studies, three did not report on whether they evaluated public or private care providers. Many studies (N=21) only included providers in the private sector, while a smaller number (N=12) only included public sector providers. A notable subset (N=11) studied providers in the same general location in both the public and private sectors, using the same questionnaires for the two groups. As such, this subset of studies provides direct comparisons of the quality of care delivered by these two sectors.

With regard to the quality of the studies based on our pre-determined rating system [Tables 2 and 3, pages 55-56], none of the studies used methodologies that were considered high quality for measuring the actual practices or behaviours of providers. Five studies were considered high in quality for measuring provider knowledge for some ISTC standards, as they used hypothetical case scenarios (similar to vignettes) as part of their questionnaires. Twenty-six studies used high quality sampling strategies (i.e., either random or comprehensive sampling), and the survey response rate was high or very high in twenty-three studies.

Data on ISTC standards: Only one study[20] explicitly used ISTC as benchmark for quality. From all other studies, we extracted the data and matched them to the relevant ISTC standards. There were eight ISTC standards for which five or more studies provided data: Standard 1 (6 studies), Standard 2 (26 studies), Standard 5 (7 studies), Standard 8 (17 studies), Standard 9 (16 studies), Standard 10 (9 studies), Standard 13 (5 studies) and Standard 18 (6 studies). Results pertaining to the key standards: sputum examination for diagnosis (standard 2), initiation of the recommended drug regimen among new TB cases (standard 8), and patient support to ensure adherence (standard 9) were each having 10 or more studies are presented here. The results pertaining to the remaining standards (1, 5, 10, 13, 18) are given in appendix 2.

Standard 2 [Aware/use sputum smear for persons with presumptive pulmonary TB]

Of the 26 studies that provided information on this standard [Figure 2, page 64], 21 studies assessed awareness or knowledge, and five studies assessed practices. There was considerable heterogeneity in the proportion of providers who were aware that patients with suspected pulmonary TB must undergo sputum examination. It ranged from as low as 17%[21] to as high as 94%.[22] Five studies that provided information on practices (mostly by interviewing patients regarding provider practices) reported that, of persons with cough of 2-3 weeks duration, only 11%[23] to 59%[24] were advised to undergo sputum examination.

Standard 8 [Aware/use correct treatment regimen for new case of TB]

Of the 17 studies that provided information on this standard, 14 studies assessed knowledge and 3 studies assessed practices [Figure 3, page 65]. For this standard, we counted any drug regimen as meeting this standard as long as it contained the right drugs and duration of therapy (e.g., two months of isoniazid, rifampicin, pyrazinamide, and ethambutol followed by four months of isoniazid and rifampicin), irrespective of whether it was a daily regimen or an intermittent regimen. Almost all studies reported that less than 50% of health care providers had knowledge of the correct anti-TB treatment regimen for patients with newly diagnosed pulmonary TB. Knowledge on either the right combination of drugs or on the duration of anti-TB treatment was lacking.

Studies reporting on practice had heterogeneous findings, possibly explained by the settings in which these studies were conducted. Two studies[25,26] assessed practices among in-patients in tertiary care, hospital settings and found very high rates of adherence to guidelines. In contrast, one study[27] assessed the correctness of both the combination of drugs and the dosages in the outpatient setting and found that, in most cases, the dosages as well as the drug combinations were not aligned with ISTC.

Standard 9 [Aware/use of a supervised including DOT approach for treatment of TB]

Of the 16 studies that provided information on this standard, 10 studies reported on whether health care providers used directly observed therapy (DOT) or a supervised approach for adherence monitoring, and six studies reported on whether providers had appropriate knowledge of DOT or a supervised approach [Figure 4, page 66]. Of studies that assessed practice, 7 of 10 studies reported that less than half of the providers used DOT or a supervised approach. Most of their TB patients received un-supervised treatment. On the other hand, of the studies that assessed knowledge, 4 of 6

studies reported that more than 90% of the providers were aware of the DOT or a supervised treatment approach. Two studies[28,29] reported that younger doctors or trainees were more likely to believe in the DOT approach.

Quality of care in public *versus* the private sector

Eight studies provided direct comparisons of the quality of care delivered by public versus private sectors for standards 2, 8 and 9. Barring one study,[27] in all other studies, adherence to all ISTC standards was found to be consistently higher ($P<0.05$) in the public sector [Figure 5, page 67]. Five studies reported that public sector providers were more likely to know that sputum smear examination is the primary test for TB (Standard 2).[30,23,31,32]

One study[27] suggested that public providers were marginally more likely than private providers to write an appropriate prescription for drug-susceptible TB (10% versus 5%). Prescription errors by private providers (e.g., too few drugs in the regimen, unnecessary use of fluoroquinolones and aminoglycosides) were more than the errors made by public providers. Also, studies reported that public providers were twice more likely to report the correct combination of drugs to treat drug-susceptible TB,[27,33] and use intermittent therapy as recommended by the RNTCP,[27,31,33,34] and not use streptomycin as part the treatment regimen for new TB cases.[27] Regarding patient-centered approaches to TB management including directly observed or supervised therapy (Standard 9), two studies reported higher rates of supervision of adherence in the public sector.[28,33,34]

We found six studies that reported the proportion of providers exposed to formal training on RNTCP guidelines for TB care, through workshops organised by the RNTCP. Among private providers 17-58% reported having attended an educational session on TB care,[20,35,31,33,36,37] while 73-92% of government providers reported having attended such a training session,[31,33] and wherever the levels of training were high, awareness levels and self-reported practices were better. In addition, the only intervention-based study in this review found dramatic improvements in knowledge of multiple ISTC guidelines among private sector providers, one year after educational workshops or one-to-one training sessions.[19]

2.2.5 Discussion

To our knowledge, this is the first systematic review that has assessed health care providers' knowledge and practices by using International Standards of TB care as the benchmark. Our systematic review on the quality of TB care in India shows major gaps in provider knowledge and practice when benchmarked against international standards. There were wide variations in the awareness of health care providers on the importance of suspecting TB in persons with cough of more than 2-3 weeks duration (from Appendix 2, pages 71-72) and using sputum smears for persons with presumed TB. Similarly, with regards to TB treatment, there were wide variations in the awareness of the correct regimen for patients with first episodes of pulmonary TB, and a third reported using DOT or a supervised approach for treatment support. These variations may in part explain the observed diagnostic delays shown in systematic reviews[5] and contribute to high levels of treatment failure and drug resistance reported in recent studies.[38,39] These data emphasize the need for greater investment into strategies that facilitate effective dissemination and implementation of ISTC and Standards for TB Care in India.

In studies that included both public and private health care providers, adherence to ISTC standards as measured by knowledge levels was found to be relatively higher in the public sector. This is perhaps due to the training and monitoring of public sector providers by the RNTCP, and to the use of standardized protocols for case finding and treatment. In contrast, little has been done to train the vast number of private sector providers (both qualified and unqualified).

Our review findings also suggest the presence of a 'know-do' gap. As compared to self-reported or observed practices, knowledge levels regarding appropriate treatment of TB trended towards higher rates, especially with respect to using sputum smear microscopy and DOT. The use of standardized patients' studies coupled with vignettes and chart abstraction is well suited to identifying the 'know-do' gap, but none of the existing studies used this methodology.

2.2.6 Limitations

Despite a thorough literature search, we may have missed some studies from India, especially if they were published in non-indexed journals. Also, we have not formally explored potential publication bias, as there is no statistical test for the type of data we analyzed. Included studies had their own limitations, and were mostly based on questionnaire surveys of knowledge. The quality of

most studies for assessing either knowledge and/or practice was not high and the study methodologies were also diverse. Despite the fact, that more than 50% of TB patients in India seek care from the public sector[9], more studies focused on private sector providers (32 studies) with relatively fewer studies focusing on public sectors providers (23 studies). However, studies that assessed the difference between public and private sectors did not provide information on whether the providers were mutually exclusive. This information is useful as public providers can be private providers on off-hours, nights and weekends. Included studies were mostly from urban areas, and did not represent all regions of the country. Thus, urban versus rural differences in quality of care were not addressed. Lastly, we are not able to assess if quality of care was related to patient load or characteristics of the health facilities, primarily because the included studies did not provide any information on these aspects.

2.2.7 Implications for policy and practice

Our findings raise several issues relevant to policy. First, there must be substantial investment in training providers on national and/or International TB guidelines both in the public and private sector. Second, given the dominance of the private sector, and lower levels of quality as compared to the public sector, serious efforts need to be made to engage the private sector in TB control and educate and incentivize them to follow national and international standards. This is particularly critical for reducing diagnostic delays, as patients often begin their pathways to care in the private sector.[40]

Third, there is a need to expand the availability of recommended diagnostic and treatment services across the country and mechanisms for all health care providers, including private sector doctors, to link their patients to these services without any obstacles. It is critical to ensure that all patients have access to affordable, quality care, regardless of where they seek care.[41] Fourth, monitoring health care providers' knowledge and practices, should become a part of the routine TB surveillance system so that necessary corrective steps can be undertaken and the progress can be tracked.[42] Using implementation research to systematically understand and identify barriers and enablers of adherence to standards would provide an opportunity for developing targeted interventions and policy shifts that could improve TB care.

In addition, our findings also raise methodological questions about how the quality of TB care should be measured. Available studies provide a reasonable picture of provider knowledge (i.e., "what they know") and, to some extent, providers' self-reported behaviour ("what they say they do"); however, these studies fail to provide any information about the behaviour of providers in real life ("what they actually do"). None of the studies used standardized patients. Standardized patients (also known as 'mystery clients') are normal (non-diseased) persons from the local community who are trained to visit health care providers, present as though they have TB symptoms, and seek medical advice and care (without the providers being aware that these people are actors). The standardized patients then undergo a debriefing by researchers, in which they narrate the care and advice they received from the health care providers. While standardized patient studies are resource intensive and harder to implement, such methods have been used to successfully interrogate quality of care for other medical conditions in the Indian context.[13] A pilot study on standardized patients for TB care is underway in India (J Das, personal communication) and might pave the way for evidence-based decisions on this approach.

Also, future studies should use rigorous, vignette-based questionnaires to assess provider knowledge. Studies suggest that assessment of both knowledge and behavior through well-designed vignettes may reflect provider knowledge and behavior better than chart abstraction[15,43]. Studies assessing knowledge and self-reported behaviour are still helpful in that they provide upper bounds for these various quality indicators; in other words, correct knowledge of TB care is *necessary* for appropriate provider behaviour, though it certainly is not *sufficient* to ensure appropriate behaviour. As such, even though the rates of adherence to ISTC standards are quite low in this study, we anticipate that studies of actual provider behaviour using standardized patients may show even lower rates of adherence.

In conclusion, our review suggests poor quality of TB care across several international standards, particularly in the private sector. Thus, measurement and improvement of quality of care should be a central component of India's new goal of universal access to quality TB care.

Author contribution

SS and MP identified the research question and drafted the study protocol. SS and GG developed the search strategy and conducted the literature search. SS, RS and PS extracted the data. SS, RS and MP analysed and interpreted the data. The manuscript was written by SS, RS, PS & MP. All other authors provided critical review and comments to the review protocol and the manuscript.

Acknowledgements

This study was supported by Grand Challenges Canada, and the Bill and Melinda Gates Foundation (OPP1091843). SS is a recipient of fellowships from the Canadian Thoracic Society, and the International Union against TB and Lung Disease. RS is supported by a Harvard T32 HIV Post-doctoral Clinical Research Fellowship (NIAID AI007433). PS is supported by a UCSF T32 Post-doctoral Clinical Research Fellowship in Pulmonary and Critical Care Medicine (NHLBI 5T32HL007185). MP is a recipient of a career award from the Fonds de recherche du Québec – Santé. None of these funding sources had any involvement in writing of the manuscript or the decision to submit it for publication. The authors have not been paid to write this article by industry or other agency. The corresponding author (M Pai) has full access to all the data, and has final responsibility for the decision to submit for publication.

Conflicts of interest

None of the authors has a financial interest or conflict. Madhukar Pai serves as a consultant to the Bill and Melinda Gates Foundation.

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2.2.9 Tables and figures

Table 1: A comparison of the International Standards for Tuberculosis Care (ISTC) to India's Revised National Tuberculosis Control Program (RNTCP) guidelines

International Standards for Tuberculosis Care		**RNTCP Guidelines**
Standard 1	Unexplained productive cough >2-3 weeks should be evaluated for TB	An individual with cough >2 weeks should be considered a TB suspect
Standard 2	TB suspects should have at least 2 sputum samples submitted for microscopic examination	TB suspects should have 2 sputum samples collected for microscopic examination
Standard 3	Extrapulmonary TB (EPTB) suspects should have a specimen obtained from the suspected site of involvement for microscopy, culture, and histopathologic examination	EPTB should be diagnosed based on positive tissue culture from an extrapulmonary site, positive histological findings, consistent radiological findings, or strong clinical evidence
Standard 4	Chest X-ray (CXR) findings concerning for TB merit sputum examination	CXR alone is unreliable for diagnosing TB (implies sputum examination should be performed for concerning CXR findings)
Standard 5	Criteria for smear negative diagnosis: 2 negative sputum smears, CXR findings consistent with TB, and lack of response to broad-spectrum antibiotics. Used of fluoroquinolones for empiric treatment should be avoided.	Criteria for smear negative diagnosis: 4 negative sputum samples, failure of cough to improve on broad-spectrum antibiotics, and CXR findings suggestive of TB. Fluoroquinolones, rifampicin, and streptomycin should never be used for empiric treatment.
Standard 6	Describes the workup and criteria for diagnosis of intra-thoracic TB in children, including sputum or gastric washing evaluation, radiography, history of recent contact with an active TB case, use of tuberculin skin testing (TST) or interferon gamma release assay (IGRA), and obtaining tissue or fluid for evaluation in cases of suspected EPTB	Similar workup recommended to diagnose TB in children, including sputum examination, CXR, history of contact with an active TB case in the last two years, and use of TST.
Standard 7	Providers should assess TB medication adherence and address poor adherence to therapy when it occurs	A directly observed treatment (DOT) provider should help the patient in taking the treatment, thereby ensuring adherence
Standard 8	Defines recommended first-line treatment: 2HRZE + 4HR, with dosing conforming to international recommendations. Fixed dose combinations are preferred.	Same recommended first-line regimen and dosing standards, though intermittent (every other day or thrice weekly) therapy is preferred. Multi-blister combi-packs containing all the drugs are provided by the government.
Standard 9	A patient-centered approach is recommended, which may include training of a treatment supporter, DOT, and incentives to improve adherence.	All standard treatment regimens are supposed to be provided by DOT in RNTCP areas.
Standard 10	For monitoring response to therapy, 2 sputum smears should be repeated after completion of the initial 2 months of therapy	For monitoring response to therapy in smear-positive TB cases, 2 sputum smears should be repeated at 2 months, 4 months, and at the time of treatment completion
Standard 11*	Drug-susceptibility testing should be performed for all previously treated	Drug-susceptibility testing should be performed for individuals who are close contacts of known multi-

	patients, patients who remain sputum smear positive after 3 months of treatment, and patients who default, fail, or relapse on a course of treatment	drug-resistant TB (MDR-TB) patients with a positive sputum smear, patients who remain sputum smear positive after 5 months of treatment, and patients who default, fail, or relapse on a course of treatment with a positive sputum smear (i.e., sputum smear positive "Category II" patients)
Standard 12*	Patients with suspected or confirmed MDR-TB should be treated initially with a specialized regimen with at least four drugs to which the organism is presumed or known to be susceptible	Patients with suspected MDR-TB should be treated with a standardized regimen of 6 drugs
Standard 13	Written record of TB therapy should be maintained for all patients	Treatment cards for all patients on treatment should be maintained at RNTCP DOTS centers
Standard 14	HIV testing is recommended universally for all TB patients in high HIV prevalence settings	Routine HIV testing of all newly diagnosed TB patients with unknown HIV status is recommended
Standard 15	TB therapy should not be delayed in HIV patients. All patients with HIV co-infection should be evaluated for initiation of antiretroviral therapy (ART) if appropriate. Cotrimoxazole prophlyaxis is recommended.	All HIV co-infected TB patients are considered seriously ill and should be started on TB therapy expeditiously. These patients should be referred to National AIDS Control Program centers for consideration for initiation on ART and administration of cotrimoxazole prophylaxis.
Standard 16*	HIV-infected patients without evidence of active TB should be treated for presumed latent tuberculosis infection	No similar recommendation has been made by the RNTCP
Standard 17	Comorbid conditions that may affect TB treatment outcomes should be assessed and addressed, such as diabetes mellitus, smoking, and substance use	Routine screening for diabetes mellitus should be performed for all TB patients with unknown diabetes status. Relevant comorbid conditions such as smoking and pregnancy should be recorded on the treatment card.
Standard 18	Close contacts of active TB patients should be evaluated, especially children <5 years of age, HIV-infected contacts, persons with symptoms suggestive of TB, and contacts of patients with MDR-TB	All household contacts of individuals with smear positive TB should be screened for TB symptoms, and those with cough should undergo sputum examination.
Standard 19	Household contacts <5 years of age or who are HIV-infected without active TB should receive isoniazid chemoprophylaxis	Household contacts <6 years of age who are asymptomatic should receive isoniazid chemoprophylaxis
Standard 20	Healthcare facilities that take care of TB patients should have an infection control plan	RNTCP guidelines for infection control in hospital settings recommend administrative controls, environmental controls, and personal protective measures
Standard 21	All TB cases must be reported to local public health authorities	All TB cases, including those detected in the private sector, must be mandatorily notified to designated nodal officers in the districts.

Table 2: Quality level and limitations of various study methodologies that may be used to assess quality of care in developing country settings

Study methodology or design	Quality level: Measurement of knowledge	Quality level: Measurement of practice	Major limitation of study method
Standardized patient studies*	High	Very high	Gold standard method, but highly resource-intensive
Clinical observation studies of providers *with* case and patient-mix adjustments**	High	Medium	Hawthorne effect ***
Clinical observation studies of providers *without* case and patient-mix adjustments	Medium	Low	Hawthorne effect
Chart abstraction or prescription audits *with* case and patient-mix adjustments	Medium	Medium	May be very limited by incomplete, poor quality, or absent documentation
Chart abstraction or prescription audits *without* case and patient-mix adjustments	Low	Low	May be very limited by incomplete, poor quality, or absent documentation
Surveys of *providers* using *vignettes or mock prescription writing* to assess knowledge, attitudes, and behaviors	Very high	Low	Hawthorne effect
Surveys *providers* using basic questions or self-report to assess knowledge, attitudes, and behaviors	Medium	Low	Hawthorne effect
Surveys of *patients* to assess provider practices	Uncertain due to lack of validation	Uncertain due to lack of validation	Recall limitations on the part of patients

** Standardized patients: Standardized patients (also known as 'mystery clients') are normal (non-diseased) persons from the local community who are trained to visit health care providers, present as though they have TB symptoms, and seek medical advice and care (without the providers being aware that these people are actors)*

*** Case and patient mix refers to the different clinical presentation and characteristics (e.g., sputum positive, sputum negative, different age and sex groups etc.,)*

**** Also known as "observer effect", which refers to change in people's behavior when they know that they are being 'observed'.*

Table 3: Criteria for assessing the quality of studies

Variables evaluated for quality assessment	Quality level
Sampling strategy	
Random or comprehensive sampling	Very high
Use of a list frame validated in the field, with subsequent population-weighting of results	Very high
Validated list frame and population-weighting *not* used	Medium to low
Convenience sampling	Medium to low
Survey response rate	
91-100%	Very high
76-90%	High
51-75%	Medium
0-50%	Low
Studies with a response rate of <90%, in which statistical adjustments such as inverse probability weights are *not* used and upper and lower bound estimates are *not* provided for final figures	Quality level drops one notch
Provider mix	
Includes a mix of allopathic, AYUSH, and non-qualified providers in both the private and government sectors	High
Includes some subset of the above	Medium

Table 4: Characteristics of studies included in the systematic review on management of TB in India

Citation (year)	Location	Urban, rural, both, or unknown	Provider mix[a]	Methodology	Sampling strategy	Sample size[b]	Survey non-response rate (%)	ISTC standards evaluated
Achanta (2013) [20]	Visakhapatnam, Andhra Pradesh	Both	Private; allopathic, AYUSH; specialists, generalists	Questionnaire; vignettes*	Random*	201 providers	32	1-13
Anandi (2002)[44]	Naraingarh, Haryana	Rural	Private; AYUSH, nonqualified; generalists	Questionnaire	Random*	74 providers	5*	2, 7, 8, 9
Agarwal (2009)[45]	Khajuraho, Madhya Pradesh	NR	Sector NR; allopathic; specialists	Questionnaire; vignettes*	Convenience	52 providers	46	8
Atre (2007) [46]	Mumbai and Pune, Maharashtra	Both	Public; allopathic; training NR	Questionnaire	Comprehensive*	889 patients	NR	11
BanuRekha (2009)[47]	Chennai and Vellore, Tamil Nadu	Both	Public; allopathic; generalists, paramedical staff	Chart abstraction; questionnaire; focus group discussions	Comprehensive*	253 charts / patients; 40 providers	32	18, 19
Banu Rekha (2013)[48]	Chennai and Vellore, Tamil Nadu	Both	Public; allopathic; generalists, paramedical staff	Chart abstraction; questionnaire; focus group discussions	Comprehensive*	87 charts/household contacts	4	18,19
Baveja (2012) [49]	Navi Mumbai, Maharashtra	Urban	Private; allopathic; medical students	Questionnaire	Convenience	200 providers	NR	2, 8, 9
Bharaswadkar (2014)[50]	Pune, Maharastra	Urban	Private; allopathic and AYUSH; Generalists	Questionaire; vignettes	Random	249 providers	7	2, 3, 8, 11

Bishnu (2011)[51]	Paraganas district, West Bengal	Both	Private; allopathic; generalists	Chart abstraction; questionnaire	Comprehensive*	1633 charts; 169 patients; 24 providers	NR for charts; 17% for patients*	14
Chadha (2014)[52]	Mysore, Shivamoga and Chikmagalur; Karnataka	Both	Public; Allopathic;	Questionnaire	Convenience	256 smear negative TB suspects and 19 Providers	NR	4, 5
Chander (2013)[18]	Rampur, Himachal Pradesh	Both	Public; allopathic; training NR	Questionnaire, chart abstraction	Random*	61 patients / charts / providers	13*	3
Das Gupta (2008)[53]	Kolkata, West Bengal	Urban	Private; allopathic; training NR	Questionnaire	NR	233 providers	NR	1, 2, 9, 18
Datta (2010)[21]	Hooghly district, West Bengal	Urban	Private; allopathic; specialists, generalists	Questionnaire	Random*	260 providers	NR	2, 4, 9, 10, 18
De Costa (2008)[54]	Ujjain district, Madhya Pradesh	Both	Private; allopathic, AYUSH, non-qualified; generalists, paramedical staff	Questionnaire	Random*	143 providers	1*	2, 9, 13
Dhingra (2002)[55]	Delhi, Union Territory	Urban	Public, private; tradition NR; generalists	Questionnaire	Comprehensive*	269 patients	0*	2
Fochsen (2006)[30]	Ujjain district, Madhya Pradesh	Rural	Public, private; tradition NR; training NR	Questionnaire	Random*	445 patients	NR	2
Garg (2013)[56]	Delhi, Union Territory	Urban	Private; allopathic; generalists	Questionnaire	Random*	101 providers	NR	2, 9, 13

George (2013)[23]	Multiple districts in Uttar Pradesh and Karnataka	Urban	Public, private; allopathic, AYUSH, non-qualified; training NR*	Questionnaire	Random*	1500 patients	NR	2
Greaves (2007)[35]	Thiruvananthapuram, Kerala	Both	Private; allopathic; specialists, generalists	Questionnaire	Random, convenience	45 providers	4*	2, 9, 13
Jaggarajamma (2009)[24]	Chennai, Tiruvallur, and Kancheepuram, Tamil Nadu	Both	Private; tradition NR; training NR	Questionnaire	Convenience	104 patients	0*	2
Kutare (2012)[37]	Bangalore, Karnataka	Urban	Sector NR; allopathic; generalists	Questionnaire	Convenience	207 providers	20*	1, 2, 5, 8, 12
Khadse (2011)[57]	Nagpur, Maharashtra	Urban	Private; allopathic, AYUSH, non-qualified; specialists, generalists	Questionnaire	Convenience	103 providers	2*	1, 2, 5, 8, 9, 10
Kondapaka (2012)[25]	Hyderabad, Andhra Pradesh	Urban	Public; allopathic; specialists	Chart abstraction; prescription audit	Random*	1132 patients	7*	8, 12
Krishnan (2009)[19]	Chennai, Tamil Nadu	Urban	Private; allopathic; specialists, generalists	Questionnaire	Random*	200 providers	NR	2, 4, 9, 10
Maseeh (2004)[26]	Ludhiana, Punjab	Urban	Private; allopathic; training NR	Chart abstraction	Convenience sampling	118 charts / patients;	0*	8

Mishra (2013)[27]	Nagpur, Maharashtra	Urban	Public, private; allopathic; specialists, generalists	Prescription audit	Convenience sampling	210 prescriptions / patients	NR	8
Nagaraja (2012)[28]	Mysore, Karnataka	Both	Public, private; tradition NR; specialists, generalists	Questionnaire	NR	311 providers	22*	9
Pattanshetty (2010)[22]	Udupi district, Karnataka	Both	Public, private; allopathic; specialists, generalists	Questionnaire	Random*	116 providers	7*	2, 6
Rajeswari (2002)[58]	Chennai and Tiruvallur, Tamil Nadu	Urban	Private; allopathic; paramedical staff	Questionnaire	Random*	150 providers (pharmacists)	NR	9 (5%, aware about DOTS, 67% want to participate in DOTS)
Rajpal (2007)[29]	Delhi, Union Territory	Urban	Public, private; allopathic; generalists	Questionnaire	Convenience	287 providers	8*	2, 8, 9
Roy (2005)[59]	Khardah, West Bengal	Urban	Private; allopathic; training NR	Questionnaire	Convenience	55 providers	32	2, 8, 10
SangeethaBalamurugan (2013)[60]	Salem, Tamil Nadu	Urban	Private; allopathic; generalists	Questionnaire	NR	150 providers	NR	2, 8, 12
Sarkar (2011)[61]	Jalpaiguri district, West Bengal	Rural	Public; allopathic; training NR	Questionnaire	NR	4875 patients	7*	5
Shivaramakrishna (2014)[62]	Krishnagiri and Tiruvalur, Tamil Nadu	Both	Public; allopathic; generalists, paramedical staff	Questionnaire	Random	271 household contacts	20	18,19

Srivastava (2011)[31]	Gwalior, Madhya Pradesh	Both	Public, private; allopathic; training NR	Questionnaire	Convenience	200 providers	NR	1, 2, 10, 13
Suganthi (2008)[32]	Bangalore, Karnataka	Urban	Public, private; tradition NR; training NR	Questionnaire	Random*	61 patients	25	2
Suryakantha (2006)[63]	Davangere, Karnataka	Urban	Private; allopathic; generalists	Questionnaire	Comprehensive*	124 providers	NR	1, 2
Thakur (2006)[36]	Chandigarh, Punjab	Urban	Private; allopathic; training NR	Questionnaires, vignettes*	Random*	114 providers	NR	2, 8, 9, 21
Thomas (2006)[17]	Tiruvallur district, Tamil Nadu	Both	Public; allopathic; training NR	Questionnaire	Comprehensive*	423 patients	NR	5
Thomas (2009)[64]	Mysore, Karnataka; Tiruchirappalli, Tamil Nadu	Both	Public; allopathic; training NR	Questionnaire	Random*	495 patients	17*	14, 15
Udwadia (2010)[6]	Mumbai, Maharashtra	Urban	Private; allopathic, AYUSH; specialists, generalists	Questionnaire, vignettes*	Convenience	106 providers	5*	8, 12
Vandan (2009) [33]	Lucknow, Uttar Pradesh	Urban	Public, private; allopathic; generalists	Questionnaire	Comprehensive*	141 providers	17*	1, 2, 5, 9, 10
Vijay (2009)[65]	Mysore, Karnataka; Tiruchirappalli, Tamil Nadu	Both	Public; allopathic; training NR	Chart abstraction; questionnaire	Comprehensive*	4701 patients / charts	0*	14, 15
Vyas (2003)[34]	Ahmedabad, Gujarat	Urban	Public, private; allopathic; training NR	Questionnaire	Random*	225 providers	26	2, 9

Yadav (2006)[66]	Jamnagar, Gujarat	Urban	Sector NR; tradition NR; generalists	Questionnaire	Random*	42 providers	NR	2, 10
Yadav (2012) [67]	Meerut, Uttar Pradesh	Urban	Private; allopathic; specialists, generalists	Questionnaire	NR	154 providers	9*	8, 10

Abbreviations: AYUSH, ayurvedic, unani, siddha, and homeopathy; ISTC, International Standards of Tuberculosis Care 2009; NR, not reported;
[a]For each study, the following aspects of the provider mix are described: *sector* (public and/or private); *medical tradition* (allopathic, AYUSH, and/or non-qualified); and *training* (specialists, generalists, paramedical staff, and/or medical students)
[b]The sample could consist of the number of *providers* interviewed, the number of *patients* interviewed, or the number of *patient charts / prescriptions* audited
*Means that a specific indicator for a study meets "high" or "very high" quality; otherwise, it can be assumed to "medium", "low", or "uncertain" in quality for that indicator. The following study characteristics were evaluated using quality criteria: provider mix, methodology, sampling strategy, and survey non-response rate (see Tables 1 and 2).

Figure 1: Flow diagram indicating the process of selecting the studies for a systematic review on TB management in India

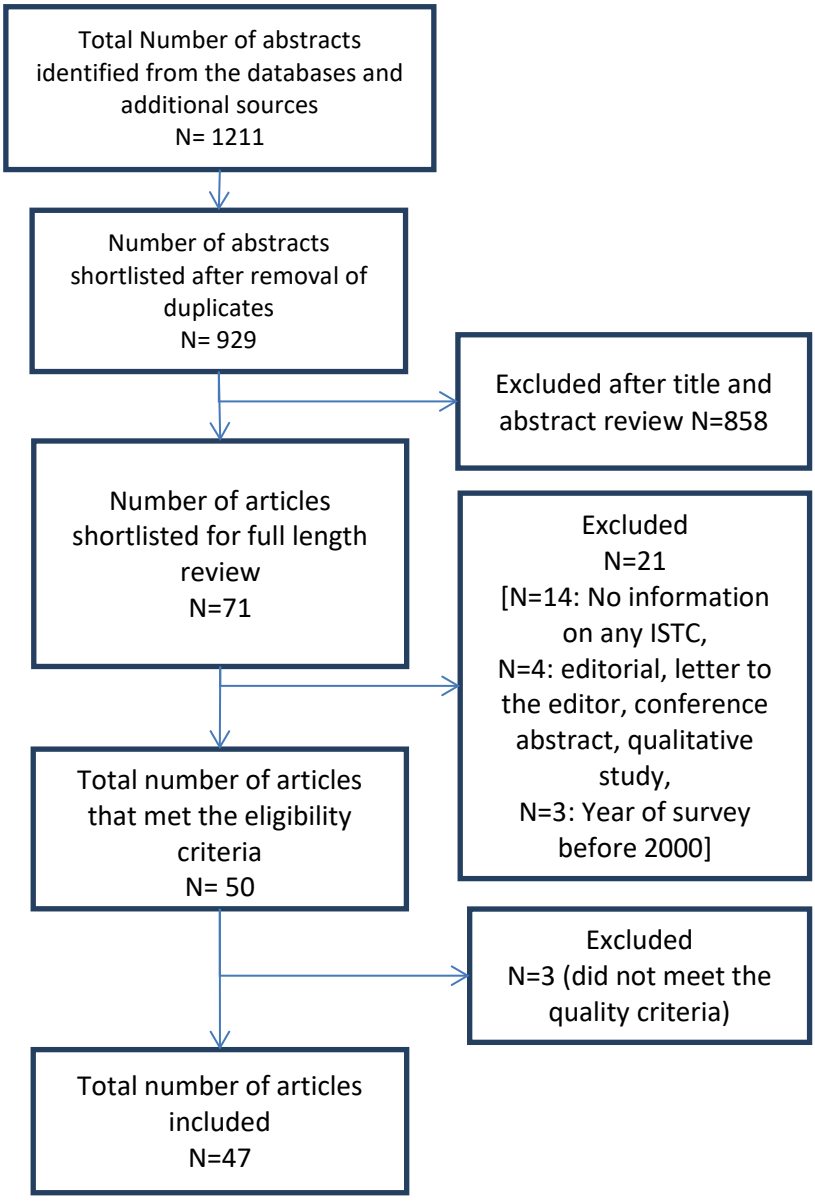
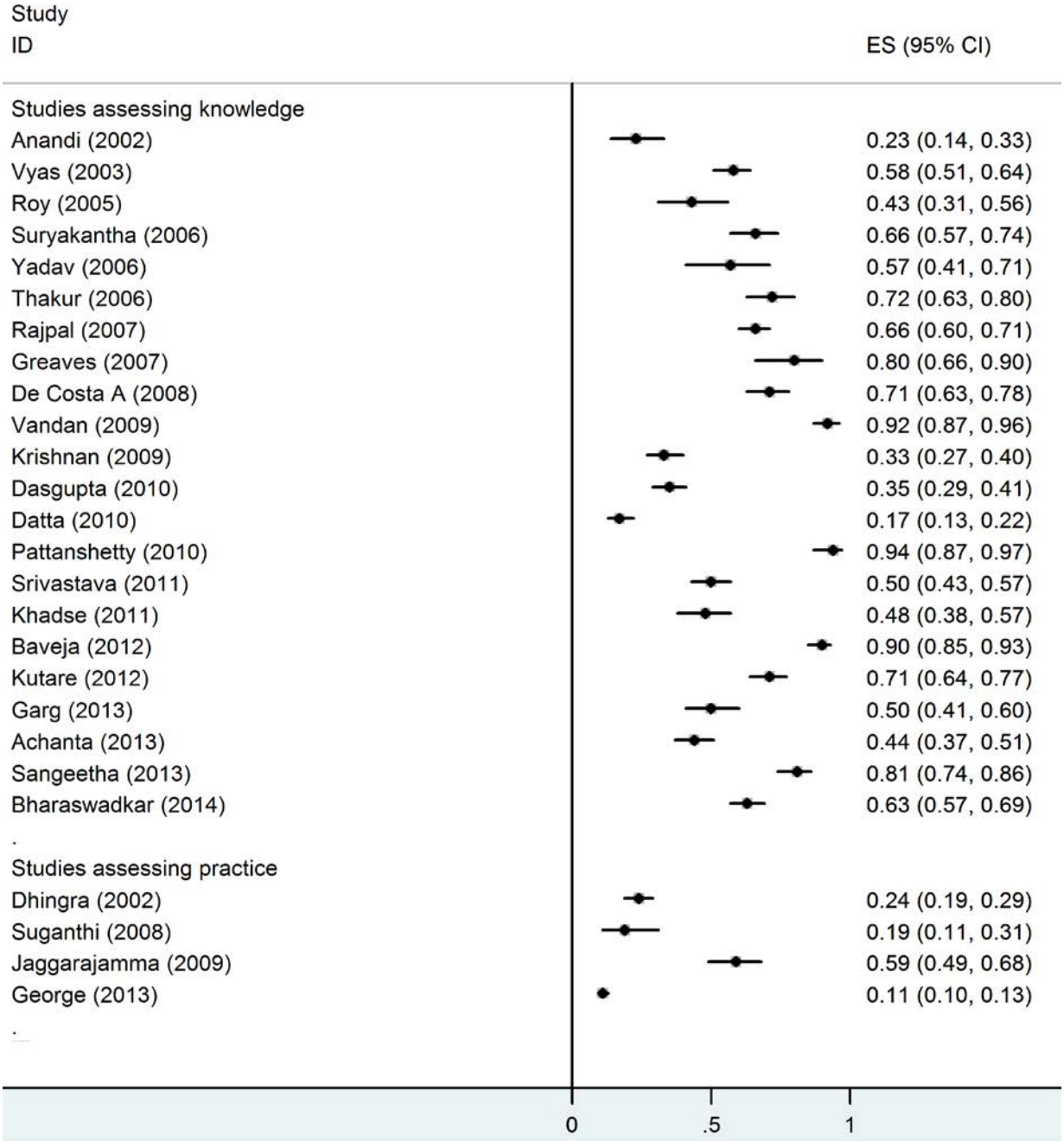
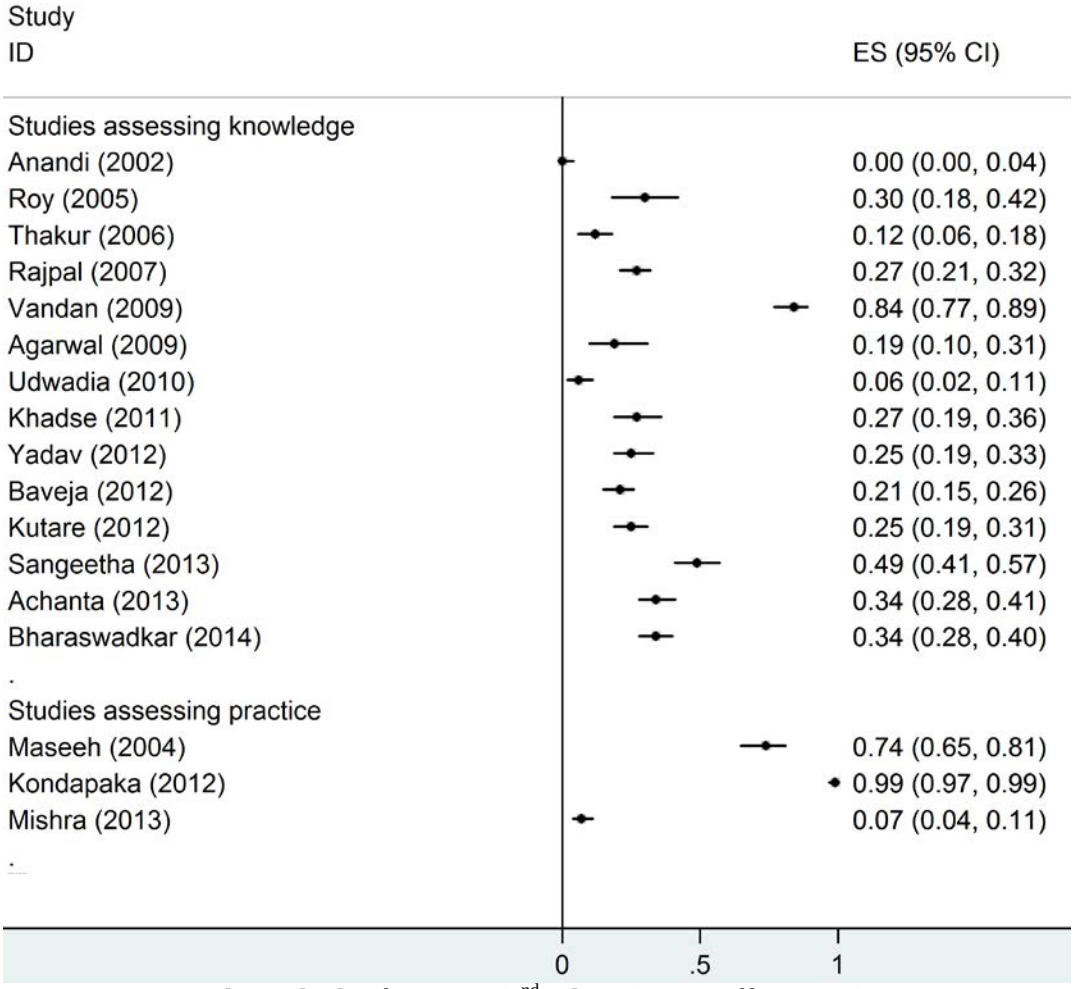


Figure 2: Forest Plot of Studies on ISTC Standard 2 [Aware/ use of sputum smear for persons with presumptive pulmonary TB]



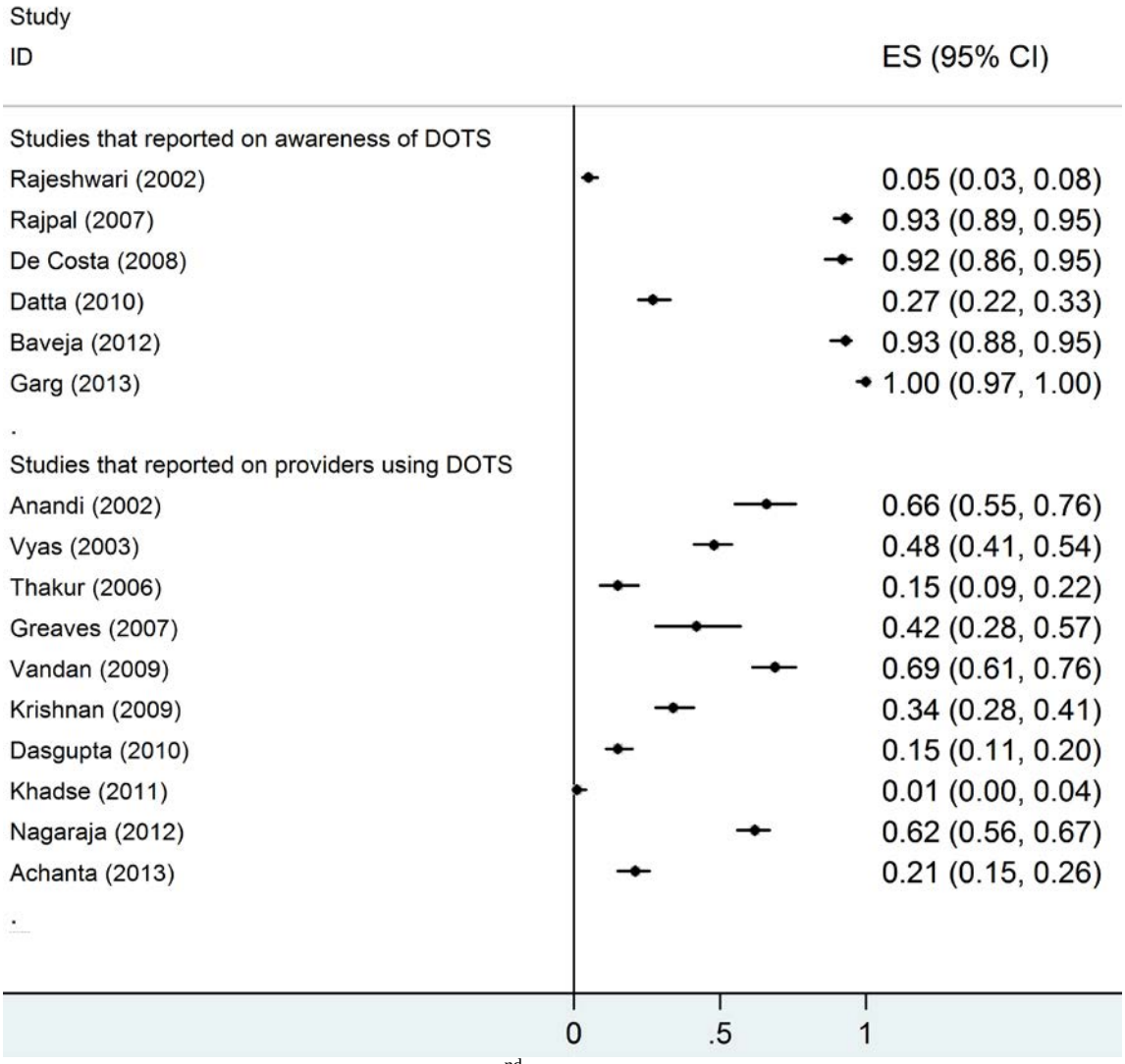
ISTC=International Standards of TB care (2nd Edition); ES= Effect size (proportion meeting standard)

Figure 3: Forest Plot of Studies in India on ISTC Standard 8 [Aware/ use of the correct treatment regimen for a new case of TB]



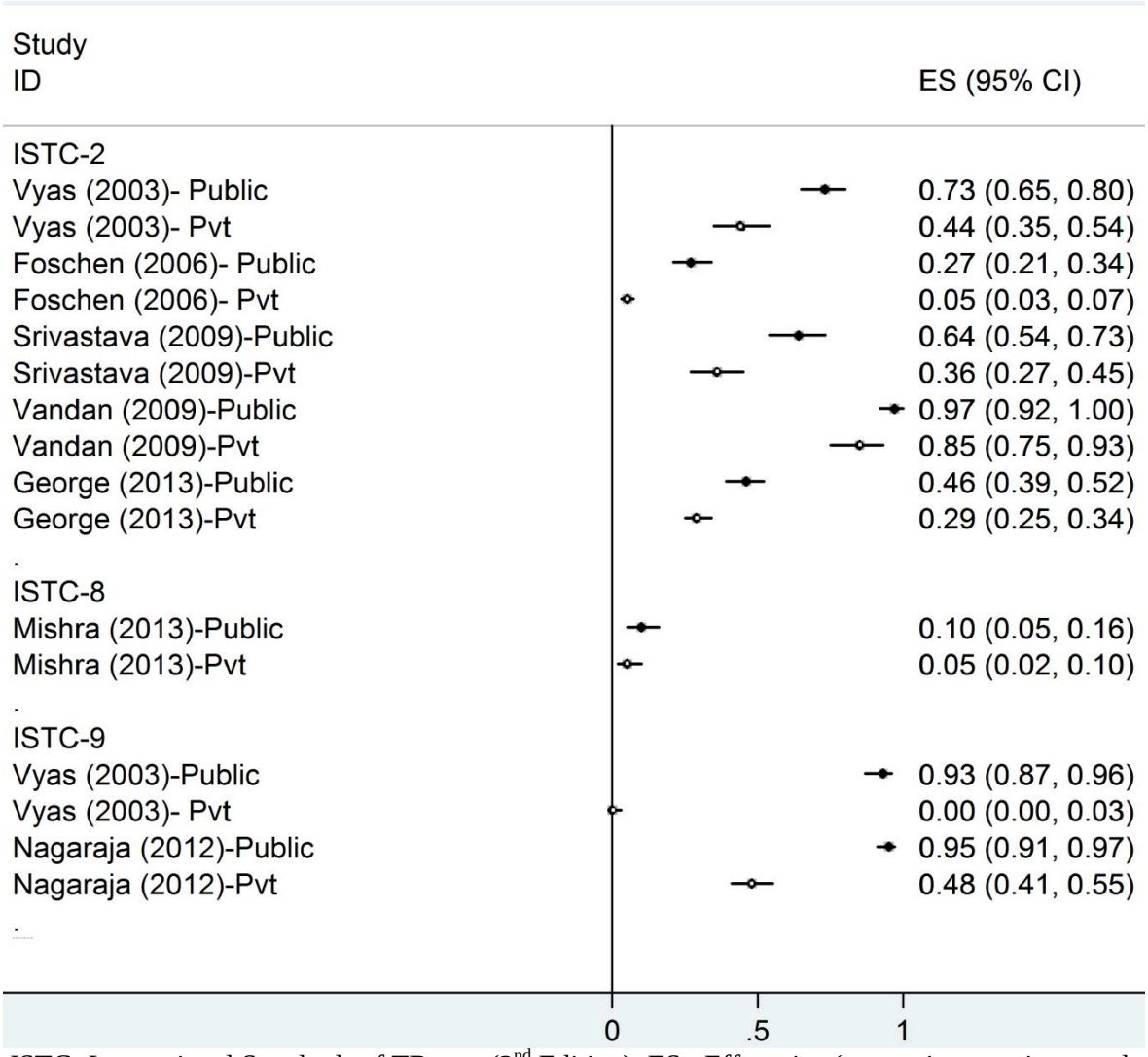
ISTC=International Standards of TB care (2nd Edition); ES= Effect size (proportion meeting standard)

Figure 4: Forest Plot of Studies in India on ISTC Standard 9 [Aware/ use of a supervised approach, including DOT, for the treatment of TB]



ISTC=International Standards of TB care(2nd Edition); ES= Effect size (proportion meeting standard)

Figure 5: Comparison of public versus private health care providers' awareness/ practice on ISTC standards 2, 8 & 9 in India



ISTC=International Standards of TB care (2nd Edition); ES= Effect size (proportion meeting standard)

2.2.10 Appendix (Manuscript 1)

Appendix-1

PubMed Search Update, September 17, 2014

(((((("tuberculosis"[mesh]) OR ("mycobacterium tuberculosis"[mesh]) OR (tuberculosis[tw]) OR (tb[tw])) AND (("India"[Mesh]) OR (India*[tiab]) OR (India[ad]))) AND ((((("Health Knowledge, Attitudes, Practice"[Mesh]) OR ("Quality of Health Care"[Mesh]) OR (knowledge[tiab]) OR (manage*[tiab]) OR (practic*[tiab]) OR (standard*[tiab]) OR (awareness[tiab]) OR (complian*[tiab]) OR (attitude*[tiab])) AND (("health personnel"[mesh]) OR (provider*[tiab]) OR (medical officer*[tiab]) OR (physician*[tiab]) OR (doctor*[tiab]) OR (clinician*[tiab]) OR (private practi*[tiab]) OR (public practi*[tiab]) OR (medical practi*[tiab]) OR (pharmacist*[tiab]) OR (nurse*[tiab]) OR (paramedic*[tiab]) OR ((chemist[tiab] OR chemists[tiab])) OR (AYUSH[tiab]) OR (Ayurved*[tw]) OR (Unani[tiab]) OR (Siddha[tiab]) OR (Homeopath*[tiab]) OR (practitioner*[tiab]) OR (allopath*[tiab]) OR ("internship and residency"[mesh]) OR (intern[tiab] OR interns[tiab] OR internship*[tiab]) OR (resident[tiab] OR residents[tiab]) OR ((residency[tiab] OR residencies[tiab])) OR (medical student*[tiab]) OR (health personnel[tiab]))) OR ("Physician's Practice Patterns"[Mesh]) OR ("Standard of Care"[mesh]) OR ("Guideline Adherence"[Mesh]) OR ("Inappropriate Prescribing"[MESH]) OR (("International Standards"[tiab] AND "Tuberculosis Care"[tiab])) OR (ISTC[tiab]) OR (treatment practice*[tiab]) OR (diagnostic Practice*[tiab]) OR (Prescription Practice*[tiab] OR prescribing practice*[tiab])) AND (("2000/01/01"[PDat] : "2014/12/31"[PDat]))) AND (("2013/10/11"[Date - Entrez] : "3000"[Date - Entrez])))

Web of Science Search Update, September 17, 2014

TS=((tuberculosis OR tb)) AND TS=(India*) AND TS=(((knowledge OR attitude* OR practi* OR quality OR manage* OR complian* OR standard* OR awareness OR attitude*) AND (health personnel OR provider* OR medical officer* OR physician* OR doctor* OR clinician* OR private practi* OR public practi* OR medical practi* OR pharmacist* OR nurse* OR paramedic* OR chemist OR chemists OR AYUSH OR Ayurved* OR Unani OR Siddha OR Homeopath* OR practitioner* OR intern OR interns OR internship* OR resident OR residents OR medical student* OR residency OR residencies)) OR ("guideline adher*" OR inappropriate prescri* OR standard of care OR practice pattern* OR international standards for tuberculosis care OR treatment practice* OR ISTC OR diagnostic practice* OR prescription practice* OR prescribing practice*))

Timespan: 2000-2014. Indexes: SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH.

Database: Embase <1996 to 2014 Week 37>

Search Strategy:

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2 mycobacterium tuberculosis/ (36754)
3 tuberculosis.mp. (111962)
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7 india*.mp. (144992)
8 india.ad. (332698)
9 or/6-8 (395635)
10 attitude to health/ (64707)
11 exp health care quality/ (1834369)
12 professional knowledge/ (9381)
13 exp professional practice/ (217631)
14 "medical record review"/ (57260)
15 case management/ (7514)
16 knowledge.tw. (417133)
17 manage*.tw. (842603)
18 clinical practice/ (167874)
19 practic*.tw. (682501)
20 complian*.tw. (100327)

21 professional standard/ (23125)
22 medical audit/ (32487)
23 awareness.tw. (95142)
24 attitude*.tw. (86772)
25 or/10-24 (3412417)
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27 provider*.tw. (103177)
28 medical officer*.tw. (1746)
29 physician*.tw. (271531)
30 doctor*.tw. (88726)
31 clinician*.tw. (147782)
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Appendix 2: Results of studies on ISTC standards 1, 5, 10, 13 & 18

Standard 1 [Aware/suspect TB in persons with more than 2 weeks of cough]

Six studies provided information on this standard, and all assessed knowledge [Appendix 2, Figure 1, page 73]. The proportion of healthcare providers who were aware that TB should be suspected in persons with cough of 2-3 weeks or more ranged from 21%[53] to 81%.[63] One study compared public versus private and reported that 89% of government providers knew that cough >2-3 weeks warranted sputum examination (Standard 1), as opposed to only 48% of private providers.[31] [Appendix 2, Figure 3, page 75]

Standard 5 [Aware/use a combination of sputum smear negative report and chest X-Ray for diagnosis of sputum smear negative pulmonary TB]

Of the 7 studies that provided information on this standard, 4 studies reported on awareness and two studies[61,17] reported on practice [Appendix 2, Figure 1, page 73]. The correct knowledge for this standard ranged from as low as 4%[37] to as high as 69%.[57] The 3 studies assessing practice followed patients in the government's TB registers who had submitted two sputum samples that were both smear-negative. While two studies found that 39% of patients subsequently received a chest radiograph to complete the diagnostic evaluation for smear-negative TB, one study found that it was only 5%.[16,61,52] One study that compared public versus private reported that 39% of public providers could correctly cite the appropriate criteria for diagnosis of smear-negative TB (Standard 5) as compared to only 26% of private providers.[33] [Appendix 2, Figure 3, page. 75]

Standard 10 [Aware/use sputum microscopy to monitor response to therapy]

Nine studies reported on this standard, and all assessed provider knowledge [Appendix 2 Figure 1, page 73]. Except for two studies[20,33], all other studies reported that less than 40% of the providers were aware that sputum smear microscopy is required for monitoring response to therapy for smear-positive patients. The remaining providers either used clinical improvement and/or chest radiography to assess response to therapy. Two studies that compared public versus private showed that public providers were more likely to order follow-up sputum smears as part of treatment monitoring. [31,33] [Appendix 2, Figure 3, page 75]

Standard 13 [Maintain written record of TB patients initiated on treatment]

Five studies assessed whether providers maintained written records of treatment [Appendix 2, Figure 2, page 74]. All five studies reported low levels of record maintenance. In one study,[56] it was found that none of the health care providers in their study reported having a system to maintain written records. Another study[54] assessed willingness of the health care providers to maintain records and found that the majority of private sector providers were not willing to keep records. One study that compared public versus private showed that 95% of public providers reported keeping a written treatment record for patients (Standard 13) as compared to 2% of private providers.[31] [Appendix 2, Figure 3, page 75]

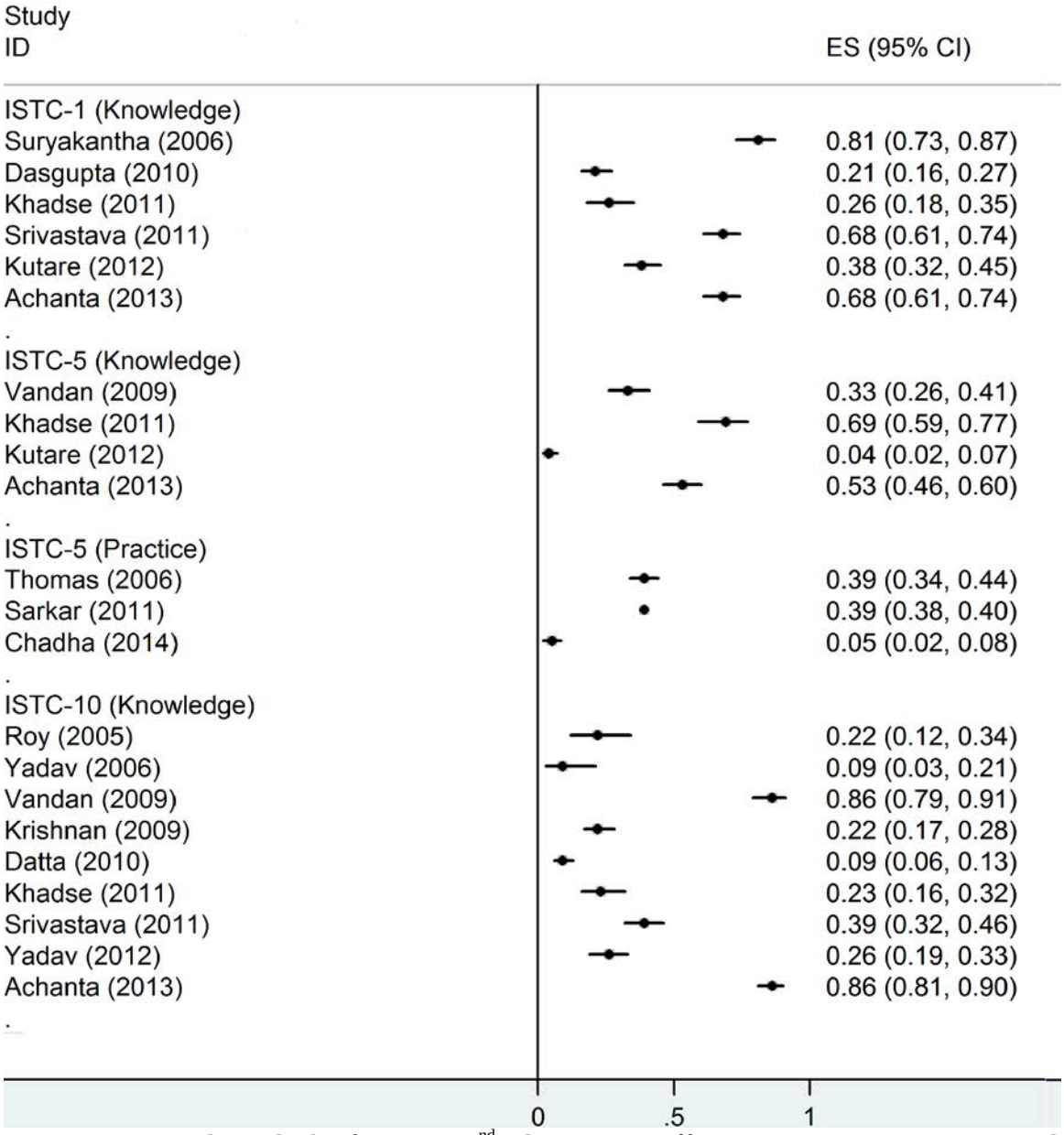
Standard 18 [Screening household contacts for TB]

Of the 6 studies, 2 studies assessed providers' knowledge on screening household contacts, in-particular children aged <6 years and four studies assessed practice pertaining to screening children. The studies that assessed knowledge were both done among providers in the private sector and showed very low levels (13%[21] and 19%[53]) of screening. The practice of screening children aged <6 years was assessed in four studies, all in the public sector treated TB patients, and the levels ranged from 14%[47] to 80%[62].

Drug-resistant tuberculosis

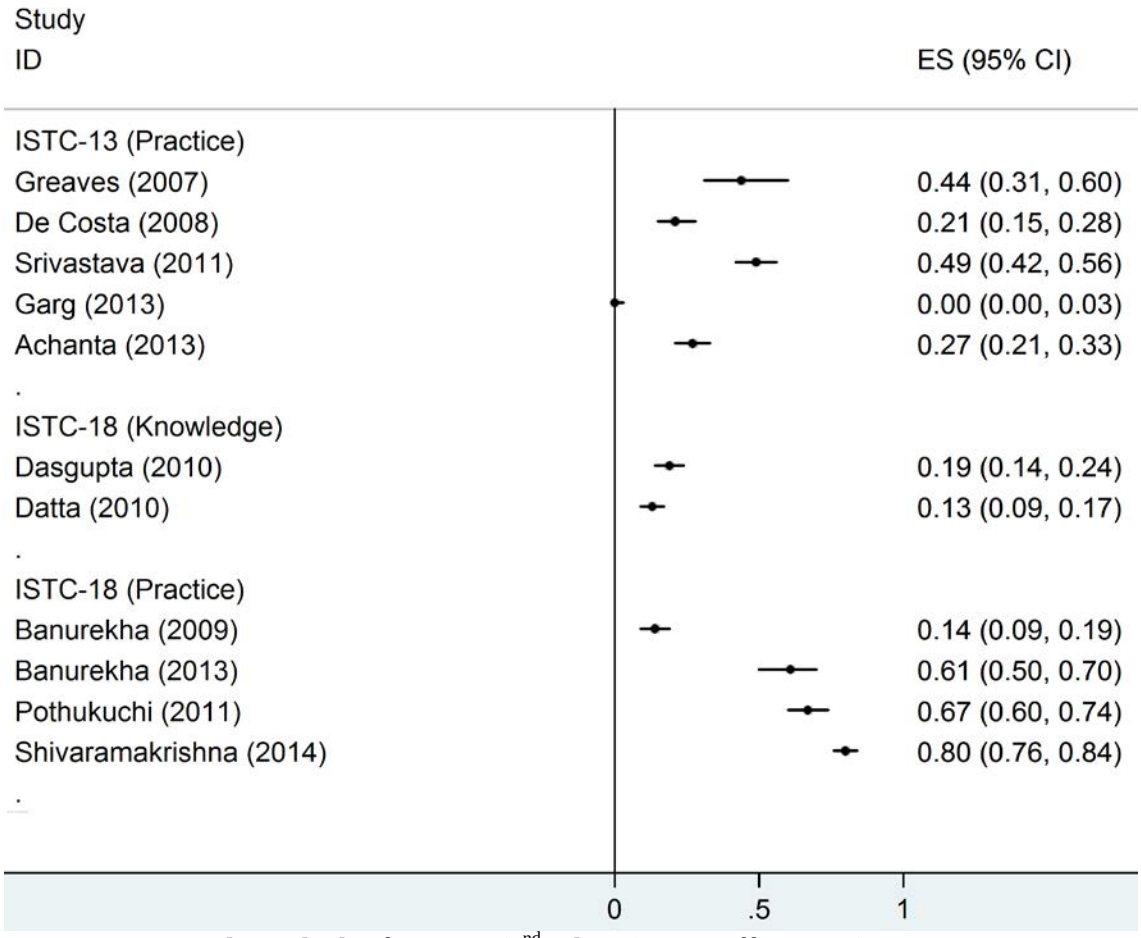
Included studies provided limited information on how Indian providers diagnose and manage drug-resistant TB. ISTC Standard 11 recommends culture and drug-susceptibility testing (DST) for individuals with a history of prior TB treatment, ongoing smear-positivity after three months of treatment, and treatment failure or relapse. The only study evaluating this standard found that 39% of providers report performing DST in such cases.[20] Another study of patients registered with the RNTCP in Mumbai and rural areas around Pune suggests that many such patients were "missed" by the system: 11% of patients who had already been placed on first-line TB therapy actually had a history of prior TB, which should have merited DST during the initial provider assessment.[46]

Appendix 2, Figure 1: Forest Plot of Studies on ISTC* Standard 1 in India [Aware/Suspect TB in persons with cough of 2-3 weeks], ISTC Standard 5 [Aware/use of a combination of chest X-Ray and sputum examination for diagnosis of sputum negative pulmonary TB] and ISTC Standard 10 [Aware/ use of sputum microscopy to monitor response to therapy]



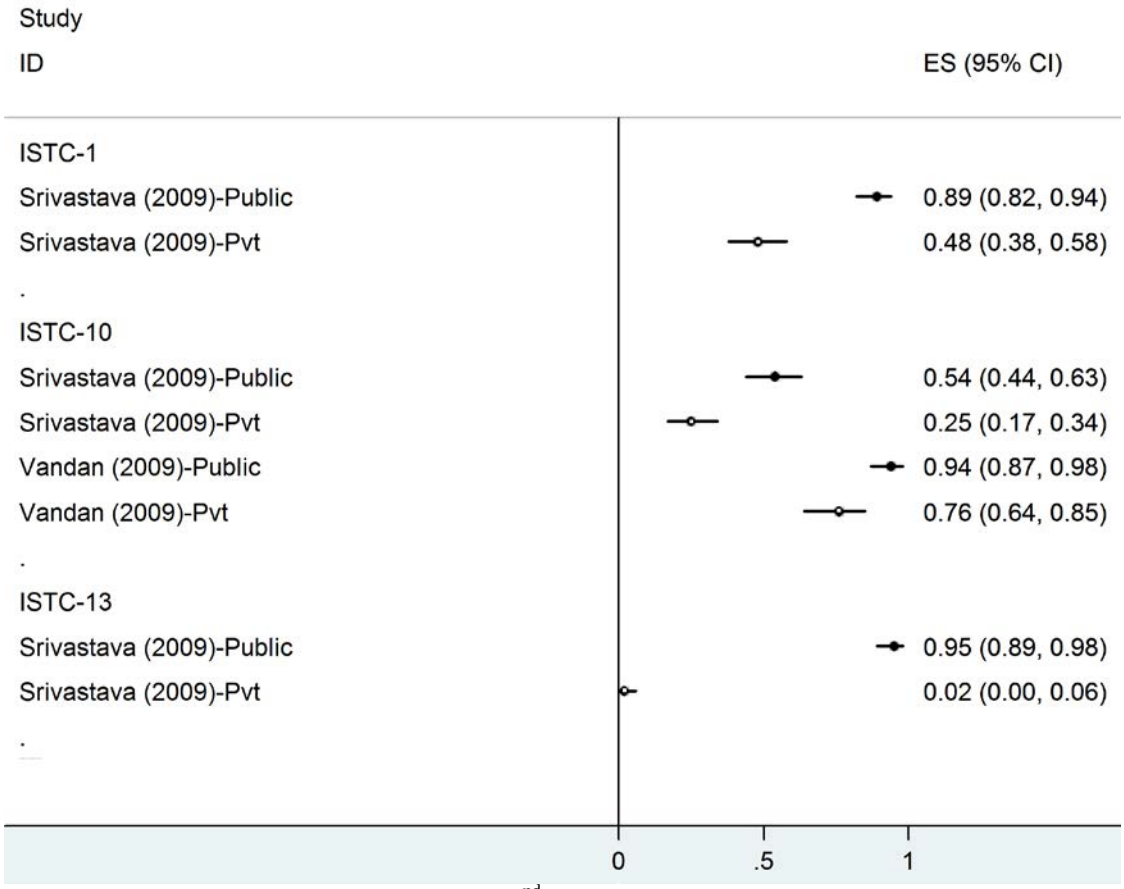
ISTC=International Standards of TB care (2nd Edition); ES= Effect size (proportion meeting standard); (knowledge)= Studies assessing knowledge; (Practice)= Studies assessing practice

Appendix 2, Figure 2: Forest Plot of Studies in India on ISTC Standard 13 [Maintenance of a written record of TB patients initiated on treatment] and ISTC Standard 18 [screening household contacts for TB]



ISTC=International Standards of TB care (2nd Edition); ES= Effect size (proportion meeting standard); (knowledge) = Studies assessing knowledge; (Practice) = Studies assessing practice

Appendix 2, Figure 3: Comparison of public versus private health care providers' awareness/ practice on ISTC standards 1, 10 & 13 in India



ISTC=International Standards of TB care (2nd Edition); ES= Effect size (proportion meeting standard);

Chapter 3: Pharmacy practices for patients with tuberculosis

3.1 Preface

Studies that have assessed the care-seeking behavior of TB patients in India have revealed that they initially visited local chemists/pharmacists, and sought 'over-the counter' (OTC) medical advice and drugs for the relief of their symptoms. These studies, however, do not provide any insight into the content of medical advice or the nature of drugs they received from the pharmacists.

Furthermore, according to the State of the World's Antibiotics report (2015), India consumes the most antibiotics of any country and ranks second in the world in per capita antibiotic use. India also has the highest rates of drug resistant bacterial pathogens in the world, probably driven by rampant antibiotic misuse, a high burden of infectious diseases, easy access to antibiotics (mostly OTC), and a fragmented, unregulated, privatized healthcare system. Indeed, nearly 750,000 pharmacies (chemist shops) provide healthcare to 25% of the population, primarily the poor who cannot afford to consult a doctor. In India, all antibiotics and steroids are listed in "schedule H" under the Ministry of Health and Family Welfare Department of Health's Drugs and Cosmetics Rules, 1945. This means that, legally, dispensing them to patients requires a prescription from a qualified medical practitioner. However, because of weak enforcement of the schedule 'H' drug policy, pharmacists give antibiotics to patients without prescriptions.

Apart from specific anti-TB drugs, antibiotics such as fluoroquinolones and steroids are known to affect TB disease and its symptoms. Data show that fluoroquinolones are among the most widely used antibiotics in India. When these drugs are taken for a short duration of time, the symptoms of TB subside temporarily, which can lead to a delay in diagnosis and treatment. Fluoroquinolone monotherapy in patients with TB disease can cause fluoroquinolone drug resistance. Ideally, for patients presenting with TB symptoms, the pharmacists are expected to refer them to a qualified healthcare provider without dispensing drugs such as antibiotics and steroids. However, we do not know whether pharmacists dispense these drugs (especially fluoroquinolones) to persons with TB symptoms and disease without a valid prescription from qualified medical practitioners. We used the standardized patient methodology for this study. The use of standardized patients to study pharmacist practice is not new, but our study was the first one to use standardized patients for assessing how pharmacists manage persons with suspected and diagnosed TB. The **overall goal** was to assess 'over-the-counter' medical advice and drug dispensing practices of pharmacists for

standardized patients presenting with classic symptoms of pulmonary TB and with those with sputum smear positive pulmonary TB disease. For this I did a secondary analysis of the data from an ongoing study involving 622 pharmacies in Delhi, Mumbai and Patna in India. The study will be published in Lancet infectious diseases (expected date: 24th Aug, 2016).

3.2 Manuscript-2: Use of standardised patients to assess antibiotic dispensing for tuberculosis by pharmacies in urban India: a cross-sectional study

Authors: Srinath Satyanarayana, MD[1], Ada Kwan, MHS[2], Benjamin Daniels, MS[2], Ramnath Subbaraman[3], MD, Andrew McDowell, PhD[1], Sofi Bergkvist, MS[4], Ranendra K. Das, PhD[5], Veena Das, PhD[6], Jishnu Das, PhD[2,7]*, Madhukar Pai, MD, PhD[1]*

[1]McGill International TB Centre & Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montreal, Canada

[2]Development Research Group, The World Bank, Washington DC, USA

[3]Division of Infectious Diseases, Brigham and Women's Hospital and Harvard Medical School, Boston, USA

[4]ACCESS Health International, Hyderabad, India

[5]Institute for Social and Economic Research on Development and Democracy, Delhi, India

[6]Department of Anthropology, Johns Hopkins University, Baltimore, USA

[7]Center for Policy Research, New Delhi, India

*Contributed equally

Manuscript details

Word count: Abstract- 250 words: Main text -3554 words

Number of tables: 2

Number of figures: 4

Number of references: 29

Number of supplementary appendices: 1

Short title: Antibiotic use by pharmacies in India

Key words: Pharmacy, Antimicrobial resistance, Antibiotic use, tuberculosis, standardized patients

3.2.1 Abstract

Background: Antibiotic use in India is the highest of any country. Patients frequently receive prescription-only drugs directly from pharmacies.

Methods: In a cross-sectional study, we used unannounced standardized patients (SPs) to assess how pharmacies managed patients presenting with (Case 1) classic pulmonary tuberculosis (TB) symptoms and (Case 2) confirmed TB with a positive sputum report. In Delhi, Mumbai and Patna, 622 pharmacies were sampled. SPs presented each case once to every pharmacy between April 2014 and November 2015. Ideal management for both cases was defined *a priori* as referral to a health care provider without dispensing antibiotics and/or steroids.

Findings: SPs completed 1200 of 1244 (96%) interactions. Ideal management occurred among 80 of 599 Case 1 interactions (13%; 95% CI: 11–16) and 372 of 601 Case 2 interactions (62%; 95% CI: 58–66). Antibiotic use was significantly lower in Case 2 (98 of 601 interactions (16%; 95% CI: 13–19)) than in Case 1 (221 of 599 interactions (37%; 95% CI: 33–41)). First-line anti-TB drugs were never dispensed in any city. The differences in antibiotic and/or steroid use and number of medicines dispensed between Case 1 and Case 2 were almost entirely attributable to the difference in referral behavior.

Interpretation: A minority of urban Indian pharmacies correctly managed patients with presumed TB, but a majority correctly managed a case of confirmed TB. No pharmacist dispensed anti-TB drugs for either case. Lack of a confirmed diagnosis is a key driver of antibiotic misuse and could inform antimicrobial stewardship interventions.

Funding

Grand Challenges Canada (Grant ID: S5 0373-01), Bill & Melinda Gates Foundation (grant OPP1091843), Knowledge for Change Program, World Bank Development Research Group.

3.2.2 Introduction

Antimicrobial resistance (AMR) is a global health emergency[1,2] with the indiscriminate use of antibiotics implicated as a major driver.[3,4] Although India ranks first in the world in total antibiotic use, the absence of data linking antibiotic use to underlying illnesses makes it harder to assess the appropriateness of such use given India's high infectious disease burden. With one of the highest prevalence rates of drug-resistant bacterial pathogens in the world, identifying the sources and circumstances of antibiotic *abuse* as opposed to *use* is a critical first step to understanding what can be done about it.[4] Here, we develop a unique methodology to address this gap, focusing our attention on a specific illness, tuberculosis (TB), and a specific source of healthcare — pharmacies.

Our choice of TB, a disease that affects 2.2 million Indians every year, as a lens through which to investigate antibiotic use is driven by several factors. The symptoms of early pulmonary TB are common, non-specific, non-severe and persistent. In this case, assessing pharmacist behavior provides a realistic and externally valid estimate of unnecessary antibiotic use. Further, indiscriminate drug use can harm both the patient and the efficacy of existing anti-TB treatments. For instance, TB symptoms subside temporarily with the use of fluoroquinolones or corticosteroids, delaying diagnosis and leading to the possibility that patients receive multiple antibiotic courses for the wrong diagnosis.[5] Partial courses of anti-TB drugs can result in drug-resistance.[6] Finally, international and national guidelines for the optimal management of TB cases[7,8] allow us to assess the extent of antibiotic misuse.

Our focus on pharmacies is premised on the belief that their practices contribute to the availability and use of antibiotics in the population.[4] This is in part due to their widespread availability—more than 750,000 private retail pharmacies provide easy access to medications.[9] But it also reflects the willingness of pharmacists to provide prescription-only medication to patients. Despite clear guidelines on the use of over-the-counter versus prescription-only drugs,[10] enforcement is widely believed to be suboptimal.[11,12] Pharmacies are thought to be dispensing antibiotics and anti-TB drugs without prescriptions. Many TB patients *do* seek medical advice and drugs from pharmacies[13], driven by the ease of access and the possibility of avoiding consultation charges by doctors.[14]

We have previously assessed the quality of TB care in India by healthcare providers using standardized patients (SPs) and use a similar methodology to study the practices of staff at pharmacies.[15] While SPs are routinely used to assess pharmacy practices in low- and high-income countries [16], to our knowledge, no study has used SPs to assess pharmacy practices for TB in India. In our previous study, we validated the use of SPs for TB and demonstrated (a) the viability and accuracy of this method for measuring quality of TB care along a number of dimensions, including very low likelihood of detection; (b) minimal to no study participation risk for either SPs or healthcare providers; and (c) high levels of accurate recall of the clinical interaction among SPs. This paper complements our previous validation study by extending the methodology to pharmacists. The methodology developed here addresses the dual objectives of, first, assessing pharmacists' behavior and drug-use for a 'patient' with a complaint, but no prescription. Second, it allows us to assess how case management and drug use differs when the diagnosis is unknown versus confirmed.

3.2.3 Methods

Study design and setting

This cross-sectional study was conducted in Delhi, Mumbai and Patna. TB is a major problem in all three cities, with notification rates of 294, 210, and 77 per 100,000, respectively.[17] However, these rates are likely underestimated as many cases treated in the private sector are not notified.[18] All three cities are battling rising rates of drug-resistant TB, especially in the city of Mumbai[19], and it is widely believed that pharmacists are a key component of the dispensing landscape and often a first contact for primary care.

Guidelines for pharmacies are specified under the Ministry of Health and Family Welfare's Drugs and Cosmetics Rules Act, 1945.[10] All antibiotics and steroids are listed under two different schedules—Schedule H and Schedule H1. Schedule H drugs cannot be given to patients without a prescription from a qualified medical practitioner. In 2013, regulations were further tightened, with anti-TB drugs (isoniazid, rifampicin, ethambutol, pyrazinamide) and some fluoroquinolones (such as moxifloxacin and levofloxacin, used in the treatment of TB) listed on a newly created 'Schedule H1'. For H1 drugs, pharmacies require both a prescription from a qualified medical practitioner and

a separate register to record the name and address of the prescriber, the patient, the names of the drugs and the quantity supplied.[20] Schedule X, the most restrictive list, includes drugs such as narcotics, which require a prescription from a qualified provider to be retained by the retailer for two years.[21]

Through this multi-site study we aimed to assess the medical advice and drug dispensing practices of pharmacies for SPs presenting with either presumptive TB (Case 1) or clinically confirmed TB (Case 2). By assessing the difference in antibiotic use across the two cases for the *same* pharmacists, we are able to break down the relative importance of antibiotic misuse arising from the lack of diagnosis (Case 1) versus antibiotic use despite a confirmed diagnosis for which antibiotics are contraindicated (Case 2). Our benchmark for what pharmacists should do when faced with such patients is drawn from the Government of India and the Indian Pharmaceutical Association's guidelines. These specify that pharmacies should counsel patients about TB, identify and refer persons with TB symptoms to the nearest public health facilities for TB testing and play a role in providing TB treatment.[22] Therefore, pharmacists who were adhering to these guidelines should have referred the SPs to healthcare providers without dispensing either antibiotics or steroids, both of which require a prescription.

Standardized patients

The two SP cases used in our study were adapted from our validation study in Delhi.[15] SP Case 1 presents with 2-3 weeks of cough and fever, directly seeking medicines from a pharmacy. Differential diagnosis for the case includes upper respiratory tract infection, pneumonia, asthma and acute or chronic bronchitis; antibiotic use may be warranted for some of these conditions although not without the prescription of a doctor.

SP Case 2 presents with a month of cough and fever and a TB-positive lab report from a recent sputum smear test at a government dispensary. In this case, TB is confirmed, although the SP, who presents as an uninformed patient, makes it clear that he/she does not fully understand what the report says. This creates a situation where (a) the pharmacist plausibly knows the correct diagnosis and recognizes that short-term antibiotics will not help, but (b) also realizes that the patient will still purchase antibiotics if offered, given their ignorance of the test results. SPs did not present with drug prescriptions; their opening statements and case scenarios are shown in Table 1 (page 97). After each pharmacy visit, SPs were debriefed using a structured questionnaire within one hour of

the visit. The accompanying Supplementary Appendix (pages. 107-108) provides more details on the development of the cases as well as the recruitment and characteristics of the SPs in the study. Cases are available from the authors by request.

Selection of Pharmacies, SP visits and Study Size

SPs visited 54 pharmacies in Delhi using a convenience sample from 28 low-income localities in April 2014. This phase of the study validated the approach and provided key parameter estimates for power calculations employed in Mumbai and Patna. Based on these power calculations we sent SPs to 308 randomly sampled pharmacies in Mumbai and 260 in Patna between November 2014 and November 2015. Ninety six percent of all interactions were completed as planned, and we completed *both* cases with the sampled pharmacy for 93% of the sample. The Supplementary Appendix (pages 103-116) discusses the sample and sampling weights, case development, SP recruitment, sample size calculations, drug identification and deviations from the sampling scheme (Sections 1-4, pages 103-109).

Variables and Statistical Analysis

Our unit of analysis was a pharmacy-SP interaction irrespective of who (pharmacy owners, pharmacists or pharmacy assistants) the SP interacted with. Whether the case was correctly managed was assessed from a TB perspective, consistent with Standards for TB Care in India and International Standards for TB Care.[7,8] "Ideal management" for both cases was considered as verbal or written referral to a healthcare provider (public or private), without dispensing any antibiotics, including anti-TB drugs and fluoroquinolones, or steroids (Table 1, page 97).

We calculated the proportion and 95% CI for our primary outcome, the proportion of interactions that resulted in ideal management, as well as the proportion of interactions resulting in antibiotic, fluoroquinolone and steroid use with appropriate sampling weights (Supplementary Appendix, Table A2, page 105).

To assess the difference in case management and the use of drugs across the two SP cases, we used a random intercept logit model with indicator variables for each city as additional controls. Given the design of the study, where every pharmacy was attempted with both cases, the choice of model (logit, logit with fixed-effects, or logit with random intercepts) should all yield similar unbiased estimates, with differences arising only from the small portion of pharmacies that received one case

but not the other. However, coefficients from the random intercepts model will be more precisely estimated. The Supplementary Appendix (Section 6, pages 111-114) provides a series of alternate estimates, with both marginal effects and odds-ratios from different model specifications and confirm that the results are very similar across specifications. All analyses were done using Stata 13 (Stata Corporation, College Station, TX).

Ethical issues

Approvals from the ethics committee of McGill University Health Centre in Montreal, Canada and the Institute of Socio-Economic Research on Development and Democracy (ISERDD) in New Delhi, were obtained. Both ethics committees approved a waiver from obtaining informed consent from pharmacies in Mumbai and Patna. All individuals who participated as SPs were hired as staff and trained to protect themselves from any harmful medical interventions, such as avoiding injections, invasive tests or consuming any medicines at the pharmacy.

Role of the funding source

The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

3.2.4 Results

Table 2 (page 98) provides the mean proportions of the key outcome variables in all cities combined for Case 1 (Column 1) and Case 2 (Column 2). As the sampling scheme was different for Delhi compared to Mumbai and Patna, we also provide results excluding Delhi in Columns 3 and 4, and for each city by case (also Supplementary Appendix, Section 5, pages 109-110).

Management of Case 1 – a classic case of presumed TB

Overall, 96 of 599 pharmacies (16%; 95% CI: 13–19) referred Case 1 to health care providers, but because in 16 of these 96 cases the SP was also given an antibiotic or steroid (17%; 95% CI: 11–25), ideal case management (referral to a health care provider without any antibiotics and steroids) occurred in 80 of 599 Case 1 interactions (13%; 95% CI: 11–16). Overall, antibiotics were used in 221 (37%; 95% CI: 33–41), steroids in 45 (8%; 95% CI: 6–10) and fluoroquinolones in 61 (10%;

95% CI: 8–13) of 599 interactions. Because Schedule H drugs also include prescription-only drugs that are not antibiotics or steroid (ibuprofen or cetirizine), the use of these drugs was higher at 401 of 599 interactions (67%; 95% CI: 63-71). The use of Schedule H1 drugs was notably lower (37 of 599 or 6%; 95% CI: 4-8) and Schedule X drugs and anti-TB medication were never given.

Management of Case 2 – a TB case with positive sputum report

In contrast to Case 1, 401 of 601 pharmacies (67%; 95% CI: 63–70) referred Case 2 to a health care provider (Column 2, Table 2, page 98). As before, some patients received antibiotics and/or steroids even with a referral, so ideal case management occurred in 372 of 601 interactions (62%; 95% CI: 58-66). Antibiotics, steroids and fluoroquinolones were all used much less frequently, although Schedule H drugs were still given in 188 of 601 interactions (31%; 95% CI 28-35). As before, Schedule X and anti-TB drugs were never used.

Figure 1 (page 99) uses the random-intercept model together with indicator variables for each city to estimate the difference in pharmacy behavior for the main outcome variables as odds ratios. As is clear, all of these differences are highly statistically significant and precisely estimated. For instance, the adjusted odds of pharmacies referring a SP with a sputum smear positive TB report to a health care provider without dispensing antibiotics and steroids was 21.03 (95% CI: 12.33–35.86; $p < 0.0001$) for Case 2 relative to Case 1; the odds-ratio for antibiotic use was 0.21 (95% CI: 0.15 to 0.31; $p < 0.0001$) and for fluoroquinolones 0.31 (95% CI: 0.18 – 0.53; $p < 0.0001$). We also note that of the 497 referrals across the two cases, 301 or 60.5% were to doctors in the private sector and the remaining 39.5% were to the public sector (data not shown). In only three instances was the SP referred specifically to a DOTS center.

Behavior Conditional on Referral

The differences between Case 1 and Case 2 reflect, to a significant degree, the large increase in referrals for Case 2. Figure 2 (page 100) shows the proportion of interactions that received antibiotics and/or steroids or no medicines separated by case and referral decision. Both for Case 1 and Case 2, the use of antibiotics and/or steroids as well as the total number of medicines plummets when the pharmacist refers the patient (0.75 for Case 1 (95% CI: 0.48-1.02) and 0.38 for Case 2 (95% CI: 0.29-0.46); data not shown). However, conditioning on the decision to refer, the difference in pharmacist behavior across the two cases is much smaller.

Variation across Cities

The practice of pharmacies varied across cities, although caution is warranted in interpreting these results as the specific sampling methodologies were different (Appendix Table A1, page 104). We found similar patterns across the three cities of relatively high use of Schedule H drugs, referrals and ideal case management (Figure 3, page 101). Two differences worth highlighting are that (a) compared to Mumbai, the use of antibiotics, steroids, fluoroquinolones, and Schedule H1 medications were all much higher in Patna, and (b) there was zero fluoroquinolone use in Delhi and relatively little use in Mumbai compared to Patna. These differences are robust to adjusting for differences in the SPs used across different cities, an analysis that we conduct by comparing outcomes only among the (smaller) group of SPs who were common to two or more cities (Supplementary Appendix, Section 7, pages 114-115).

Type of Medicines Dispensed

It is also of interest to look at the specific medicines given (Figure 4, page 102). For Case 1, pharmacies dispensed 2.09 medicines on average (95% CI: 1.99–2.20). The most common classes of medicines dispensed were analgesics such as paracetamol and nimesulide; antibiotics; cough syrups; and anti-allergy drugs. Among antibiotics, amoxicillin was the most common, and 61 of 599 (10%; 95% CI: 8–13) pharmacies dispensed fluoroquinolones (ciprofloxacin, levofloxacin, ofloxacin), while 45 of 599 gave steroids such as betamethasone and prednisolone (8%; 95% CI: 6–10). For Case 2, pharmacies dispensed 0.98 medicines on average (95% CI: 0.88–1.09). The classes of medicines dispensed for Case 2 were similar to Case 1, although the overall frequencies were considerably lower. This is again consistent with the result that the difference in behavior between the two cases was driven, to a large extent, by the sharp increase in referrals for Case 2.

3.2.5 Discussion

To our knowledge, this is the first study that uses SPs to examine how pharmacies in India treat patients with TB symptoms and diagnosed TB, complementing our recent study to assess TB management among healthcare providers.[15] As the SP methodology standardizes the presentation of the underlying condition across different providers,[23] the results are reliable, valid and comparable across pharmacies. The similar patterns we observe across the three cities suggest that the results may be generalizable to other urban areas in India.

A key positive finding is that none of the pharmacies in our study dispensed first-line anti-TB medications. Concerns regarding the use of anti-TB drugs by pharmacies appear to be unfounded, at least in major cities, and pharmacies are unlikely sources of irrational drug use that contributes to MDR-TB. Why pharmacists do not dispense TB drugs requires further research, but the fact that TB drugs (unlike antibiotics such as amoxicillin) are considered toxic and that TB requires long-term therapy might play a role. It is also possible that pro-activeness of the Indian National TB Control Program in including TB drugs under Schedule H1, and the requirement to document TB drug prescriptions have reduced abuse. On the negative side, our study shows that nearly 38% of the pharmacies dispensed antibiotics or steroids to persons with TB symptoms but no test results. The use of fluoroquinolones in 7% and steroids in 5% of interactions is particularly worrisome because these drugs are known to delay TB diagnosis.[5,24] In addition, fluoroquinolones are also an essential part of MDR-TB treatment regimens and emerging regimens, so quinolone abuse is a concern.[5]

The widespread use of antibiotics and steroids for respiratory symptoms also has implications for community-acquired infections more generally. Unnecessary use of fluoroquinolones is a major risk factor for creating highly resistant gram-negative enteric bacteria (e.g., extended spectrum beta-lactamase resistance) that may cause diarrheal illness, bacteremia, and other infections, especially in the Indian context.[25] The considerable use of aminopenicillins (e.g., amoxicillin) and macrolides (e.g., azithromycin) for respiratory symptoms identified in our study may contribute to resistant strains of common respiratory pathogens such as *S. pneumonia* and *H. influenzae*.[26] In addition to potentially delaying TB diagnosis, unnecessary use of steroids is associated with an increased risk of developing lower respiratory tract infection, cellulitis, herpes zoster, and candidiasis.[27]

Our study also clearly shows that a first-order problem both in the management of tuberculosis and AMR is the information that patients present to the pharmacist. Confirmed diagnosis discipline what pharmacists do, with sharp increases in ideal management and large declines in antibiotic use. This dramatic difference indicates that perhaps the primary challenge faced by pharmacists is confusion about the likely diagnosis, in which case better training regarding TB symptoms and encouraging early referrals for patient with TB symptoms might help.

Lastly, our study demonstrates the value of the SP methodology in tracking inappropriate antibiotic use.[28] While prescription audits can be used, prescriptions do not capture the off-prescription use of drugs and often do not include diagnoses.

3.2.6 Limitations

Although the behavior change in Case 2 suggests that pharmacists significantly decrease the use of unnecessary medications when the diagnosis is known, we do not fully understand why some pharmacists give antibiotics and others do not; neither can we uncover the *reasons* why pharmacists are unwilling to follow regulations regarding drug use in these three cities. It is unclear whether the variation in our data is explained by the competence/qualification of the person providing advice in pharmacies, which we did not track in the study. Qualitative evidence suggests that a combination of other factors may also be at play, including pharmaceutical industry marketing techniques, business models followed by local providers, and active demand from patients for medicines.[11,29] Pharmacists in Delhi have described overstock, near-expiry and undersupply as further factors precipitating misuse of antibiotics and restricted drugs.[11]

Second, we uncovered significantly higher use of antibiotics and quinolones in Patna relative to Mumbai pointing to some differences across cities. We are able to rule out that these differences reflect the composition of SPs deployed across cities (Supplementary Appendix, Section 6.1, pages 113-114), but with an effective sample size of only 3 cities, we cannot explain this variation. Also, our study does not provide evidence on how pharmacists in rural areas manage patients with TB or TB symptoms.

Third, our study reflects what happens when pharmacists receive a completely unknown patient as opposed to a known, regular client, or a client who *returns* to the pharmacist after one round of ineffective treatment. We note though that only 5-6% of pharmacists asked the patient to return (if they did not feel better). See Supplementary Appendix, Table A4, Columns 1 and 2 (page 110), "Asked SP to Return". Fourth, differences between Case 1 and Case 2 could reflect variation in the SP profile. As different SPs were assigned to the two cases with no crossover, we cannot assess this possibility. In general, the inclusion of SP characteristics has little impact on estimated coefficients in previous SP studies and our coefficients remain stable when we account for SP sex, height and weight (Supplementary Appendix, Section 6.1, pages 113-114).

3.2.7 Conclusion

Our study adds to the growing evidence in India on antibiotic abuse, but also underscores that the use of antibiotics is mediated by drug category and the information that patients present. Although antibiotic use is high and such use can delay diagnosis, none of the pharmacies dispensed anti-TB drugs and the use of stronger fluoroquinolone antibiotics and heavily restricted drug classes was relatively low. Furthermore, the use of all antibiotics declined sharply when the patient's diagnosis was revealed to the pharmacists. These findings can inform interventions to engage pharmacies in TB control and antimicrobial stewardship.

Author contributions

JD and MP obtained funding and designed the study. JD, AK, SS, VD, and MP developed the SP cases and scripts. AK and RKD, conducted data collection or supervised data collection. BD, SS, RS coded the data. VD, MP, and AK trained the standardized patients. SS, JD, AK and BD analyzed the data. SS, JD, BD, AK, RS, AM and MP interpreted the data. The manuscript was written by SS, JD, BD, MP, AK, and SB, and all authors provided critical review and comments to the revision of the manuscript.

Acknowledgements:

SS is supported by a fellowship from the Canadian Thoracic Society and is also a senior operations research fellow at Center for Operational Research, The Union (Paris, France). RS is supported by a Fogarty Global Health Equity Scholars Fellowship (NIAID R25 TW009338). JD and BD received funds from the Knowledge for Change Program (The World Bank). MP is a recipient of Tier 1 Canada Research Chair from Canadian Institutes of Health Research.

The authors are grateful to Puneet Dewan, Sarang Deo, Nim Pathy, Vaibhav Saria for useful input on analysis and interpretation. We also thank Rajan Singh, Purshottam, Chinar Singh, Geeta, Devender, Varun Kumar, Anand, Babloo and Charu Nanda who supervised and implemented the ISERDD field work and all the SPs for their dedication and hard work. The findings, interpretations, and conclusions expressed here are those of the authors and do not necessarily represent the views of the World Bank, its Executive Directors, or the governments they represent.

Conflicts of interest disclosure:

MP serves as a consultant for the Bill & Melinda Gates Foundation. He has no financial conflicts to disclose. All other authors have no conflicts to disclose.

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3.2.9 Tables and figures

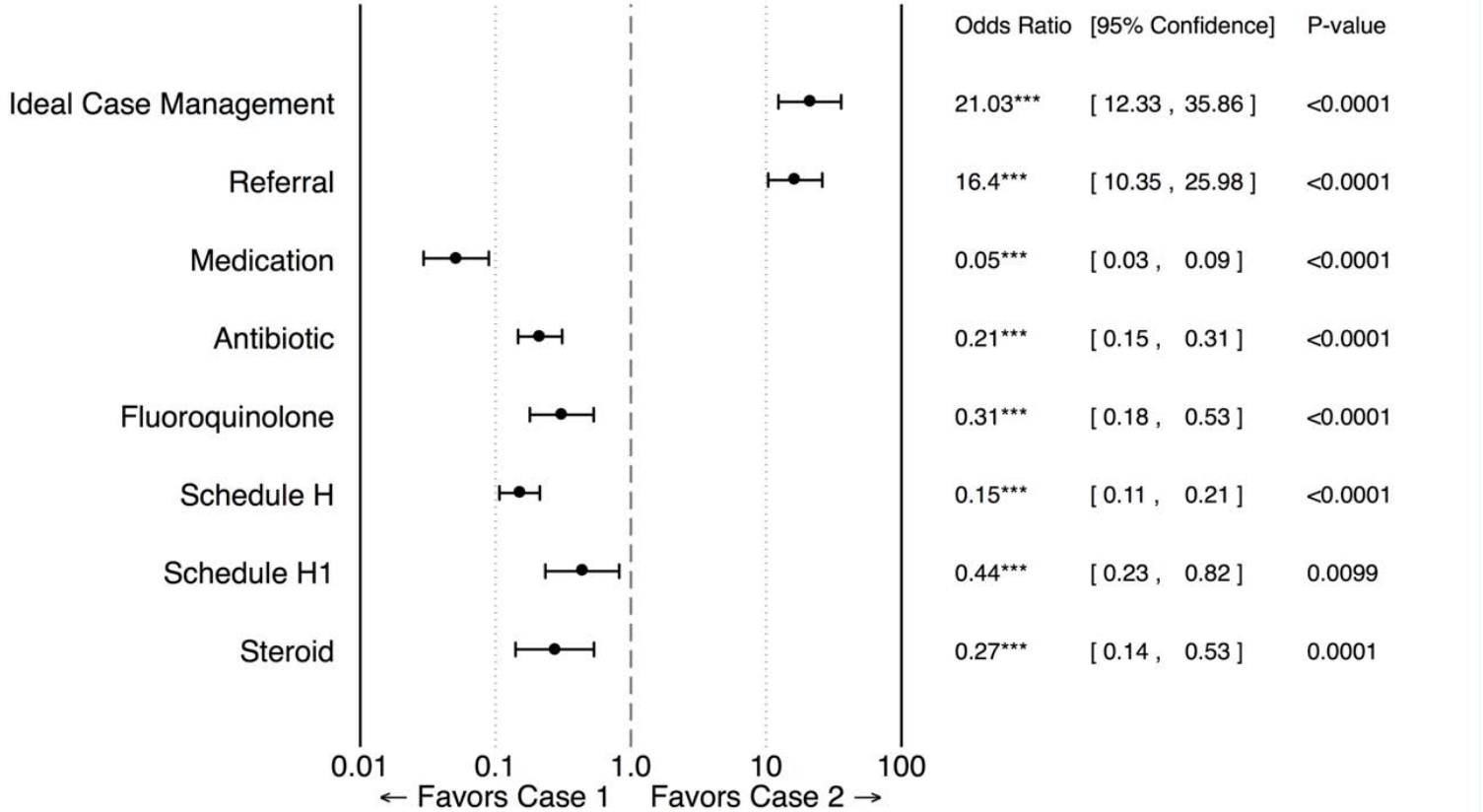
Table 1: Standardized Patients Case Descriptions

Case title	Case description	Presentation of standardized patient	Expected case management
Case 1	Classic case of presumed TB with 2-3 weeks of cough and fever and directly seeking care from a chemist or pharmacist	Case 1 presents with the opening statement, "Sir, I have cough and fever that is not getting better. Please give me some medicine." At presentation, this case has had a 2-3 week cough, which occurred more during early morning and night, accompanied by a 2-3 week, on-and-off, low-grade fever. The patient was producing sputum that did not contain any blood. The case would admit to a loss of appetite and to his or her clothes becoming a bit loose if prompted by the chemist. If the chemist asked about taking medicines for this illness, the patient would say no.	Verbal or written referral to a DOTS center or a health care provider without dispensing any antibiotics (including anti-TB drugs and fluoroquinolones) and/or steroids
Case 2	Chronic cough with a positive sputum smear report for TB from a government dispensary and directly seeking care from a chemist or pharmacist.	Case 2 presents with a positive sputum smear result visiting a chemist, presenting with the opening statement, "Sir, I am having cough for nearly a month now and also have fever." While showing a positive sputum report to the chemist, the patient continues, "I went to the government dispensary and they asked me to get my sputum tested. I have this report. Can you please give me some medicine?" At presentation, this case has had a cough for a month and produces sputum without blood, accompanied by a one-month, on-and-off, low-grade fever, which was more during evening times. Similar to case 1, the case would admit to a loss of appetite and to his or her clothes becoming a bit loose if prompted by the chemist. If the chemist asked about taking medicines for this illness, the patient would say no.	Verbal or written referral to a DOTS center or a health care provider without dispensing any antibiotics (including anti-TB drugs and fluoroquinolones) and/or steroids

Table 2: Management of Case 1 and Case 2 for all cities and for Patna and Mumbai only

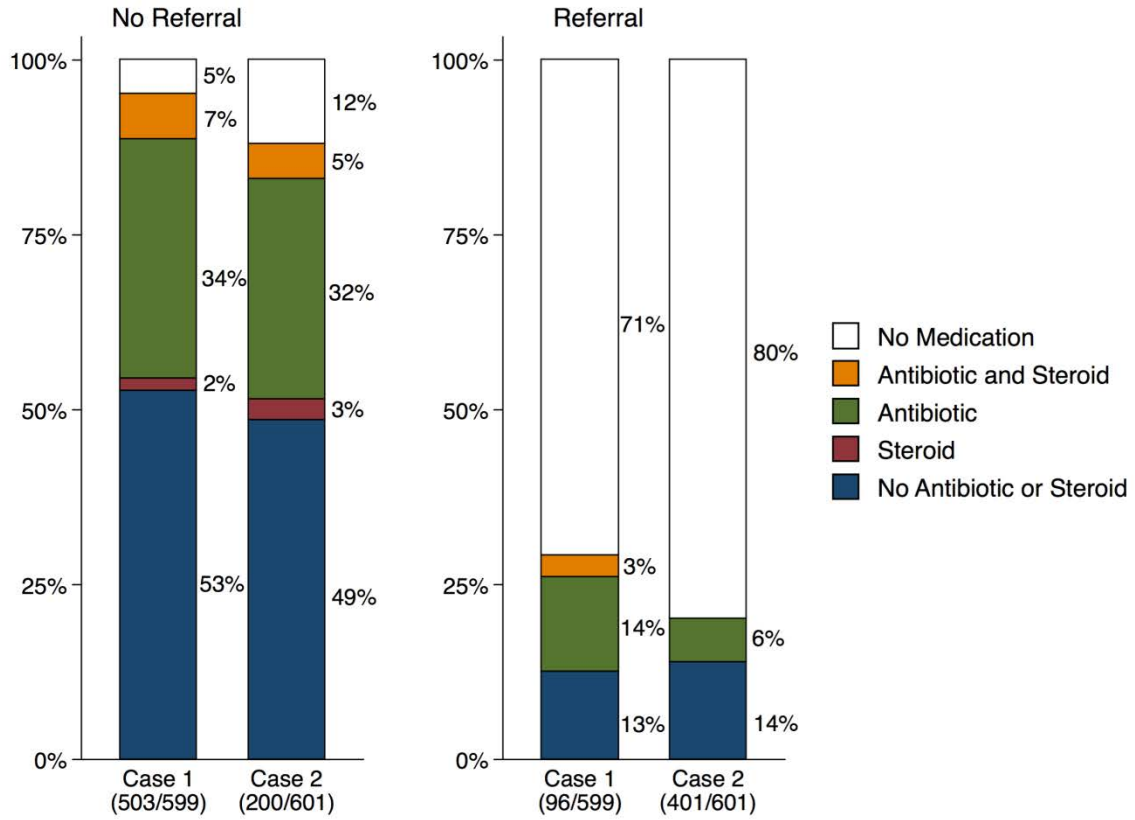
	(1)	(2)	(3)	(4)
	All Cities		Patna and Mumbai Only	
	Case 1	Case 2	Case 1	Case 2
Number of Interactions	***599***	***601***	***548***	***548***
Referral	96/599	401/601	75/548	362/548
	0.16 [0.13–0.19]	0.67 [0.63–0.70]	0.14 [0.11–0.17]	0.66 [0.62–0.70]
Ideal Case Management	80/599	372/601	64/548	335/548
	0.13 [0.11–0.16]	0.62 [0.58–0.66]	0.12 [0.09–0.14]	0.61 [0.57–0.65]
	Medications			
Number of Medicines	2.09	0.98	2.07	0.97
	[1.99–2.20]	[0.88–1.09]	[1.97–2.18]	[0.86–1.08]
Antibiotic	221/599	98/601	200/548	88/548
	0.37 [0.33–0.41]	0.16 [0.13–0.19]	0.36 [0.32–0.41]	0.16 [0.13–0.19]
Steroid	45/599	16/601	37/548	13/548
	0.08 [0.05–0.10]	0.03 [0.01–0.04]	0.07 [0.05–0.09]	0.02 [0.01–0.04]
Antibiotic or Steroid	230/599	104/601	208/548	94/548
	0.38 [0.34–0.42]	0.17 [0.14–0.20]	0.38 [0.34–0.42]	0.17 [0.14–0.20]
Fluoroquinolone	61/599	23/601	61/548	23/548
	0.10 [0.08–0.13]	0.04 [0.02–0.05]	0.11 [0.08–0.14]	0.04 [0.03–0.06]
Schedule H	401/599	188/601	367/548	172/548
	0.67 [0.63–0.71]	0.31 [0.28–0.35]	0.67 [0.63–0.71]	0.31 [0.27–0.35]
Schedule H1	37/599	19/601	31/548	16/548
	0.06 [0.04–0.08]	0.03 [0.02–0.05]	0.06 [0.04–0.08]	0.03 [0.02–0.04]
Schedule X	0/599	0/601	0/548	0/548
	0 [–]	0 [–]	0 [–]	0 [–]
Anti-Tuberculosis	0/599	0/601	0/548	0/548
	0 [–]	0 [–]	0 [–]	0 [–]

Figure 1: Odds ratios for case management outcomes – Case 2 : Case 1



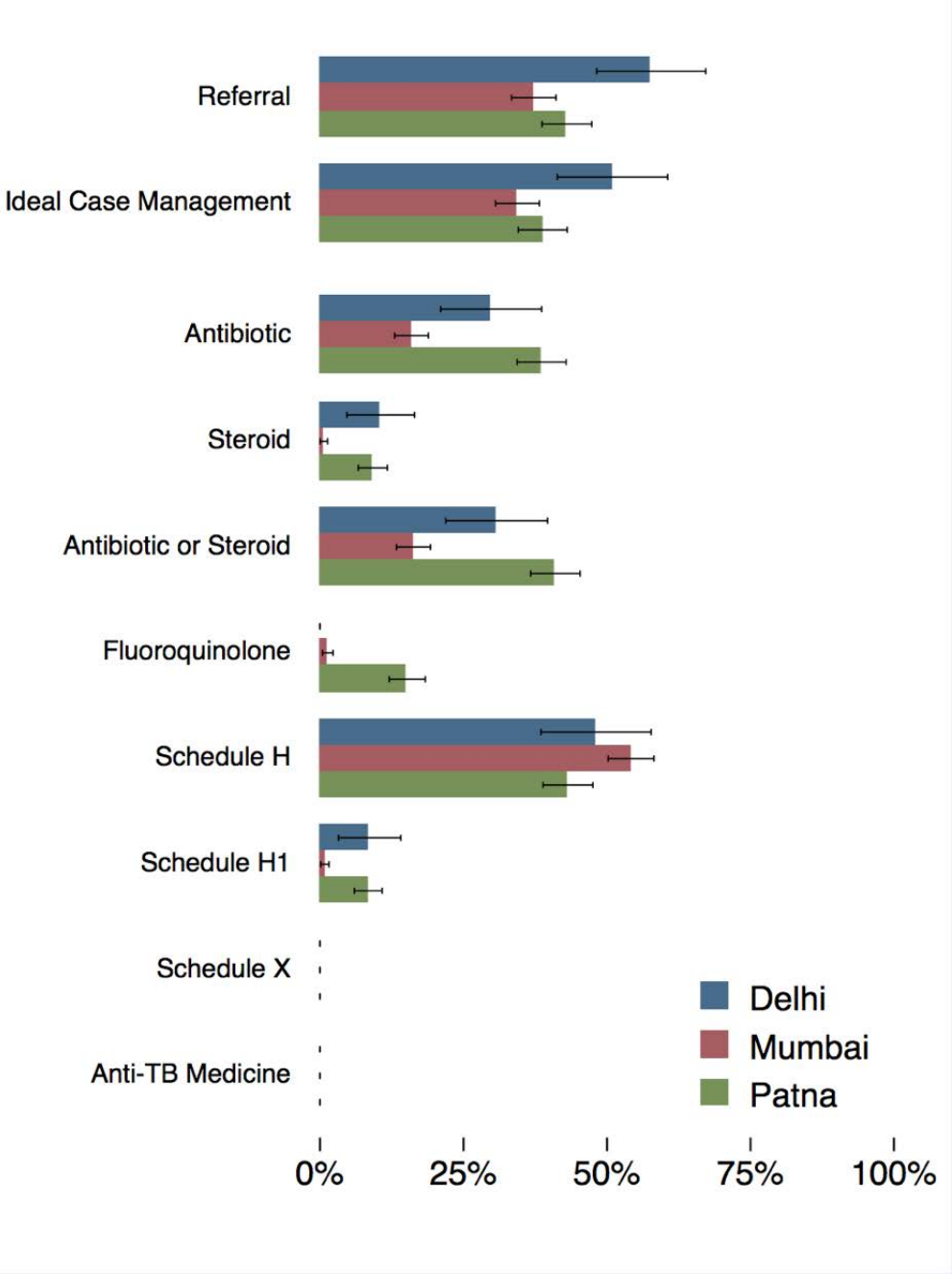
Notes: Reported odds ratios are from a random-intercepts model using each pharmacy as its own control, with city fixed effects. Odds ratios greater than 1 favor Case 2. Stars indicate statistical significance of the estimated coefficients: *** = $p < 0.01$; ** = $p < 0.05$; * = $p < 0.1$. Referral is any instance in which the pharmacy staff recommended that the SP seek further care from a health care provider. Ideal case management for both cases is defined as a referral without the dispensing of antibiotics or steroids. Schedule H, H1, and X medications are defined as per the Drugs and Cosmetics Act, 1945, of the Ministry of Health and Family Welfare, Government of India and its amendments.

Figure 2: Medication use by referral decisions for two standardized patient cases



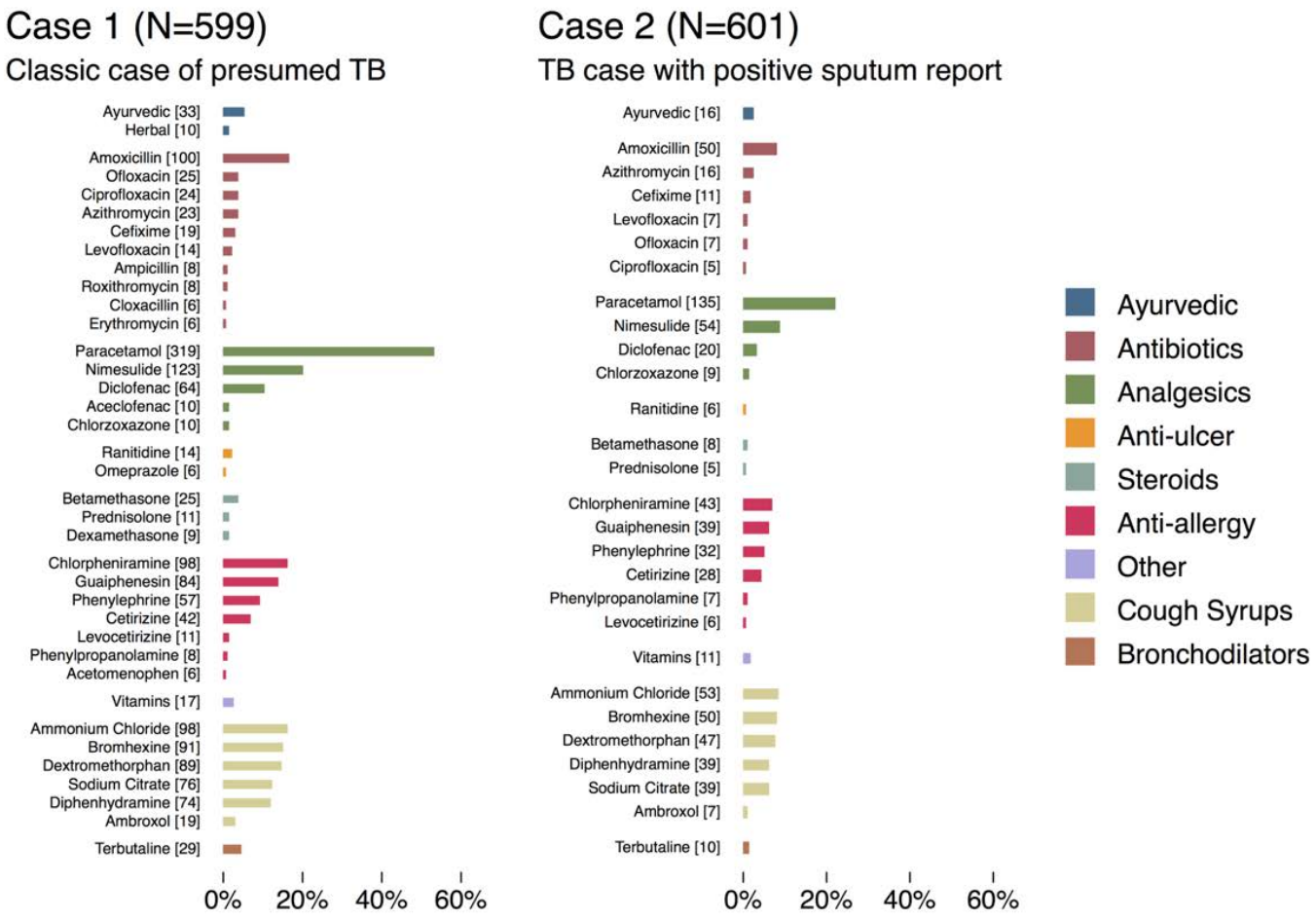
Notes: Each panel describes the use of medications in each case; the first shows pharmacies that did not refer the SP to another healthcare provider (left panel) and the second shows those who did (right panel). Both cases are presented in proportions so the total use sums to 100%; the proportions making referral decisions are shown below the case labels in each panel. Case 1 presents presumed TB with 2-3 weeks of cough and fever; Case 2 presents chronic cough with a positive sputum smear report for TB from a government dispensary. Percentages indicate the number of interactions within each case-referral category dispensing the indicated types of medications; numbers may not add to 100% due to rounding.

Figure 3: Management of both Case 1 and Case 2 combined by city



Notes: Referral is any instance in which the pharmacy staff recommended that the SP seek further care from a health care provider. Ideal case management for both cases is defined as a referral without the dispensing of antibiotics or steroids. Schedule H, H1, and X medications are defined as per the Drugs and Cosmetics Act, 1945, of the Ministry of Health and Family Welfare, Government of India and its amendments.

Figure 4: Active ingredients in medicines given for each case



Notes: This figure reports the frequency with which each listed active ingredient was contained in medicines given to SPs for each case. The number in brackets is the number of interactions in which that active ingredient was observed. Case 1 presents presumed TB with 2-3 weeks of cough and fever; Case 2 presents chronic cough with a positive sputum smear report for TB from a government dispensary.

3.2.10 Appendix (Manuscript 2)

Supplement to:

Use of standardised patients to assess antibiotic dispensing for tuberculosis by pharmacies in urban India: a cross-sectional study

Srinath Satyanarayana, Ada Kwan, Benjamin Daniels, Ramnath Subbaraman, Andrew McDowell, Sofi Bergkvist, Ranendra K. Das, Veena Das, Jishnu Das, Madhukar Pai

Supplementary Methods

1. Process of selecting the pharmacies

Appendix Table A1 (page 104) summarizes pharmacy recruitment and study implementation across the three cities. In Delhi, 54 chemists from 28 low-income localities were convenience sampled as a pilot study for methodological validation and power calculations. In urban Patna (defined as Patna, Danapur, and Phulwarisharif blocks) and 15 high-slum population wards of Mumbai, a lane-by-lane mapping exercise conducted between January and August 2014 served as a complete list of pharmacies that were operating in these areas at the time.

Additionally, during the data collection period for this study in Mumbai and Patna, urban TB programs implemented by Private-Provider Interface Agencies (PPIA) were recruiting and enrolling pharmacist or pharmacist assistants into TB referral and treatment networks in both Mumbai and Patna. At the time of sampling for our study in these two cities, we decided to stratify our sample by PPIA program enrollment. The description of the program serves to support sampling weights (Appendix Table A2, page 105) applied to achieve the urban area estimates for Mumbai and Patna but stratified findings based on PPIA program enrollment are not presented in this paper. From the mapping lists in Mumbai and Patna, we obtained lists of enrolled pharmacies in the PPIA program (in Patna as of September 25, 2014 for round 1 and as of September 15, 2015 for round 2; in Mumbai as of January 30, 2015 for round 1 and as of September 30, 2015 for round 2) and matched them back to the complete mapping lists to obtain a sampling universe stratified by PPIA enrollment status.

From these lists, in urban Patna, we randomly selected 125 pharmacies from the 268 pharmacies enrolled into the PPIA program and 125 from the 602 pharmacies not enrolled in the program across the two sampling rounds. The geographical frame covered all 40 wards in Danapur block, all 28 wards in Phulwari Shariff block, and 34 wards selected in collaboration with the PPIA out of 73 wards in Patna block. For both

of the random samples in Patna, we provided a reserve list, which could replace originally sampled pharmacists found to be permanently closed at the time of data collection for the purposes of surveillance. One pharmacist became enrolled in the PPIA program between the data collection rounds and 10 others were closed and replaced by an identically sampled replacement in the second round.

In Mumbai, four of the 15 high-slum population wards were purposively selected for this study in collaboration with the PPIA to reflect different geographical areas with both registered and unregistered slums and accessible transit for our field team. These four wards had a total of 1,160 pharmacies covering a total population of 3,181,264, of which 2,275,555 people (72%) were living in an area identified as a slum.[1,2] In the same four wards, we assigned SP visits to all chemists enrolled into the PPIA program (48 as of September 2015) and then randomly selected 250 chemists from 1,094 chemists who were not enrolled into the urban TB program in the four wards across the two sampling rounds. This included three chemists who became enrolled in the PPIA program between rounds 1 and 2, as well as 10 that were closed and replaced by an identically sampled replacement in the second round. We used Stata Version 13 (Stata Corp, College Station, TX) to generate the random samples in Patna and Mumbai.

Appendix Table A1. Study Design by City

(1) Period	(2) Data collection dates	(3) Chemist recruitment	(4) Number of standardized patients	Intera
Delhi (Pilot)	April 1–23, 2014	Convenience sample for pilot	9 unique SPs	51 Case
				53 Case
Delhi Total			9 unique SPs	54 unic
Patna Round 1	November 5–12, 2014	Random sampling of chemists enrolled in an urban TB program in urban Patna (enrollment date of September 25, 2014), and random sampling of chemists not enrolled in an urban TB program (all Danapur block, all Phulwarisharif block, and purposively selected areas in Patna block).	9 unique SPs	122 Case
Patna Round 2	November 19–29, 2015	Identical random sampling to extend Case 1 sample (enrollment date of September 15, 2015). Case 2 sent to all chemists now in Case 1 sample. Identically sampled replacement used if Round 1 chemist unavailable in Round 2.	8 unique SPs	128 Case
				250 Case
Patna Total			12 unique SPs	260 uni
Mumbai Round 1	April 1–11, 2015	Random sample for chemists not enrolled in an urban TB program and a census of all chemists enrolled in the program in four wards (enrolment date of January 30, 2015)	13 unique SPs	169 Case
Mumbai Round 2	October 7 – November 3, 2015	Identical random sampling and census (enrolled date as of September 30, 2015), to extend Case 1 sample. Case 2 sent to all chemists now in Case 1 sample. Identically sampled replacement used if Round 1 chemist unavailable in Round 2.	8 unique SPs	129 Case
				298 Case
Mumbai Total			14 unique SPs	308 uni

Appendix Table A2. Pharmacies Eligible for Sampling and Observation Weighting by City

(1) City	(2) Sample	(3) Pharmacies	(4) Interactions	(5) City-Sample Observation Weight		(6)
Delhi	**Full Sample**	n/a	Case 1: 51 Case 2: 53		=	1.00
Mumbai	**PPIA**	48	Case 1: 45 Case 2: 48	(48/1142)/(48/298)	=	0.261
Mumbai	**Non-PPIA**	1094	Case 1: 253 Case 2: 250	(1094/1142)/(250/298)	=	1.142
Patna	**PPIA**	268	Case 1: 125 Case 2: 126	(268/870)/(126/250)	=	0.611
Patna	**Non-PPIA**	602	Case 1: 125 Case 2: 124	(602/870)/(124/250)	=	1.395

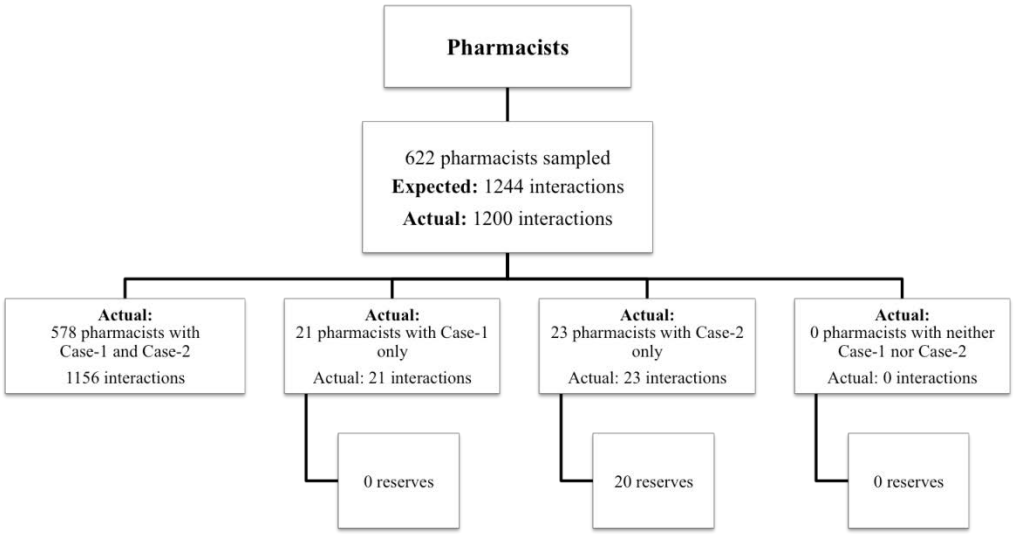
1.1 Deviations from Sampling Protocol

We had anticipated the possibility of being unable to reach all our sampled pharmacies in our design by oversampling and selecting a random subset of pharmacies to be held in reserve for the samples in each city. In practice after our pilot in Delhi, the SPs were sent to conduct the interaction at the sampled pharmacist at a given location up to two times, and if the interaction could not be successfully completed in two visits (e.g., the pharmacist had closed his shop), the originally sampled pharmacist was dropped and replaced with a reserve.

Given a total of 622 pharmacists, we should have had 1244 interactions, since each pharmacist was assigned two cases and one interaction per case. Since pharmacists were assigned two cases, reserves were pulled in for the remaining case if one had already been successfully completed (e.g., in the previous round). Since our reserves were used at the interaction rather than the pharmacy level, we could have situations where Case 1 was completed with one pharmacy, which then shut down or moved and Case 2 had to be completed with a reserve. We consider the 44 unpaired visits where 1 case was completed to be "missing" their paired visit to the same pharmacy.

Across cities, 1 pharmacist from the convenience sample in Delhi received Case 1 but not Case 2 and 3 received Case 2 but not Case 1. In Patna and Mumbai, there were 20 originally sampled chemists who successfully received Case 1 but did not receive Case 2. For each of these instances, a reserve was used as a replacement for the Case 2 interaction through an identical sampling strategy. This resulted in 20 pharmacy reserve pharmacists who received Case 2 only (10 in Mumbai and 10 in Patna), resulting in 40 unmatched interactions. In Patna and Mumbai, reserves were used either because (i) the sampled pharmacy shop was permanently closed or had moved to another location, or (ii) the pharmacist was not available during the data collection period. See Appendix Figure A1 (page 106).

Appendix Figure A1. Pharmacist sampling and visit completion



2. Standardized Patient Cases and Recruitment

We have previously described the validation of the SP methodology for presentations of tuberculosis.[3] We demonstrated that (1) participation in the study had minimal to no risk for the SPs or health care providers, (2) the likelihood of SP detection among visited providers was 5%, which was very low (and lower than other studies), confirming that SPs were considered real by health providers who were visited, and (3) the abilities of the SPs to recall what occurred during the interaction was strongly correlated with what actually happened. Additionally, because the SPs pay the fees requested by the healthcare provider, there is no loss to provider income from participation in the study.

Simultaneously with the interactions published in the Delhi pilot study, the two cases in this paper were designed and piloted in Delhi for presentation at pharmacies. After the pilot in Delhi, the cases were adjusted for the Patna and Mumbai contexts.

For each case, both the clinical case presentation and social contexts were developed and agreed upon by a technical advisory group, which included international and national TB experts and clinicians. Clinical aspects were standardized across the three cities, and the scripts were adjusted to account for different social and family contexts across cities. Script development occurred under the guidance of an anthropologist (VD) and with the support of supervisors and participating SP recruits. Scripts were in English and Hindi for the three cities and additionally translated into Marathi for Mumbai.

A different cohort of SPs, in apparently healthy condition, was recruited and trained in each city; some of the SPs participated in data collection in more than one city. The 24 individuals (7 females and 17 males) hired as SPs in total included both new recruits and individuals who had participated in previous SP

studies assessing other health conditions. The SPs, although recruited specifically to fit each case, differed in age, gender, height, and weight. The average age of all the SPs was 30. The youngest was 21, and the oldest was 39. The 17 males weighed 50 to 74 kilograms and were 160 to 184 centimeters tall. The 7 females weighed 46 to 72 kilograms and were 147 to 160 centimeters tall.

In each round of data collection and in each city, SPs were assigned to either Case 1 or Case 2 and never to both cases in order to avoid detection, since each sampled chemist was assigned to receive both cases. Further details on the cohort for each city were as follows:

- In Delhi, a total of nine individuals were recruited and trained for three weeks. Five individuals (three female) were trained as Case 1, and four different individuals (one female) were trained as Case 2.
- In Patna, a total of 12 individuals participated as SPs. During the first round, nine individuals (four female) were trained for 5 days (October 27 – November 4, 2014) to depict Case 1. Then during the second round, eight individuals were rehired and received two days of refresher training (November 17 - 18, 2015).
- In Mumbai, a total of 14 individuals participated as SPs. During the first round, 13 individuals (two female) were trained for 10 days (March 20 – 31, 2015) to depict Case 1. During the second round, eight individuals were rehired and received two days of refresher training (October 5 - 6, 2015).

The training of SPs ensured that they (a) correctly presented the cases, (b) correctly recalled the interaction with the pharmacy staff, and (c) avoided detection. The first two aims were achieved through classroom training in case presentation and testing of recall, as well as mock interviews and dry runs that were supervised in the field.

For the third aim, SPs were taught to avoid detection by the following methods. First, our recruitment strategy ensured that SPs came from low-income areas or slums from the same cities in which the project was located, and the areas from which they came were far from the field sites. This meant that their clothing, mannerisms, and speech were very close to the ordinary patients who visited pharmacists, but they would not have been personally known in the study areas. Second, previous observations in pharmacies and chemist shops were conducted by supervisors in order to observe the patterns of interaction (e.g., mode of address), and we ensured that SPs approximated those patterns of interaction. Third, during the training, SPs were taught to internalize completely the characters and the details of their mock stories through which the character was made alive to them. In mock interviews during training, supervisors would add unscripted questions with regard to family or neighborhood that SPs could answer spontaneously because they were of the actual social background that was being approximated in the characters they were portraying. Finally, dry runs were conducted in which the supervisor was present in the shop on the pretense of buying something such as toothpaste or an over-the-counter cough syrup and thus could watch the interaction and offer corrections later.

The different number of training days across cities and rounds of data collection was determined by how many of the individuals in the cohort were new recruits and among the experienced SPs, how recent their last experience was depicting the case they were assigned. For example, some SPs who participated in Patna data collection as Case 1 had worked with us in the Delhi pilot, and a briefer, refresher training was conducted.

3. Identification of drugs given by pharmacists

In order to assess drug use, all labelled medicines prescribed by the pharmacies were digitized and stored and then coded by two doctors with expertise in TB (SS) and infectious diseases (RS). Blinded from any provider identifying details, they identified and categorized medicines as steroids, anti-TB drugs, fluoroquinolones, or other broad-spectrum antibiotics under maker-checker procedure. They also identified whether the individual drug is listed under Schedule H, Schedule H1, or Schedule X of India's Ministry of Health and Family Welfare's Drugs and Cosmetics Rules Act, 1945,[4] or its amendments. Discrepancies in categorization between the two coders were resolved by consensus.

It is important to mention that Schedule H drugs also include common prescription-only drugs such as Ibuprofen and Cetirizine. Similarly, some but not all fluoroquinolones are listed on Schedule H1. For instance, Ciproflaxacin and Ofloxacin remain in Schedule H, but Levofloxacin, Moxifloxacin, Prulifloxacin and Sparfloxacin are Schedule H1 drugs. Finally, loose or unlabeled pills were dispensed in 28 of 1200 interactions, and we made no further attempts to identify them.

4. Sample size calculations

Appendix Table A3 (page 109) shows our sample size calculations for various assumptions of interaction outcome frequencies, which we calibrated against the results from the Delhi pilot sample. Based on the results of the pilot study in Delhi a sample size of 250 pharmacies per city would allow us to estimate the proportion of ideal case management for each case with a precision of +/-5%. In Delhi, ideal case management was 31% for Case 1 and 70% for Case 2 (under "Ideal Case Management" in Table 2, Columns (1) and (2) page 98). As seen from Column (3) in Table A3 (page 109), the sample size required for an outcome proportion of 30% is 252 in Mumbai and 236 in Patna. As the computation is symmetric around 50%, this is the same sample size required for an outcome proportion of 70% as well. Note that we did not account for potential design effects as we chose equal probability samples from the entire list frame, as opposed to a clustered random sample. Given that this is a binary outcome variable, the specific formula is:

$$n = [Np(1-p)]/ [(d^2/Z^2*(N-1)+p*(1-p)]$$

where:

n = Required sample size per SP city-case set
N = Population size
p = Hypothesized outcome proportion in the population
d = Absolute confidence limits (as % of 100)
Z = Z-score (for 95% Confidence levels Z-score=1.96).[5]

Appendix Table A3. Sample Size Calculations

	Binary outcome frequency scenarios				
	(1)	(2)	(3)	(4)	(5)
Mumbai					
Pharmacies in sampling frame	1,142	1,142	1,142	1,142	1,142
Hypothetical outcome proportion	10%	20%	30%	40%	50%
Width of confidence interval	+/-5%	+/-5%	+/-5%	+/-5%	+/-5%
Confidence level	95%	95%	95%	95%	95%
Required sample size	**124**	**203**	**252**	**279**	**288**
Patna					
Pharmacies in sampling frame	870	870	870	870	870
Hypothetical outcome proportion	10%	20%	30%	40%	50%
Width of confidence interval	+/-5%	+/-5%	+/-5%	+/-5%	+/-5%
Confidence level	95%	95%	95%	95%	95%
Required sample size	**120**	**192**	**236**	**260**	**267**

5. Clinical outcomes by city and case

In the main text we provide key outcome variables for all cities and for Patna and Mumbai only, for both cases combined. To accompany the description in the text, Appendix Table A4 (page no. 110) below provides the full set of outcome variables for each city and case.

Appendix Table A4. Clinical outcomes for Case 1 and 2 combined across cities and by city.

	(1) All Case 1	(2) All Case 2	(3) Delhi Case 1	(4) Delhi Case 2	(5) Mumbai Case 1	(6) Mumbai Case 2	(7) Patna Case 1	(8) Patna Case 2
Number of Interactions	***599***	***601***	***51***	***53***	***298***	***298***	***250***	***250***
Referral	96/599	401/601	21/51	39/53	36/298	186/298	39/250	176/250
	0.16 [0.13–0.19]	0.67 [0.63–0.70]	0.41 [0.28–0.55]	0.74 [0.62–0.85]	0.11 [0.07–0.15]	0.61 [0.55–0.67]	0.15 [0.10–0.19]	0.70 [0.64–0.76]
Ideal Case Management	80/599	372/601	16/51	37/53	31/298	174/298	33/250	161/250
	0.13 [0.11–0.16]	0.62 [0.58–0.66]	0.31 [0.19–0.44]	0.70 [0.57–0.82]	0.09 [0.06–0.13]	0.58 [0.52–0.64]	0.12 [0.08–0.16]	0.64 [0.57–0.70]
Medications								
Antibiotic	221/599	98/601	21/51	10/53	57/298	38/298	143/250	50/250
	0.37 [0.33–0.41]	0.16 [0.13–0.19]	0.41 [0.28–0.55]	0.19 [0.08–0.29]	0.18 [0.14–0.23]	0.12 [0.08–0.15]	0.58 [0.51–0.65]	0.20 [0.14–0.25]
Steroid	45/599	16/601	8/51	3/53	3/298	1/298	34/250	12/250
	0.08 [0.05–0.10]	0.03 [0.01–0.04]	0.16 [0.06–0.26]	0.06 [0–0.12]	0.01 [0–0.02]	0 [0–0.01]	0.14 [0.09–0.18]	0.05 [0.02–0.08]
Antibiotic or Steroid	230/599	104/601	22/51	10/53	58/298	39/298	150/250	55/250
	0.38 [0.34–0.42]	0.17 [0.14–0.20]	0.43 [0.30–0.57]	0.19 [0.08–0.29]	0.19 [0.14–0.23]	0.12 [0.08–0.16]	0.60 [0.54–0.67]	0.22 [0.16–0.27]
Mentioned TB in Interaction	12/599	118/601	1/51	14/53	4/298	47/298	7/250	57/250
	0.02 [0.01–0.03]	0.20 [0.16–0.23]	0.02 [0–0.06]	0.26 [0.15–0.38]	0.01 [0–0.03]	0.16 [0.12–0.20]	0.03 [0.01–0.05]	0.22 [0.17–0.28]
Fluoroquinolone	61/599	23/601	0/51	0/53	5/298	3/298	56/250	20/250
	0.10 [0.08–0.13]	0.04 [0.02–0.05]	0 [–]	0 [–]	0.02 [0–0.03]	0.01 [0–0.02]	0.22 [0.17–0.28]	0.09 [0.05–0.13]
Schedule H	401/599	188/601	34/51	16/53	207/298	116/298	160/250	56/250
	0.67 [0.63–0.71]	0.31 [0.28–0.35]	0.67 [0.54–0.80]	0.30 [0.18–0.43]	0.70 [0.64–0.75]	0.38 [0.32–0.44]	0.65 [0.59–0.72]	0.23 [0.17–0.28]
Schedule H1	37/599	19/601	6/51	3/53	2/298	3/298	29/250	13/250
	0.06 [0.04–0.08]	0.03 [0.02–0.05]	0.12 [0.03–0.21]	0.06 [0–0.12]	0.01 [0–0.02]	0.01 [0–0.01]	0.11 [0.07–0.15]	0.05 [0.02–0.08]
Schedule X	0/599	0/601	0/51	0/53	0/298	0/298	0/250	0/250
	0 [–]	0 [–]	0 [–]	0 [–]	0 [–]	0 [–]	0 [–]	0 [–]
Anti-Tuberculosis	0/599	0/601	0/51	0/53	0/298	0/298	0/250	0/250
	0 [–]	0 [–]	0 [–]	0 [–]	0 [–]	0 [–]	0 [–]	0 [–]
Interaction Statistics								
Asked SP to Return	34/595	30/594	3/51	7/53	1/296	1/291	30/248	22/250
	0.06 [0.04–0.08]	0.05 [0.03–0.07]	0.06 [0–0.12]	0.13 [0.04–0.22]	0 [0–0.01]	0 [0–0.01]	0.12 [0.08–0.17]	0.10 [0.06–0.14]
Duration of Interaction (min)	1.73	1.62			1.37	1.49	2.27	1.80
	[1.60–1.86]	[1.49–1.76]			[1.25–1.49]	[1.41–1.57]	[1.98–2.55]	[1.46–2.14]
Number of Questions Asked	1.44	1.20	1.27	1.06	1.06	1.07	1.99	1.41
	[1.30–1.57]	[1.09–1.31]	[0.92–1.63]	[0.77–1.34]	[0.86–1.25]	[0.92–1.22]	[1.75–2.23]	[1.18–1.63]
Price (INR)	61.02	44.15	47.45	36.70	50.70	58.56	77.92	40.23
	[56.30–65.75]	[38.23–50.07]	[34.71–60.20]	[19.98–53.42]	[46.00–55.39]	[49.83–67.30]	[68.88–86.96]	[30.01–50.45]
Price (USD)	0.98	0.71	0.76	0.59	0.81	0.94	1.25	0.64
	[0.90–1.05]	[0.61–0.80]	[0.56–0.96]	[0.32–0.85]	[0.74–0.89]	[0.80–1.08]	[1.10–1.39]	[0.48–0.81]
Number of Lab Tests Ordered	0.01	0.01	0.02	0.00	0.01	0.02	0.00	0.01
	[0.00–0.02]	[0.00–0.02]	[0–0.06]	[–]	[0–0.03]	[0.00–0.04]	[–]	[0.00–0.02]
Any Medication Given	507/599	257/601	38/51	20/53	267/298	149/298	202/250	88/250
	0.85 [0.82–0.88]	0.43 [0.39–0.47]	0.75 [0.63–0.86]	0.38 [0.25–0.51]	0.91 [0.88–0.94]	0.50 [0.44–0.56]	0.83 [0.78–0.88]	0.36 [0.30–0.42]
Number of Medicines	2.09	0.98	2.29	1.15	1.79	0.96	2.51	1.00
	[1.99–2.20]	[0.88–1.09]	[1.81–2.78]	[0.69–1.61]	[1.67–1.90]	[0.82–1.10]	[2.32–2.69]	[0.80–1.20]

Notes: Data are either mean and 95% confidence interval for continuous variables; or observed proportion, estimated population proportion, and 95% confidence interval for binary variables. Referral indicates any situation in which the chemist recommended the SP to visit a health care provider. Ideal case management is defined as a referral without the dispensing of antibiotics or steroids. USD prices calculated using the 1 Aug 2015 exchange rate of 0.016USD/INR. Schedule H, H1 and X medications are defined as per the Drugs and Cosmetics Act, 1945, of the Ministry of Health and Family Welfare, Government of India and its amendments.

6. Model for estimating the odds ratios of management behaviours for the two cases at each pharmacy

Using an econometric model, we are interested in estimating the differences in case management and medication use across a patient with presumptive TB (Case 1) and a patient with confirmed TB (Case 2), to determine the extent to which the behaviors of pharmacies change based on the confirmation of the diagnosis. We utilize the following variables:

Y_{ij} = Outcome (1 = Yes, 0 = No) for pharmacist *i* in SP case *j*, where Outcome can be ideal case management, antibiotic use, or any other binary outcome variable;

C_{ij} = Case Exposure (Case 1 = 0; Case 2 =1) for pharmacist *i* in SP case *j*;

L_i = Study location for pharmacy *i* (Delhi = 1, Mumbai = 2, Patna = 3)

Suppose we are first interested in estimating the marginal effects of Case Exposure on ideal case management. For marginal effects, linear models like OLS are consistent for binary variables, but not efficient. Nevertheless, they require fewer assumptions on the structure of the error term and are therefore robust to misspecification in the functional form of the error term. Suppose that every pharmacy has an unobserved ability level, v_i, such that pharmacies with higher v_i are also more likely to correctly manage the patient. Therefore,

$Y_{ij} = a + b.C_{ij} + c.L_i + v_i + e_{ij}$

If we were to observe real patients, it may be the case that patients who do not know their diagnosis choose a higher v_i pharmacy. Therefore, the choice of the pharmacy by the patient confounds the estimated marginal effect we are interested in. However, with two SP visits to each pharmacy, one for each case, the difference in Y_{i1} and Y_{i2} yields a consistent estimate of b, purged of v_i. Note that the simple linear OLS model can be estimated either through pairwise differences, i.e., by subtracting each pharmacy's performance in Case 1 from its performance in Case 2, or using the conditional expectation function, and noting that because every pharmacy receives both cases, the $E(v_i \mid \text{Case 1}) = E(v_i \mid \text{Case 2})$. This is the difference between OLS with and without fixed-effects at the level of the pharmacy. Finally, the same argument will hold for why the OLS with random intercepts, which assumes that $\text{Corr}(v_i, C_{ij}) = 0$ will yield the same coefficients. Specifically, because there is no active choice and both pharmacies received two cases each, correlations between the pharmacy-specific intercept and the choice of cases are ruled out by design. In practice, there will be two differences between the marginal effects estimated through OLS, OLS with fixed-effects and OLS with random intercepts:

- Precision will be higher with the random intercepts model, as (a) there are fewer degrees of freedom in the fixed-effects model (a fixed-effect is estimated for each pharmacy) and (b) the OLS does not take into account the specific error structure.
- In practice, the actual estimates may also differ because not every case was completed with every pharmacist. For instance, if low-ability pharmacies are more likely to close and Case 1 was attempted

first, we may have more Case 1 interactions with higher ability pharmacists. Similarly, the inclusion of city-level indicator variables helps eliminate any potential effects arising from differences in the number of cases of each type across cities.

Estimates of odds-ratios using a logit error structure may differ because the non-linearity in the logit function implies that the logic of the conditional expectation function no longer holds. That is, since $E(F(v_i \mid \text{Case 1})$ is not $F(E(v_i \mid \text{Case 1})$, additional differences may arise between the logit model, the logit model with fixed-effects and the logit model with random intercepts. In practice, given that most of our outcome variables have observed proportions between 20% and 80%, these differences should be small since the logit function is close to linear in this range.

In our econometric model, we fit a random intercept logistic regression model to estimate the differences between the management of Case 1 and Case 2, producing odds-ratios for Case 2 : Case 1. The random intercepts logit model is illustrated below with the following variables: v_{0i} = Random intercept for pharmacy *i* in [1 , 622] and

$$\text{Logit}(Y_{ij}) = \beta_0 + v_{0i} + \beta_2 * C_{ij} + \beta_3 * L_i + \varepsilon_{ij}$$

where the exponentiation to the 'e' of the coefficient β_2 is interpreted as the odds ratio for optimal management of Case 2 against Case 1 by each pharmacy. The random intercepts v_{0i} are distributed ~N $(0, \sigma_p^2)$, and ε_{ij} is distributed as a standard logistic distribution.

Appendix Table A5 (below) first shows the proportions for the outcome variables we consider for each of the two cases. The odds-ratios presented in Column (7) reflect estimates from a logit model *without* random intercepts, fixed-effects or city-level indicator variables.

Appendix Table A5. Summary of differences between Case 1 and Case 2 - No Controls Logit Model

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Variable	Case 1	N	Proportion	Case 2	N	Proportion	Odds Ratio	95% Lower Bound	95% Upper Bound	P-Value
Ideal Case Management	80	599	0.13	372	601	0.62	10.54	7.91	14.05	0.0000
Referral	96	599	0.16	401	601	0.67	10.51	7.97	13.85	0.0000
Medication	507	599	0.85	257	601	0.43	0.14	0.10	0.18	0.0000
Antibiotic	221	599	0.37	98	601	0.16	0.33	0.25	0.44	0.0000
Fluoroquinolone	61	599	0.10	23	601	0.04	0.35	0.21	0.58	0.0000
Schedule H	401	599	0.67	188	601	0.31	0.22	0.18	0.29	0.0000
Schedule H1	37	599	0.06	19	601	0.03	0.50	0.28	0.87	0.0150
Steroid	45	599	0.08	16	601	0.03	0.34	0.19	0.60	0.0002

Appendix Table A6 (page 113). then shows estimates of the marginal effects using linear models that include city fixed effects (Columns 1-3) and from non-linear logit models that include city fixed effects (Columns 4-6). (For all regression coefficients, *** = p<0.01, ** = p<0.05, * = p<0.1.) For both types of models, we show the base estimates, pharmacy fixed-effects estimates, and pharmacy random-intercepts estimates. We also report the p-value from a Hausman test comparing the fixed-effects and the random-intercepts coefficients from Columns

(5) and (6). When this test does not return a significant result, it indicates that the random-intercepts assumption is likely to be fulfilled.

Appendix Table A6. Summary of differences between Case 1 and Case 2 under various city-fixed-effects models

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
	Linear Differences			Odds Ratios				Proportions	
	OLS	OLS Fixed Effects	OLS Random Intercepts	Logit	Logit Fixed Effects	Logit Random Intercepts	Hausman Test P-value	Case 1	Case 2
Ideal Case Management	0.485***	0.488***	0.485***	10.876***	21.143***	21.031***	0.838	0.134	0.619
Referral	0.506***	0.509***	0.507***	11.047***	16.474***	16.398***	0.863	0.160	0.667
Medication	-0.419***	-0.420***	-0.419***	0.130***	0.051***	0.051***	0.772	0.846	0.428
Antibiotic	-0.206***	-0.202***	-0.205***	0.309***	0.220***	0.214***	0.193	0.369	0.163
Fluoroquinolone	-0.063***	-0.057***	-0.063***	0.325***	0.340***	0.309***	0.030	0.102	0.038
Schedule H	-0.357***	-0.353***	-0.356***	0.220***	0.154***	0.151***	0.397	0.669	0.313
Schedule H1	-0.030**	-0.028**	-0.030***	0.483**	0.467**	0.437***	0.150	0.062	0.032
Steroid	-0.049***	-0.045***	-0.048***	0.321***	0.297***	0.274***	0.072	0.075	0.027

As Table A6 (above) shows, all marginal effects are identical whether estimated through OLS, fixed-effects or random-intercepts models. For odds ratios, the fixed-effects and random-intercepts models are again identical for all outcome variables except fluoroquinolone use, but even there the absolute difference between the coefficients is small. However, the fixed-effects and random intercepts models differ from models that do not account for the error structure. This is due to the inclusion of some pharmacies that received only 1 case combined with the fact that at low proportions, small differences in the proportions can lead to large differences in the odds-ratios. Given the consistency of the estimates across all specifications, our inability to reject the validity of the assumptions required for the random-intercepts model, and the higher precision of the model, we report results from the random intercept model shown in Column (6) in the main text.

6.1 Accounting for SP characteristics

In Appendix Table A7 (page 114), we reproduce the results from Figure 1 (page 99), alongside a second set of results that controls for the visible SP characteristics that could be correlated with pharmacist behavior – sex, age, height and weight. As can be seen from the table below, the 95% confidence intervals for the model with SP characteristics included indicate that the estimated odds ratios do not significantly differ from those reported in our main specification, leading us to believe that any confounding due to SP effects is statistically insignificant as well as small in absolute magnitude. For ideal case management and referral, the point estimates of the odds-ratios are larger, but again, this reflects the low proportions and small changes as seen by the overlapping confidence intervals. Moreover, the models without SP characteristics had lesser AIC and BIC values when compared to models with SP characteristics, indicating that addition of SP characteristics did not improve the model fit. Therefore, we choose to present the parameter estimates without SP characteristics included in it.

Appendix Table A7. Summary of differences between Case 1 and Case 2, controlled for SP characteristics

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Final Model				Controlled for SP Characteristics			
Variable	Odds Ratio	95% Lower Bound	95% Upper Bound	P-Value	Odds Ratio	95% Lower Bound	95% Upper Bound	P-Value
Ideal Case Management	21.03	12.33	35.86	0.0000	38.70	17.63	84.93	0.0000
Referral	16.40	10.35	25.98	0.0000	23.53	12.31	44.96	0.0000
Medication	0.05	0.03	0.09	0.0000	0.03	0.01	0.06	0.0000
Antibiotic	0.21	0.15	0.31	0.0000	0.19	0.11	0.33	0.0000
Fluoroquinolone	0.31	0.18	0.53	0.0000	0.31	0.14	0.66	0.0024
Schedule H	0.15	0.11	0.21	0.0000	0.11	0.07	0.18	0.0000
Schedule H1	0.44	0.23	0.82	0.0099	0.37	0.14	0.95	0.0379
Steroid	0.27	0.14	0.53	0.0001	0.19	0.07	0.48	0.0005

7. Using the same SPs to re-examine differences across cities

In the text, we pointed to mean differences across cities in several outcome variables. A potential confounder could be that the use of different SPs in the three cities led to different results. Fortunately, we are able to directly test for this by using the subsample of interactions where the same SP was used in multiple cities. When we do so, controlling for the case and the SP's identity, we find that Delhi and Patna were statistically indistinguishable at the 5% level of significance on every outcome save for fluoroquinolone use, which could not be computed in logistic regression since none were observed in Delhi.

Compared to Mumbai, Delhi was again statistically indistinguishable. Note, however, that the estimated differences remain of substantial magnitude; however, the reduced sample size due to the rigorous matching dramatically reduces the precision of these estimates. In this case it was impossible to calculate odds-ratios for fluoroquinolone and steroid use since no fluoroquinolones were observed in Delhi and no steroids were observed in the matching subsample of Mumbai data.

Comparing Mumbai and Patna, where the sample size of overlapping SPs is substantial, we found that pharmacies in Patna used dramatically more antibiotics, fluoroquinolones, Schedule H1 medications, and steroids for the same SP presenting the same case. However, pharmacies in Patna were not significantly more or less likely to manage cases correctly, refer SPs to other providers, or use medication in general for the same SPs presenting the same cases. The full details are summarized in Appendix Table A8 (page 115).

Appendix Table A8. Differences in case management between cities, controlled for SP case and identity

Variable	(1) Delhi	(2) Patna	(3) Mumbai	(4) Overall
Ideal Case Management	53/104 (0.51)	194/500 (0.39)	205/596 (0.34)	452/1200 (0.38)
Referral	60/104 (0.58)	215/500 (0.43)	222/596 (0.37)	497/1200 (0.41)
Medication	58/104 (0.56)	290/500 (0.58)	416/596 (0.7)	764/1200 (0.64)
Antibiotic	31/104 (0.3)	193/500 (0.39)	95/596 (0.16)	319/1200 (0.27)
Fluoroquinolone	0/104 (0)	76/500 (0.15)	8/596 (0.01)	84/1200 (0.07)
Schedule H	50/104 (0.48)	216/500 (0.43)	323/596 (0.54)	589/1200 (0.49)
Schedule H1	9/104 (0.09)	42/500 (0.08)	5/596 (0.01)	56/1200 (0.05)
Steroid	11/104 (0.11)	46/500 (0.09)	4/596 (0.01)	61/1200 (0.05)

	Odds Ratio	95% Lower Bound	95% Upper Bound	P-Value
Patna : Delhi (Odds ratios greater than 1 favor Patna)				
Ideal Case Management	0.7240	0.3541	1.4806	0.3763
Referral	0.6701	0.3382	1.3277	0.2511
Medication	0.7721	0.3880	1.5365	0.4613
Antibiotic	1.4114	0.7221	2.7586	0.3136
Fluoroquinolone	n/a			
Schedule H	0.5705	0.2943	1.1057	0.0964
Schedule H1	0.6503	0.2442	1.7320	0.3892
Steroid	0.6882	0.2686	1.7631	0.4363
Delhi : Mumbai (Odds ratios greater than 1 favor Delhi)				
Ideal Case Management	1.9545	0.7402	5.1613	0.1762
Referral	2.0437	0.7578	5.5114	0.1579
Medication	0.7753	0.3244	1.8530	0.5670
Antibiotic	2.1217	0.8788	5.1223	0.0944
Fluoroquinolone	n/a			
Schedule H	1.0833	0.4752	2.4695	0.8490
Schedule H1	4.8000	0.6027	38.2299	0.1384
Steroid	n/a			
Patna : Mumbai (Odds ratios greater than 1 favor Patna)				
Ideal Case Management	0.9954	0.5434	1.8232	0.9881
Referral	1.5124	0.8566	2.6701	0.1538
Medication	0.6737	0.3948	1.1497	0.1475
Antibiotic	4.7785	3.0754	7.4246	0.0000
Fluoroquinolone	33.2856	7.9153	139.9730	0.0000
Schedule H	0.6745	0.4468	1.0182	0.0609
Schedule H1	9.5375	2.8050	32.4294	0.0003
Steroid	18.8219	4.3794	80.8932	0.0001

Notes: This analysis uses the subsample of interactions for each city pair for which the same individuals presented SP cases in both cities. For Patna-Delhi, N = 63 Delhi interactions and 229 Patna interactions by six SPs who worked in both cities; for Delhi-Mumbai, N = 35 Delhi interactions and 141 Mumbai interactions by three SPs who worked in both cities; and for Patna-Mumbai, N = 240 Patna interactions and 227 Mumbai

interactions by four SPs who worked in both cities. Regressions are controlled for case and SP identity using fixed effects.

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Chapter 4: Gender differences in quality of TB care

4.1 Preface

TB affects both men and women. In almost all countries (including India), the notification rates of TB are higher in men compared to women. Globally, 6.3 million TB cases were notified in the year 2014. Overall global male to female ratio was 1.7: 1 and in India, the ratio was 2:1. Although, more men than women are diagnosed with TB and die from it, TB is nevertheless a leading infectious cause of death among women. Higher TB notification rates in men partly due to epidemiological and biological differences in exposure, risk of infection, and progression from infection to disease. In addition, in countries like India, gender inequality, socioeconomic and cultural factors may be acting as barriers in accessing health care. This may be leading to under-notification rates of TB in women. The fear and stigma associated with TB have a greater impact on women than on men, often leaving them in a more vulnerable position.

It is widely believed that medical care seeking behaviour of men and women suffering from TB is largely determined by how they and those around them perceive the symptoms, regard the diagnosis, accept the treatment, and stay with it. Gender may influence each of these and affect early detection of the disease and its outcome. The recent systematic review on delays in TB diagnosis and treatment in India showed that on an average, there is a time-gap of nearly 2 months between the onset of TB symptoms and diagnosis. Studies that have assessed gender differences have shown that on an average, women are diagnosed later in the course of TB disease when compared to men. It is not known to what extent health care providers contribute to this delay in diagnosis due to the gender differences in their practices. There have not been any studies that have specifically assessed this aspect. We have used standardized patient methodology in order to assess this aspect.

The **overall goal** of this study is to assess the gender differences in diagnostic and treatment practices of health care providers for male and female standardized patients presenting with classical symptoms of TB in Delhi, Mumbai and Patna cities of India.

4.2 Manuscript-3: Gender differences in the quality of tuberculosis care in India: a standardized patient study

Authors: Srinath Satyanarayana, MD[1], Ada Kwan, MHS[2], Benjamin Daniels, MS[2], Ramnath Subbaraman, MD[3], Ranendra K. Das, PhD[4], Veena Das, PhD[5], Jishnu Das, PhD[2,6], Madhukar Pai, MD, PhD[1]

[1]McGill International TB Centre & Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montreal, Canada
[2]Development Research Group, The World Bank, Washington DC, USA
[3]Division of Infectious Diseases, Brigham and Women's Hospital and Harvard Medical School, Boston, USA
[4]Institute for Social and Economic Research on Development and Democracy, Delhi, India
[5]Department of Anthropology, Johns Hopkins University, Baltimore, USA
[6]Center for Policy Research, New Delhi, India

Manuscript details
Word count: Abstract- 450 words: Main text -4806 words
Number of tables: 9; Number of references: 19

Short title: Gender differences in quality of TB care

Key words: tuberculosis, standardized patients, gender, health care providers, India

4.2.1 Abstract

Background

In India, twice as many male tuberculosis (TB) patients are notified when compared to females. Female TB patients are more likely to be diagnosed late when compared to male patients. However, it is unclear whether quality of TB care by healthcare providers varies by gender of the patients.

Objectives

To assess the gender differences in diagnostic and treatment practices of private sector health care providers [allopathic, AYUSH and other (unqualified)] for male and female standardized patients presenting with pulmonary TB symptoms and disease.

Methods

We used male and female standardized patients (SPs) depicting four different case scenarios in three urban areas of India: Delhi, Mumbai and Patna. Case-1 presented with classic symptoms of TB; Case-2 presented with classic symptoms of TB along with a chest radiograph suggestive of TB; Case-3 presented with classic symptoms of TB and a sputum smear report positive for acid fast bacilli; and Case-4 presented with symptoms of TB, a positive sputum smear report and a previous history of TB disease. The correctness of case management was ascertained from a TB disease perspective using the Standards of TB Care in India as a benchmark. We assessed gender differences in correct management by pooling the data across three cities (overall), and also stratified by a) cities, b) types of SP cases and c) health care providers' qualification.

Results

There were 3007 SP visits to providers in 1346 health facilities of which 836 (28%) visits were by female SPs. Overall, across all sites, providers, and cases, 35% (95% CI: 33-38) of the male SP visits and 39% (95% CI:35-42) of the female SP visits were correctly managed. There was no statistically significant difference in the odds of correct management between male SPs and female SPs after adjusting for the four types of cases, provider qualification, three cities, and accounting for individual provider effects [adj OR 1.08 (95% CI: 0.87-1.34)]. Allopathic (MBBS) providers were more likely to manage cases correctly [52% (95% CI; 49-56)], when compared to providers of alternative systems of medicine [18%; 95% CI: 16-20)]. However, Allopathic (MBBS) providers

were more likely to correctly manage male SPs than female SPs (adj OR 1.51 times; 95% CI: 1.08-2.07). With the exception of this finding, stratified analysis across the three cities and across the four types of cases did not show any statistically significant gender differences in quality of care.

Conclusions

In India, the levels of correct management of standardized patients who presented with TB symptoms and TB disease were low. Overall, there was no statistically significant gender in the management of male and female standardized patients except that allopathic providers managed male SPs differently than female SPs. Further research is necessary to understand the reasons for poor quality of TB care, and gender differences among allopathic providers.

4.2.2 Introduction

Tuberculosis (TB) affects nearly 9.6 million people annually and is one of the major global public health problems.[1] In almost all countries, the notification rates of TB are higher in males when compared to females. Although more men than women are diagnosed with TB and are reported to die from it, TB is still one of the leading causes of death among women accounting for nearly 5% of deaths in women aged 15-49 years.[2] Globally, of the 6.3 million TB cases notified in 2014, the male to female ratio was 1.7:1 and in India, the highest TB burden country in the world with 1.5 million notified cases, the ratio was 1.9:1.[1]

Higher TB notification rates in men is probably due to epidemiological and biological differences in exposure to TB bacteria, risk of infection following exposure, and progression from infection to disease.[3] However, in low and middle income countries like India, where poverty is widespread, it could also be due to gender inequality, socioeconomic and cultural factors which may be preventing women from accessing health care.[4] Gender inequality refers to the relative social and economic empowerment or disempowerment of an individual due to the social construction of his/her roles, responsibilities, behaviour, attributes and activities solely on the basis of their biological sex.[5] It is well known that TB-related fear and stigma affects women more than men, resulting in disproportionate adverse socio-economic impact.[6] However, a study from south India shows that despite having to face more stigma and inconvenience, females when compared to males, were more likely to access health services, be notified under TB control programme and adhere to treatment.[7] Therefore, it is uncertain how the gender differences in notification rates reflect access to or quality of medical care, stigma, or actual epidemiological differences – and to what extent each of these contribute to an uneven sex ratio for TB cases and what that could mean for the nearly 3 million incident cases that are missing from the notification systems globally.

A recent systematic review on delays in TB diagnosis and treatment in India showed that on an average, there is a time-gap of nearly two months between the onset of TB symptoms and diagnosis.[8] Studies that have assessed gender differences have shown that on an average, women are diagnosed later (by about a couple of weeks to a month) in the course of TB disease when compared to men.[9,10]

In any society, the differences in medical care received by men and women suffering from TB is determined by a number of factors[11] and health care providers, by their differential practices, can contribute to the observed gender differences.[4] Ideally, male and female patients with TB should receive the same quality of medical care. However, this has not been well researched. Due to natural variations in the characteristics of patients and health care providers, previous studies using patient and provider interviews have been unable to disentangle the relative contribution of patient and provider factors to the observed gender differences.[7,9,10] This can be overcome by using standardized or simulated patients (SP), where patient factors can be standardized and controlled. We have previously developed and validated the SP methodology in Delhi to study health care providers' TB related management practices in India.[12] After validation, we are using this methodology to assess health care providers TB management practices in Mumbai and Patna cities in India. We used data from this large, ongoing study to assess the gender differences in diagnostic and treatment practices of health care providers while managing SPs presenting with similar features of pulmonary TB disease.

4.2.3 Methods

Hypothesis

Our a-priori hypothesis was that there are no differences in the health care providers' correct management of male versus female standardized patients with TB symptoms and TB disease. However, if the odds ratio of correct management of male and female standardized patients was more than 1.75, then we hypothesized that this difference was of public health importance. Our a-priori hypothesis was based on the fact that none of the previous studies indicated the presence of gender differences by health care providers. We chose this odds ratio of 1.75 to denote public health significance warranting specific interventions as this corresponds to 10 to 12 point difference in correct management between the two genders in the proportion or percentage scale.

Setting

We used data from a larger, ongoing study on quality of TB care in the private sector in Delhi, Mumbai and Patna. This project is funded by the Bill & Melinda Gates Foundation, and is part of a larger intervention to improve TB care in India's private sector. In all three cities, TB is a major public health problem with the annual notification rates for the year 2014 per 100,000 population being 294 (Delhi), 210 (Mumbai) and 77 (in Patna). Similar to all other urban areas in India, there

are a large number of private health care providers who are usually the first point of care and the predominant source of TB care.[9,13] The private health care providers usually do not notify TB cases diagnosed and treated by them to the public health authorities. Therefore, the notification rates of these cities mentioned above are an underestimate of the actual TB burden. The health care providers in the private sector comprise of qualified providers of allopathic system of medicine who hold a Bachelors in Medicine and Bachelors in surgery (MBBS) degree, qualified providers of any of the other alternate systems of medicine such as Ayurveda, Unani, Siddha and Homoeopathy (collectively called as AYUSH providers) and 'other' providers who are not qualified in any of these systems of medicine. The quality of TB care in the private sector is known to be relatively sub-optimal when compared to public health care providers.[14]

Standardized patients

In general, SPs are apparently healthy individuals who are recruited from local communities and trained to enact certain tracer medical conditions in a consistent manner. They visit pre-selected health care providers un-announced as any other patient and seek medical care. Soon after the clinical interaction, the SPs are debriefed about the interaction. They complete a structured questionnaire within an hour of the visit allowing the researchers to assess the various aspects of care.

In the current study, four SP case scenarios were included: Case-1 presented with classic symptoms of TB (cough of 2 weeks or more, with fever, weight loss, and loss of appetite); Case-2 presented with classic symptoms of TB along with a chest X-Ray report suggestive of TB; Case-3 presented with classic symptoms of TB along with a sputum smear report positive for acid fast bacilli; and Case-4 presented with symptoms of TB with a previous history of TB disease plus a sputum smear report positive for acid fast bacilli. The detailed description of the cases and the expected correct case management for these cases as per the Standards of TB care in India[15] is given in **Table 1**. (page 137) These four cases correspond to the four cases described in our previous validation study of the SP methodology for TB.[12]

These case scenarios were developed and agreed by a Technical Advisory Committee made up of a multi-disciplinary team including clinicians, TB experts, anthropologists and program specialists in international and national recommendations. The case scenarios were used to understand what health care providers do when they see a patient with TB symptoms without any specific pointers

towards TB disease (Case-1) and cases with specific pointers towards TB disease such as chest X-Ray report (Case-2), a positive sputum smear report (Case-3) and previous history of TB disease and a positive sputum smear report (therefore, at high risk of drug-resistant TB) (Case-4). Each of these four cases was presented by both male and female SPs; this provided us an opportunity to study the gender differences in the health care providers' management of these cases. A different group of patient actors (SPs) was used in each city. In Delhi, there were 17 SPs (10 male, 7 female); in Mumbai, 17 SPs (12 male, 5 female); and in Patna, 12 SPs (7 male, 5 female).

Selection of health care providers for SP visits

A total of 1346 health care facilities were selected for SP visits across the 3 cities. In Delhi **100** health facilities were selected by convenient sampling from low income localities. In Patna, a pre-study mapping of all health care providers in Danapur, Phulwarisharif and Patna blocks and in Mumbai, a pre-study mapping of health care providers from 15 high slum population wards of the city formed the sampling frame, from which, a mixture of allopathic (MBBS), AYUSH and 'other' health care providers were selected for the SP visits. In urban Patna **517** health facilities and in Mumbai **729** health facilities were selected by stratified, random sampling. These areas matched the overall private sector intervention funded by the Gates Foundation. The SPs visited health facilities in Delhi during Feb - March, 2014 and in Patna and Mumbai during Nov 2014 to June, 2015.

The overall plan for the SP visits to the selected health facilities were as follows: each facility was visited by SP case-1 and one of the other three types of SP cases (case-2 or case-3 or case-4). Health facilities that contained more than one health care provider were visited by more than two standardized patients. Male or female standardized patients of each SP case type were randomly allocated to visit the selected health care facilities.

According to this plan, SPs visited 1346 health care facilities in three cities and completed 3007 interactions; 987 (73%) of the health facilities were visited by two SPs, 230 (17%) were visited by 3 SPs, 82 (6%) were visited by one SP and the remaining 47 (4%) by more than 3 SPs. The median number of SP visits to any given health facility was 2 (IQR 2 to 2; range 1-11). The number of SP-health facility interactions –total and disaggregated by city, case and providers' qualification- is given in Table 2a and 2b (page 138). Of these 3007 interactions, 2171 (73%) visits were by male SPs and the remaining 836 (27%) were by female SPs. Overall 1368 (45%) visits were to health facilities with allopathic (MBBS) qualified providers, 1056 (35%) visits were to health facilities

with AYUSH qualified providers and the remaining to health facilities with no or 'other' qualification providers.

Of the 1346 health facilities, by design, very few health facilities were visited by both a male and female SP case of the same type (76 facilities were visited by both male and female SP Case-1, six facilities were visited by both male and female SP Case-2, two facilities were visited by both male and female SP Case-3 and three health facilities were visited by SP Case-4 three facilities. Therefore, we had very limited sample size to directly estimate the difference in how health facilities managed male vs female SPs. In order to increase the effective sample size, we pooled the data from all the three cities (Delhi, Patna and Mumbai).

Data analysis

The basic unit of analysis was a health facility-SP interaction. We chose health facility rather than health provider as the unit of analysis as in some instances it was difficult to ascertain whether all SPs who visited a particular health facility met the same provider or not. All medicines prescribed by the health care providers were independently coded by two medical doctors with expertise in TB (SS) and infectious diseases (RS). The two coders were blinded from any provider and SP identifying details while classifying the medicines as steroids, anti-TB drugs, fluoroquinolones, or other broad-spectrum antibiotics. After this coding, we assessed the correctness of cases management (the primary outcome measure) as described in Table 1 (page 137).

This study design wherein most of the health facilities were visited by at least two different types of SP cases was an advantage as the health facilities visited by more than one SP (94% of them) acted as their own controls and thereby reducing confounding that may arise as a result of the differences in the health care facility characteristics.

As the SP methodology, by definition, controls for most of the patient related factors, we hypothesized that the overall differences in the management of cases by the health care providers mainly depended upon the type of case, the gender of the SP, study city and health care provider qualification. Therefore, after adjusting for the type of case, health care provider qualification, and city and by accounting for correlation of the outcomes at each health facility level, the observed differences in the management can be attributed to the gender of the SP. We used generalised linear binomial (logit) mixed effects regression and linear mixed effects regression models to obtain the

conditional estimate (at each facility level) of the relative odds or relative differences of management of male SPs versus female SPs for each type of case on 12 key parameters [a composite index of essential history questions, number of essential physical examination conducted (auscultation, throat examination, temperature and weight measurement), laboratory investigations (Chest-X-Ray, sputum smear examination, Xpert MTB/RIF, a molecular TB test), prescription of drugs (number of drugs prescribed, antibiotics, fluoroquinolones, anti-TB drugs and steroids) and whether TB was mentioned to the patients].

We fit a random intercept logistic regression model to estimate the relative odds between the 'correct' management of male SPs and female SPs. The model is illustrated below with the following notations:

- Logit (Y_{ijkqs})= log odds of correct management at health facility 'i', for case 'j' , with gender 'k', with provider qualification 'q' at city 's',
- v_{0i} = Random intercept for each health facility *i* (i=1 to 1346),
- G=Gender of the SP (k=Female, Male),
- C=type of SP case (j=Case-1, Case-2, Case-3 and Case-4),
- Q=Provider qualification (q=allopathic (MBBS), AYUSH, Others),
- S= Study site (s=Delhi, Mumbai and Patna).
- β=coefficients
- Model: Logit (Y_{ijkqs})= $\beta_0 + v_{0i} + \beta_1 * G_k + \beta_2 * C_j + \beta_3 * Q_{jq} + \beta_4 * S_s + \varepsilon_{ijkqs}$

where the exponentiation to the 'e' of the coefficient β_1 is interpreted as the odds ratio for management of male SPs versus female SPs at each health facility level, the random intercepts v_{0i} indicating individual health care facility effects with a distribution ~N (0, σ_p^2), and ε_{ij} , the residuals of the model with a standard logistic distribution. We assessed gender differences in correct management by pooling the data across three cities (overall)- so as to increase the sample size for answering key research question-, and also stratified by a) cities, b) types of SP cases and c) health care providers' qualification. All analyses were done by using Stata 12.1 (Stata Corporation, College Station, TX).

Assessing presence of unmeasured confounders

Other than the variables that we adjusted in our analysis, we assessed for the presence of other un-measured provider and health facility related factors that can act as confounders (such as

differences in the health providers knowledge about TB disease and its management, availability of diagnostic and treatment facilities in the vicinity etc.,). In our study each health care facility was visited by either a male or a female standardized patient of a particular case type followed or proceeded by other case types. For example, health care facilities were visited by either male SP1 or female SP1 (and very rarely both), and preceded or followed by visits by male Case-2 or female Case-2/ male Case-3 or female Case-3 / male Case-4 and female Case-4. Very rarely health care facilities were visited by the same case and gender. Therefore, when estimating the differences in correct management for male SP-1 and female SP-1, certain factors other than the provider qualification and city (such as provider knowledge or availability of diagnostic and treatment facilities etc.,), could act as unmeasured confounders. To check whether such unmeasured confounding exists, we did a balance analysis by comparing how the group of health care facilities (HCF) who received male and female SPs managed other SP case types. i.e., we checked for the following assumptions:

1. E (Yij | HCF visited by Female SP1) = E(Yij | HCF visited by male SP1). That is, whether the performance/probability of correct management (Y) for the case i (i=2,3, 4) of gender j (j=male, female) is the same in the group of health care facilities who were visited by female SP-1 and male SP-1 after adjusting for provider qualification and city fixed effects

2. E (Yij | HCF visited by Female SP2) = E(Yij | HCF visited by male SP2). That is, whether the performance/probability of correct management (Y) for the case i (i=1,3, 4) of gender j (j=male, female) is the same in the group of health care facilities who were visited by female SP-2 and male SP-2 after adjusting for provider qualification and city fixed effects

3. E (Yij | HCF visited by Female SP3) = E(Yij | | HCF visited by male SP3). That is, whether the performance/probability of correct management (Y) for the case i (i=1,2, 4) of gender j (j=male, female) is the same in the group of health care facilities who were visited by female SP-3 and male SP-3 after adjusting for provider qualification and city fixed effects

4. E (Yij | HCF visited by Female SP4) = E(Yij | | HCF visited by male SP4). That is, whether the performance/probability of correct management (Y) for the case i (i=1, 2,3) of gender j (j=male, female) is the same in the group of health care facilities who were visited by female SP-4 and male SP-4 after adjusting for provider qualification and city fixed effects.

If the above four assumptions were correct, then we can assume that there were no unmeasured confounders.

Ethics approvals

The standardized patient study has received ethical approvals from McGill University in Montreal, Canada (MUHC study code 13-269-BMB for the Delhi component, and MUHC study code 14-137-BMB for Mumbai and Patna component) and the Institute of Socio-economic Research on Development and Democracy (ISERDD) in Delhi, India. The study received waiver from obtaining informed consent from the health care providers or their facilities.

4.2.4 Results

Table 3 (page 139) shows the quality of TB care for SPs. Overall, 36% (95%CI: 34-38) of the SPs were correctly managed; higher proportion of Case-2 were correctly managed [59% (95% CI: 54-63] followed by Case-1 [39% (95% CI: 36-42)], Case-3 [32% (95% CI: 27-37)] and Case-4 [15% (95% CI: 12-19)]. Among health care providers, allopathic (MBBS) qualified providers managed relatively higher proportion of cases correctly [52% (95% CI: 49-56)], while health care providers with AYUSH qualification managed the least proportion of cases correctly [18% (95% CI: 16-20]. Among cities, providers in Mumbai [38%; 95% CI: 35-41] and Patna [38%; 95% CI: 34-42] managed relatively higher proportion of cases correctly when compared to providers in Delhi [21%; 95% CI: 15-26].

Table 3 (page 139) also shows the gender differences in the 'correct' management of cases overall and stratified by SP case type, provider qualification and city. Overall, 35% [95% CI: 33-38] of the male SPs and 39% [95% CI: 35-42] of the female SPs were correctly managed. There was no statistical difference in the odds of correct management between male SPs and female SPs after adjusting for the four types of cases, provider qualification, three cities, and individual facility effects [adjusted Odds ratio of 1.08 (95% CI: 0.87-1.34)].

Stratified analysis across the three cities and across the four types of cases did not show any statistically significant gender differences in the 'correct' management of cases. However, stratified analysis by provider qualification showed that while allopathic (MBBS) providers managed SP

cases more often correctly than providers with other qualification, their adjusted odds of correctly managing male SPs were 1.51 times [95% CI: 1.08-2.07] higher than that of female SPs.

Table 4 (page 140) shows the gender differences on 12 key parameters related to quality of TB care. Health care providers asked on an average about 48% [95% CI: 46-49] of the essential history questions to both male SP and female SPs. They conducted on an average about 1.6 [95% CI: 1.5-1.7] of the 4 essential clinical exams (auscultation, weight & temperature assessment and throat examination) to both male and female SPs. The clinical history questions that were asked and the clinical exams conducted for male and female SPs are given in detail in Table 5 (page 141). While there were some statistically significant gender differences in asking SPs about a few clinical history questions, at the composite level there were no statistically significant differences as shown in Table 4 (page 140). Table 4 further shows, that chest radiography was the most common investigation that health care providers requested SPs to get done [41% (95%CI: 39-43)] for both male and female SPs followed by sputum smear examination [13% (95% CI: 11-15) for male SPs and 19% (95% CI: 16-22) for female SPs]. Xpert MTB/RIF test was requested in 5% [95% CI: 3-6] of the male and female SPs. Health care providers prescribed at least one medication to 87% [95% CI:85-89] of the male SPs and 82% [95% CI: 80-85] of the female SPs. On an average they prescribed about 3.8 and 3.4 different medicines per interaction for male SPs and female SPs respectively. Antibiotics were prescribed for 51% [95% CI: 51-56] of the male SPs and 61% [95% CI:57-64] for female SPs; fluoroquinolone group of antibiotics were prescribed for 12% [95% CI: 10-13] of the male SPs and 16% [95% CI: 13-19] of the female SPs; anti-TB drugs were prescribed for 4% [95% CI: 3-5] of the male SPs and 6% [95% CI: 6-8] of the female SPs; and steroids were prescribed for about 6% [95% CI:5-7] of the male SPs and 7% [95% CI: 5-9] of the female SPs. Health care providers had mentioned the possibility of TB to 37% [95% CI: 34-39] of the male SPs and 40% [95% CI: 36-43] of the female SPs. After adjusting for different types of cases, provider qualification, city fixed effects and after accounting for health facility random effects we did not find any statistically significant gender differences on any of these parameters.

Assessment for unmeasured confounders

Table 6 (pages. 142-143**)** shows the differences in the correct management of other SP cases by the same health care facilities who received either male or female SPs of a particular case type. As it can be seen in this table, apart from 2 instances, there are no statistically significant differences in the management of cases by different groups of health facilities implying that the health care

facilities that were visited by male or female SPs of a particular case had similar management capacities and there is unlikely to be any unmeasured confounders. Therefore other than health care provider qualification, case-type, city fixed effects and provider random effects, we can assume that there are unlikely to be any unmeasured confounders.

Additional analysis

The detailed stratified analysis showing gender differences across the 12 parameters stratified by case type (Table 7, pages 144-146), by health care provider qualification (Table 8, page no. 147-148) and by each city (Table 9, page no. 149-150), While we found some statistically significant gender differences on some parameters, the magnitude of the gender difference was not more than 10% in most of these instances and therefore, they are unlikely to be of public health or clinical importance.

4.2.5 Discussion

To our knowledge, this is the first study in India assessing gender differences in health care providers' management of persons with features of pulmonary TB by using standardized patients and found no major differences. The strengths of the study include the SP methodology, large number of SP-health care facility visits with at least two SP visits to most of the health facilities and data from three large cities located in different parts of the country. In our analysis we assessed gender differences not only for correct management, but also on 12 different parameters and did not find any major differences that are large enough to be of public health importance. Under the assumption of no unmeasured confounding, the study results are reliable, valid and generalizable to private health care provider in these cities.

The limitations of the study include: **First**, the overall larger SP study was not primarily designed to study the gender differences in health care providers' management practices, and different recruitment challenges existed across the cities in identifying and retaining female SPs in particular. And therefore, we may not have adequate sample size/power to describe all the nuances of the gender differences in management including the sample size for our balance analysis. However, we had adequate power to assess whether the odds ratio of "correct management" not beyond 1.75 at the aggregate level (i.e., both the upper and the lower bounds of the 95% CI of the odds ratio was between 0.57-1.75, a key feature that suggests equivalence as per our definition of the maximum

permissible difference). We believe that a larger sample size would have increased the precision but not the relative levels of central estimates of the odds ratios and therefore, from a public health point of view, we feel that the gender differences in health care providers are unlikely to be huge. **Second**, in this study, our methodology reflects what health care providers do when they come across a completely 'unknown' or a 'new' patient seeking medical care. If their practices are different for those patients that frequently visit them for all types of ailments and are 'known' to them, then extrapolating this study findings to those patients may not be appropriate. **Third**, we have assumed that at the individual facility level, health care provider practices are consistent for a particular case presentation. If the practice is inconsistent, then our study design may not be able to identify correctly the characteristics of individual health care facilities who manage correctly and those who do not. In such a scenario, the average estimates for the group are more likely to be consistent rather than at the individual level. **Fourth**, we assessed the correctness of case management from an allopathic medicine system perspective. Nearly 55% of health care providers included in our study did not have a qualification in allopathic medicine and their systems of medicine may recommend an alternative way of managing TB and therefore assessing their management from allopathic perspective may appear incorrect. A recent ethnographic study from Mumbai show that more than 90% of the non-allopathic qualified providers interviewed followed allopathic system for diagnosis and treatment for TB and therefore assessing their practice from an allopathic system perspective does not appear to be unreasonable.[16] **Lastly**, our study was entirely focused on private healthcare providers in India, and does not provide any insights into whether male and female patients are managed differently in the public sector national TB program.

Despite these limitations, there are three major findings from our study that have public health implications. **First,** the overall levels of correct management were low for both genders across cases and health care provider categories and this should be a cause for major concern from the TB control point of view. Irrespective of the genders, health care providers were not asking the relevant questions, were not suspecting TB, and were not ordering microbiological tests that would help diagnose TB early. Instead, more than 80% of the health care providers prescribed medicines, half of which contained antibiotics, majority of which, do not have any role in TB care. The prescription of fluoroquinolone antibiotics and steroids is particularly worrisome as they can suppress symptoms and lead to delays in TB diagnosis.[17] **Second,** at the aggregate level there were no statistically significant gender differences in the management of cases. Therefore, our concerns

about health care providers being responsible for gender differences in the delays in diagnosis and/or inappropriate management may not be true. **Third,** our stratified results indicate that despite providing higher levels of correct management, health facilities with allopathic (MBBS) qualified health care providers are more likely to show gender differences with an adjusted odds ratio of 1.5 in favor of male SPs. The reasons why allopathic (MBBS) providers showed these gender differences are not clear. This could partly be due to their prior knowledge of TB being more common in males than females. Though this is epidemiologically true, health care providers are expected not to show any differences in managing patients of either gender with features highly suggestive of TB. Therefore, there is an urgent need to better understand provider behavior with regards to gender, and undertake measures to reduce these differences in practices.

4.2.6 Conclusion

This study along with many other previous studies examined in a recent systematic review [14] contribute to the growing body of evidence showing considerable deficiencies in health care providers' management of TB in India. The low levels of correct management for both male and female SPs and the presence of gender differences at health facilities with allopathic providers is of concern. Qualitative research aimed at understanding the reasons for low levels of correct management, gender differences by allopathic providers and targeted interventions aimed at addressing these reasons - are urgently needed to improve TB management in both genders. Since, India is the country with highest number of TB cases in the world, addressing these deficiencies and creating a health system environment that promotes optimal care, especially in the private sector, will have a major impact on global TB control.

4.2.7 References (Manuscript 3)

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4.2.8 Tables

Table 1: Standardized patient case scenarios and their correct management according to Standards of TB Care in India

Standardized Patient Case scenarios	Expected correct Case management
Case-1: Classic case of presumed tuberculosis with 2–3 weeks of cough, fever, loss of appetite, loss of weight	Recommendation for sputum testing or chest radiograph, or referral to a public DOTS centre or qualified provider
Case-2*: Classic case of presumed tuberculosis in a patient who has had 2–3 weeks of cough and fever and history of taking a broad-spectrum antibiotic (amoxicillin) for 1 week, given by another health-care provider, with no improvement and also carrying a Chest X-Ray and its report suggestive of TB	Recommendation for sputum testing or Chest X-Ray, or referral to a public DOTS centre or qualified provider
Case-3: Cough of 4 weeks with fever, loss of appetite, loss of weight and a positive sputum smear report for tuberculosis from a public health facility	Either referral to a public DOTS centre, a qualified private provider or specialist, or (in the case of a qualified private provider) initiation of treatment with standard, four-drug, first-line anti-tuberculosis therapy (isoniazid, rifampicin, pyrazinamide, and ethambutol [the HRZE regimen])
Case-4: Chronic cough, a positive sputum smear report for tuberculosis from a public health facility, and, if asked, a history of previous, incomplete treatment for tuberculosis, which would raise the suspicion of multidrug-resistant tuberculosis	Recommendation for any drug-susceptibility test (culture, line probe assay, or Xpert MTB/RIF) or referral to a public DOTS centre or a specialist

***** In Delhi, there was a small change in SP Case-2 presentation- they did not carry the Chest X-Ray and its report

Table 2a: Standardized patient (SP)-health facility visits disaggregated by case, gender and city

Cities	Female SP	Male SP	Total
Delhi			
Case1	38	37	75
Case2	19	56	75
Case3	14	36	50
Case4	22	28	50
Delhi Subtotal	**93 (37%)**	**157 (63%)**	**250**
Patna			
Case1	209	423	632
Case2	76	76	152
Case3	81	82	163
Case4	87	87	174
Patna subtotal	**453 (40%)**	**668 (60%)**	**1121**
Mumbai			
Case1	77	727	804
Case2	127	120	247
Case3	33	171	204
Case4	53	328	381
Mumbai Subtotal	**290 (18%)**	**1346 (82%)**	**1636**
Grand Total	**836 (28%)**	**2171 (72%)**	**3007 (100%)**

Table 2b: Number of standardized patient-health facility visits disaggregated by case, gender and health care facilities with provider qualification

Type and gender of	Health care facilities with provider Qualification			Total
	Allopathic (MBBS)	AYUSH	Others	N (%)
Case1-Male	504	463	220	1,187 (39)
Case1-Female	187	59	78	324 (11)
Case2-Male	115	87	50	252 (8)
Case2-Female	114	61	47	222 (7)
Case3-Male	119	114	56	289 (10)
Case3-Female	70	25	33	128 (4)
Case4-Male	172	209	62	443 (15)
Case4-Female	87	38	37	162 (5)
Total -N (%)	**1368 (45%)**	**1056 (35%)**	**583 (20%)**	**3,007 (100)**

*For description of cases, please see table 1; MBBS= Bachelor of Medicine, Bachelor of Surgery; AYUSH= Ayurveda, Unani, Siddha and Homeopathy

Table 3: Gender differences in the correct management of standardized patients presenting with pulmonary TB symptoms and disease

	Total		Male SPs		Female SPs		Gender differences (Male :Female)		
	N	Proportion correctly managed (95% CI)	N	Proportion correctly managed (95% CI)	N	Proportion correctly managed (95% CI)	Adjusted OR*	95% CI	P-value
Overall	3007	0.36 (0.34-0.38)	2171	0.35 (0.33-0.38)	836	0.39 (0.35-0.42)	1.08	(0.87-1.34)	0.475
Stratified by SP Case Types									
Case-1	1511	0.39 (0.36-0.42)	1,187	0.39 (0.36-0.42)	324	0.37 (0.32-0.43)	1.40	(0.88-2.24)	0.157
Case-2	474	0.59 (0.54-0.63)	252	0.57 (0.51-0.63)	222	0.59 (0.53-0.66)	1.68	(0.75-3.74)	0.206
Case-3	417	0.32 (0.27-0.37)	289	0.31 (0.26-0.37)	128	0.34 (0.25-0.42)	0.55	(0.23-1.30)	0.177
Case-4	605	0.15 (0.12-0.19)	443	0.15 (0.12-0.18)	162	0.17 (0.10-0.22)	1.00	(0.55-1.80)	0.998
Stratified by Provider qualification									
Allopathic (MBBS) Providers	1368	0.52 (0.49-0.56)	910	0.56 (0.52-0.59)	458	0.46 (0.41-0.50)	1.51	(1.08-2.07)	0.011
AYUSH Providers	1056	0.18 (0.16-0.20)	873	0.16 (0.13-0.19)	183	0.27 (0.20-0.33)	0.72	(0.44-1.15)	0.169
Other Providers	583	0.31 (0.28-0.36)	388	0.31 (0.26-0.36)	195	0.33 (0.26-0.39)	0.74	(0.46-1.20)	0.228
Stratified by City									
Delhi	250	0.21 (0.15-0.26)	157	0.21 (0.14-0.27)	93	0.20 (0.12-0.29)	0.86	(0.43-1.71)	0.661
Patna	1121	0.38 (0.34-0.42)	668	0.40 (0.36-0.44)	453	0.34 (0.29-0.38)	1.30	(0.94-1.79)	0.108
Mumbai	1636	0.38 (0.35-0.41)	1,346	0.35 (0.32-0.37)	290	0.52 (0.46-0.58)	0.93	(0.64-1.35)	0.712

For definitions of Case-1, Case-2, Case-3 & Case-4 and the correct management- please see Table 1; MBBS= Bachelor of Medicine& Bachelor of Surgery; AYUSH= Ayurveda, Unani, Siddha and Homeopathy; mixed effect logit models used to assess adjusted odds ratios, robust standard errors.
*Adjusted for case type, provider qualification, city fixed effects and health facility random effects except for the stratifying variable
Note: SE for means and proportions are robust standard errors adjusted for 1346 clusters at health facility level.

Table 4: Overall Gender differences in management of standardized patients (SPs) with TB symptoms and disease by health care providers in 3 cities (pooled)

Parameters	Male SPs (N=2171)	Female SPs (N=836)	Difference in means / odds ratios after adjusting for SP case, provider qualification, city fixed effects and provider random effects		
	Mean (95% CI)	Mean (95% CI)	Mean difference (Male-Females)*	95% CI	P-value
History Checklist Completion%	0.48 (0.46-0.49)	0.47 (0.45-0.49)	-0.008	(-0.02 to 0.01)	0.396
Number of clinical exams conducted (#)	1.58 (1.53-1.63)	1.58 (1.50-1.67)	0.013	(-0.06 to 0.087)	0.732
Number of medicines prescribed	3.80 (3.70-3.91)	3.38 (3.23-3.52)	0.058	(-0.09 to 0.21)	0.454
Health care providers-Prescribed	**Proportion**	**Proportion**	**Adjusted Odds ratios****		
Chest X-Ray	0.41 (0.39-0.43)	0.41 (0.37-0.44)	1.20	(0.95 to 1.53)	0.125
Sputum smear examination	0.13 (0.11-0.15)	0.19 (0.16-0.22)	0.90	(0.67 to 1.19)	0.453
Xpert MTB/RIF	0.05 (0.03-0.06)	0.05 (0.03-0.06)	1.22	(0.81 to 1.86)	0.336
Any medication	0.87 (0.85-0.89)	0.82 (0.80-0.85)	1.26	(0.92 to 1.74)	0.15
Antibiotics	0.54 (0.51-0.56)	0.61 (0.57-0.64)	0.89	(0.69 to 1.13)	0.338
Fluoroquinolones	0.12 (0.10-0.13)	0.16 (0.13-0.19)	0.90	(0.66 to 1.23)	0.512
Steroids	0.06 (0.05-0.07)	0.07 (0.05-0.09)	1.19	(0.75 to 1.88)	0.469
Anti-TB drugs	0.04 (0.03-0.05)	0.06 (0.05-0.08)	1.21	(0.79 to 1.83)	0.379
Mentioned TB	0.37 (0.34-0.39)	0.40 (0.36-0.43)	0.96	(0.78 to 1.19)	0.725

* calculated using mixed effects linear models; ** calculated using mixed effects logit models;
Note: SE for means and proportions are robust standard errors adjusted for 1346 clusters at health facility level.

Table 5: History questions and physical examination conducted by health care providers for standardized patients (SPs)

	Male SPs N=2171	**Female SPs** N=836	Gender differences (Male: Female)	
			adj OR* (95% CI)	P-Value
Patients were asked about	*Proportion (95% CI)*	*Proportion (95%CI)*		
Duration of cough	0.92 (0.91-0.93)	0.91 (0.89-0.93)	1.05 (0.79-1.40)	0.697
Sputum	0.70 (0.68-0.72)	0.68 (0.65-0.71)	1.00 (0.83-1.20)	0.992
Blood in sputum	0.24 (0.22-0.26)	0.28 (0.25-0.31)	0.99 (0.81-1.21)	0.942
Fever	0.79 (0.77-0.81)	0.73 (0.70-0.76)	1.34 (1.1-1.63)	0.004
Weight loss	0.23(0.21-0.26)	0.29 (0.26-0.32)	0.76 (0.61-0.95)	0.014
Loss of appetite	0.37(0.35-0.39)	0.44 (0.40-0.47)	0.87 (0.72-1.05)	0.153
Chest Pain	0.24 (0.22-0.26)	0.34 (0.30-0.37)	0.57 (0.47-0.70)	<0.001
Wheezing	0.03 (0.02-0.04)	0.08 (0.06-0.10)	0.35 (0.24-0.50)	<0.001
Difficulty breathing	0.22 (0.20-0.24)	0.29 (0.26-0.32)	0.64 (0.52-0.78)	<0.001
Past history of TB	0.23 (0.21-0.25)	0.25 (0.21-0.28)	1.01 (0.80-1.28)	0.902
Family history of TB	0.14 (0.12-0.16)	0.20 (0.17-0.23)	0.68 (0.53-0.88)	0.003
Alcohol consumption	0.12 (0.10-0.13)	0.00 (0.00-0.001)	47.2 (14-153)	<0.001
Diabetes Mellitus	0.05 (0.03-0.06)	0.10 (0.07-0.12)	0.55 (0.40-0.76)	<0.001
Tobacco smoking	0.23 (0.21-0.25)	0.01 (0-0.01)	53 (21-131)	<0.001
HIV infection	0.01 (0-0.02)	0.01 (0-0.01)	2.90 (1.0-8.45)	0.05
Physical examination				
Auscultation	0.80 (0.78-0.82)	0.73 (0.70-0.76)	1.19 (0.95-1.47)	0.117
Temperature	0.20 (0.18-0.22)	0.25 (0.21-0.28)	0.91 (0.74-1.11)	0.368
Throat Examination	0.37 (0.35-0.39)	0.34 (0.31-0.38)	1.10 (0.92-1.31)	0.301
Weight	0.20 (0.18-0.23)	0.26 (0.23-0.29)	0.97 (0.77-1.22)	0.81

* adjusted for case type, provider qualification, city fixed effects and facility level random effects

Note: SE for means and proportions are robust standard errors adjusted for 1346 clusters at health facility level.

Table 6: Correct management of SPs by different groups of health facilities

SP cases that also visited health facilities visited by male SP1 or female SP1	Health facilities visited by Male SP1		Health facilities visited by Female SP1		Difference in management of SP case (described in the first column)	
	N	Proportion correctly managed	N	Proportion correctly managed	Difference in proportion (95% CI)*	P-value
Male SP2	190	0.62	67	0.52	-0.03 (-0.19 to 0.13)	0.72
Male SP3	235	0.30	67	0.28	0.0001(-0.11 to 0.11)	0.999
Male SP4	372	0.15	82	0.24	-0.07 (-0.24 to 0.09)	0.415
Female SP2	177	0.60	54	0.66	-0.061 (0.23 to 0.11)	0.491
Female SP3	102	0.32	43	0.42	-0.18 (-0.40 to 0.035)	0.099
Female SP4	111	0.12	41	0.26	-0.14 (-0.27 to -0.005)	0.042
SP cases that also visited health facilities visited by male SP2 or female SP2	**Health facilities visited by Male SP2**		**Health facilities visited by Female SP2**		**Difference in management of SP case (described in the first column)**	
	N	**Proportion correctly managed**	**N**	**Proportion correctly managed**	**Difference in proportion (95% CI) ***	**P-value**
Male SP1	227	0.44	207	0.46	0.019 (-0.06 to 0.098)	0.626
Male SP3	32	0.47	27	0.44	0.006 (-0.28 to 0.29)	0.966
Male SP4	50	0.34	47	0.38	-0.032 (-0.26 to 0.20)	0.779
Female SP1	68	0.34	58	0.36	0.12 (-0.04 to 0.29)	0.155
Female SP3	11	0.45	9	0.66	0.25 (-0.85 to 1.36)	0.632
Female SP4	25	0.28	7	0.42	0.101 (-0.45 to 0.65)	0.71
SP cases that also visited health facilities visited by male SP3 or female SP3	**Health facilities visited by Male SP3**		**Health facilities visited by Female SP3**		**Difference in management of SP case (described in the first column)**	
	N	**Proportion correctly managed**	**N**	**Proportion correctly managed**	**Difference in proportion (95% CI) ***	**P-value**
Male SP1	270	0.43	126	0.43	0.012 (-0.09 to 0.11)	0.818
Male SP2	31	0.45	11	0.27	-0.14 (-0.46 to 0.18)	0.379
Male SP4	39	0.33	16	0.31	0.16 (-0.15 to 0.47)	0.319
Female SP1	71	0.36	45	0.42	0.02 (-0.16 to 0.20)	0.821
Female SP2	25	0.4	9	0.44	0.35 (-0.06 to 0.78)	0.096
Female SP4	11	0.45	3	0.33	0.45 (-0.38 to 1.29)	0.26
SP cases that also visited health facilities	**Providers who received Male SP4 and also received other SPs**		**Providers who received Female SP4 and also received**		**Difference in management of SP case (described in the first column)**	

visited by male SP4 or female SP4			other SPs			
	N	Proportion correctly managed	N	Proportion correctly managed	Difference in proportion (95% CI) *	P-value
Male SP1	399	0.4	117	0.47	0.001 (-0.09 to 0.093)	0.983
Male SP2	40	0.57	25	0.4	-0.03 (-0.29 to 0.22)	0.766
Male SP3	29	0.48	12	0.58	-0.1 (-0.49 to 0.29)	0.607
Female SP1	73	0.39	41	0.41	-0.06 (-0.25 to 0.13)	0.514
Female SP2	36	0.64	7	0.71	0.05 (-0.37 to 0.47)	0.804
Female SP3	12	0.66	3	0.66	4.93E-17 (-0.76 to 0.76)	1

*** After adjusting for provider qualification, city fixed effects by linear mixed effects GLS regressions**

Table 7: Gender differences in the management of standardized patients (SP) stratified by type of cases

SP Case 1	Male SP1 (N=1187)	Female SP1 (N=324)	Difference in means/ proportions*	95% CI	P-value
	Mean (95% CI)	**Mean (95% CI)**			
History Checklist%	0.47 (0.46-0.48)	0.5 (0.48-0.53)	-0.070	(-0.01 to -0.045)	<0.0001
Number of clinical exams	1.64 (1.58-1.70)	1.83 (1.70-1.95)	-0.120	(-0.25 to -0.004)	0.042
Number of medicines	4.12 (4.01-4.23)	3.73 (3.55-3.91)	-0.002	(-0.21 to 0.21)	0.98
	Proportion	**Proportion**			
Chest X-Ray	0.37 (0.34-0.40)	0.35 (0.29-0.40)	0.037	(-0.01 to 0.09)	0.165
Sputum smear	0.09 (0.08-0.11)	0.06 (0.04-0.09)	0.056	(0.02 to 0.09)	0.002
Xpert MTB/RIF	0.02 (0.01-0.03)	0.009 (0.00-0.02)	0.003	(-0.01 to 0.02)	0.764
Any medication	0.94 (0.93-0.95)	0.93 (0.89-0.95)	0.004	(-0.03 to 0.035)	0.792
Antibiotics	0.61 (0.58-0.63)	0.72 (0.67-0.77)	-0.038	(-0.1 to 0.02)	0.211
Fluoroquinolones	0.11 (0.09-0.13)	0.18 (0.13-0.22)	-0.016	(-0.06 to 0.03)	0.461
Steroids	0.07 (0.05-0.08)	0.09 (0.06-0.13)	-0.004	(-0.04 to 0.03)	0.825
Anti-TB drugs	0.00	0.00	-0.003	(-0.006 to 0.0004)	0.089
Mentioned TB	0.18 (0.16-0.20)	0.16 (0.12-0.20)	-0.006	(-0.05 to 0.042)	0.811
Correct management	0.39 (0.36-0.42)	0.37 (0.32-0.43)	0.040	(-0.014 to 0.090	0.145
SP case 2	**Male SP2 (N=252)**	**Female SP2 (N=222)**	**Difference in means / Proportions***	**95% CI**	**P-value**
	Mean	**Mean**			
History Checklist%	0.41 (0.38-0.45)	0.36 (0.33-0.38)	0.094	(0.05 to 0.13)	<0.0001
Number of clinical exams	1.62 (1.48-1.75)	1.31 (1.18-1.44)	0.305	(0.13 to 0.48)	0.001
Number of medicines	3.4 (3.12-3.66)	3.21 (2.90-3.51)	-0.110	(-0.50 to 0.28)	0.578
	Proportion	**Proportion**			
Chest X-Ray	0.24 (0.18-0.29)	0.27 (0.21-0.32)	-0.005	(-0.08 to 0.07)	0.904
Sputum smear	0.21 (0.16-0.26)	0.30 (0.24-0.36)	-0.060	(-0.14 to 0.017)	0.127

Xpert MTB/RIF	0.09 (0.05-0.12)	0.09 (0.05-0.13)	0.021	(-0.02 to 0.07)	0.372
Any medication	0.79 (0.74-0.84)	0.76 (0.70-0.82)	0.000	(-.074 to 0.074)	0.998
Antibiotics	0.47 (0.41-0.53)	0.53 (0.46-0.59)	-0.052	(-0.14 to 0.03)	0.236
Fluoroquinolones	0.10 (0.06-0.14)	0.13 (0.09-0.17)	-0.028	(-0.08 to 0.03)	0.332
Steroids	0.08 (0.04-0.11)	0.05 (0.02-0.08)	0.013	(-0.03 to 0.06)	0.557
Anti-TB drugs	0.15 (0.11-0.19)	0.14 (0.10-0.19)	0.043	(-0.014 to 0.10)	0.142
Mentioned TB	0.46 (0.39-0.52)	0.57 (0.50-0.63)	-0.051	(-0.14 to 0.034)	0.236
Correct management	0.58 (0.51-0.63)	0.60 (0.53-0.66)	0.054	(-0.03 to 0.14)	0.206
SP Case 3	**Male SP3 (N=289)**	**Female SP3 (N=128)**	**Difference in means/ Proportions**	**95% CI**	**P-value**
	Mean	**Mean**			
History Checklist%	0.63 (0.59-0.66)	0.51 (0.46-0.56)	0.115	(0.06 to 0.17)	<0.0001
Number of clinical exams	1.29 (1.17-1.41)	1.32 (1.15-1.48)	0.095	(-0.11 to 0.30)	0.361
Number of medicines	3.31 (3.03-3.58)	2.91 (2.53-3.30)	0.227	(-0.28 to 0.73)	0.376
	Proportion	**Proportion**			
Chest X-Ray	0.59 (0.53-0.65)	0.51 (0.43-0.60)	0.072	(-0.02 to 0.17)	0.148
Sputum smear	0.13 (0.09-0.17)	0.18 (0.11-0.24)	-0.028	(-0.10 to 0.05)	0.479
Xpert MTB/RIF	0.06 (0.03-0.09)	0.06 (0.02-0.10)	-0.029	(-0.08 to 0.02)	0.237
Any medication	0.75 (0.69-0.79)	0.73 (0.65-0.81)	0.048	(-0.05 to 0.14)	0.328
Antibiotics	0.44 (0.37-0.49)	0.55 (0.45-0.63)	0.006	(-0.1 to 0.11)	0.916
Fluoroquinolones	0.14 (0.10-0.18)	0.16 (0.09-0.22)	0.069	(-0.007 to 0.144)	0.07
Steroids	0.07 (0.04-0.10)	0.06 (0.02-0.10)	0.010	(-0.05 to 0.07)	0.718
Anti-TB drugs	0.13 (0.09-0.17)	0.13 (0.07-0.18)	0.019	(-0.05 to 0.09)	0.603
Mentioned TB	0.77 (0.71-0.82)	0.70 (0.61-0.77)	0.009	(-0.08 to 0.10)	0.849
Correct management	0.31 (0.26-0.37)	0.34 (0.25-0.42)	-0.086	(-0.19 to 0.015)	0.096

SP Case 4	Male SP4 (N=443)	Female SP4 (N=162)	Difference in means/proportions	95% CI	P-value for the difference (t-test)
	Mean	**Mean**			
History Checklist %	0.43 (0.41-0.45)	0.52 (0.47-0.56)	-0.070	(-0.12 to -0.03)	0.001
Number of clinical exams	1.59 (1.50-1.68)	1.67 (0.49-1.85)	-0.041	(-0.23 to 0.147)	0.665
Number of medicines	3.52 (3.31-3.74)	3.29 (2.96-3.62)	-0.280	(-0.68 to 0.12)	0.168
	Proportion	**Proportion**			
Chest X-Ray	0.52 (0.47-0.57)	0.64 (0.57-0.71)	0.105	(-0.14 to 0.014)	0.105
Sputum smear	0.2 (0.16-0.24)	0.31 (0.24-0.38)	-0.069	(-0.15 to 0.010)	0.086
Xpert MTB/RIF	0.08 (0.05-0.11)	0.04 (0.01-0.07)	0.018	(-0.03 to 0.07)	0.46
Any medication	0.82 (0.78-0.85)	0.79 (0.72-0.85)	-0.029	(-0.10 to 0.05)	0.453
Antibiotics	0.47 (0.42-0.51)	0.53 (0.45-0.60)	-0.019	(-0.11 to 0.08)	0.698
Fluoroquinolones	0.11 (0.08-0.14)	0.17 (0.11-0.23)	-0.010	(-0.07 to 0.05)	0.75
Steroids	0.03 (0.01-0.05)	0.08 (0.04-0.12)	-0.025	(-0.06 to 0.013)	0.202
Anti-TB drugs	0.03 (0.01-0.05)	0.02 (0.00-0.05)	0.012	(-0.021 to 0.044)	0.484
Mentioned TB	0.55 (0.50-0.60)	0.41 (0.33-0.48)	-0.002	(-0.09 to 0.09)	0.962
Correct management	0.15 (0.12-0.18)	0.17 (0.10-0.22)	0.002	(-0.07 to 0.07)	0.945

***After adjusting for provider qualification and city level fixed effects using linear mixed effects GLS regression;**
Note: SE for means and proportions are robust standard errors adjusted for 1346 clusters at health facility level.

Table 8: Gender differences in management of standardized patients (SP) stratified by health care provider qualification

Allopathic (MBBS) providers	**Male SPs (N=910)**	**Female SPs (N=458)**	**Gender difference**		
	Mean (95% CI)	**Mean (95% CI)**	**Difference in means**	**95% CI**	**P-value**
History Checklist %	0.56 (0.54-0.58)	0.53 (0.51-0.55)	0.004	(-0.022 to 0.030)	0.75
Number of clinical exams	1.96 (1.88-2.03)	1.99 (1.88-2.09)	-0.057	(-0.162 to 0.0479)	0.286
Number of medicines	3.1 (2.97-3.24)	3.1 (2.91-3.28)	0.004	(-0.184 to 0.193)	0.963
	Proportion (95% CI)	**Proportion (95% CI)**	**Difference in proportions**		
Chest X-Ray	0.69 (0.65-0.72)	0.56 (0.51-0.60)	0.091	(0.040 to 0.140)	<0.001
Sputum smear	0.22 (0.19-0.25)	0.25 (0.21-0.29)	0.005	(-0.042 to 0.051)	0.848
Xpert MTB/RIF	0.10 (0.07-0.13)	0.08 (0.05-0.10)	0.007	(-0.024 to 0.037)	0.665
Any medication	0.86 (0.84-0.88)	0.84 ().80-0.87)	0.016	(-0.022 to 0.054)	0.417
Antibiotics	0.71 (0.68-0.75)	0.71 (0.67-0.75)	0.013	(-0.036 to 0.062)	0.608
Fluoroquinolones	0.16 (0.13-0.19)	0.20 (0.16-0.23)	-0.024	(-0.066 to 0.017)	0.25
Steroids	0.05 (0.03-0.07)	0.05 (0.03-0.07)	0.006	(-0.018 to 0 .03)	0.608
Anti-TB drugs	0.09 (0.07-0.10)	0.11 (0.08-0.13)	0.002	(-0.028 to 0.033)	0.23
Mentioned TB	0.41 (0.38-0.44)	0.37 (0.32-0.41)	0.071	(.019 to 0.122)	0.007
Correct management	0.56 (0.52-0.59)	0.46 (0.41-0.50)	0.082	(0.02 to 0.15)	0.014
AYUSH Providers	**Male SPs (N=873)**	**Female SPs (N=183)**			
	Mean (95%CI)	**Mean (95%CI)**	**Difference in means**	**95% CI**	**P-value**
History Checklist %	0.41 (0.40-0.43)	0.37 (0.34-0.40)	0.007	(-0.026 to 0.040)	0.673
Number of clinical exams	1.32 (1.26-1.38)	1.15 (1.00-1.30)	0.078	(-0.060 to 0.217)	0.27
Number of medicines	4.68 (4.53-4.83)	4.24 (3.91-4.58)	0.017	(-0.310 to 0.345)	0.918
	Proportion (95% CI)	**Proportion (95%CI)**	**Difference in proportions**		
Chest X-Ray	0.18 (0.16-0.21)	0.27 (0.21-0.34)	-0.109	(-0.172 to -0.045)	0.001
Sputum smear	0.06 (0.04-0.08)	0.12 (0.08-0.17)	-0.053	(-0.097 to -0.009)	0.017
Xpert MTB/RIF	0.003 (0.00-0.01)	0.005 (0.00-0.01)	-0.003	(-0.013 to 0.007)	0.608

Any medication	0.90 (0.88-0.92)	0.87 (0.82-0.92)	0.001	(-0.046 to 0.0498)	0.95
Antibiotics	0.36 (0,33-0.40)	0.39 (0.31-0.46)	-0.079	(-0.156 to -0.002)	0.044
Fluoroquinolones	0.06 (0.04-0.08)	0.06(0.02-0.10)	-0.001	(-0.039 to 0.038)	0.977
Steroids	0.04 (0.02-0.06)	0.06 (0.03-0.10)	-0.020	(-0.055 to 0.014)	0.246
Anti-TB drugs	0.01 (0.00-0.1)	0.01 (0.00-0.01)	0.007	(-0.007 to 0.0206)	0.324
Mentioned TB	0.35 (0.32-0.38)	0.48 (0.41-0.56)	-0.098	(-0.166 to -0.031)	0.004
Correct management	0.16 (0.14-0.19)	0.27 (0.20-0.33)	-0.031	(-0.12 to 0.055)	0.483
Other providers	**Male SPs (N=388)**	**Female SPs (N=195)**			
	Mean (95% CI)	**Mean (95% CI)**	**Difference in means**	**95% CI**	**P-value**
History Checklist%	0.41 (0.38-0.44)	0.41 (0.37-0.45)	-0.042	(-0.082 to -0.003)	0.036
Number of clinical exams	1.28 (1.16-1.39)	1.04 (0.90-1.18)	0.067	(-0.086 to 0.221)	0.392
Number of medicines	3.46 (3.23-3.69)	3.24 (2.95-3.52)	0.190	(-0.155 to 0.534)	0.282
	Proportion (95% CI)	**Proportion (95% CI)**	**Difference in proportions**		
CXR	0.28 (0.23-0.33)	0.19 (0.13-0.24)	0.048	(-0.016 to 0.111)	0.142
Sputum AFB	0.08 (0.05-0.11)	0.12 (0.07-0.17)	-0.032	(-0.081 to 0.018)	0.212
Xpert MTB/RIF	0.01 (0.00-0.02)	0.005 (0.00-0.01)	0.009	(-0.010 to 0.027)	0.379
Any medication	0.82 (0.78-0.87)	0.76 (0.70-0.82)	0.062	(-0.004 to 0.128)	0.067
Antibiotics	0.52 (0.46-0.57)	0.57 (0.50-0.64)	-0.025	(-0.103 to 0.054)	0.538
Fluoroquinolones	0.14 (0.09-0.18)	0.17 (0.11-0.22)	0.010	(-0.049 to 0.069)	0.744
Steroids	0.13 (0.09-0.17)	0.14 (0.09-0.19)	0.034	(-0.023 to 0.091)	0.251
Anti-TB drugs	0.01 (0.00-0.02)	0.01 (0.00-0.03)	0.003	(-0.017 to 0.023)	0.779
Mentioned TB	0.29 (0.24-0.34)	0.38 (0.31-0.45)	-0.118	(-0.188 to -0.047)	0.001
Correct management	0.31 (0.26-0.36)	0.33 (0.26-0.39)	-0.048	(-0.125 to 0.029)	0.225

***After adjusting for case type, and city level fixed effects provider random effects using linear mixed effects GLS regression**

Table 9: Gender differences in management of standardized patients stratified by city

Delhi	Male SPs (N=157)	Female SPs (N=93)	Adjusted gender differences* (male vs females)		
	Mean (95% CI)	**Mean (95% CI)**	**Difference in means**	**95% CI**	**P-value**
History Checklist % (mean)	0.19 (0.16-0.21)	0.23 (0.20-0.25)	-0.028	(-0.05 to -0.005)	0.017
Number of clinical exams	1.52 (1.35-1.69)	1.45 (1.23-1.67)	0.120	(-0.075 to 0.315)	0.227
Number of medicines	4.58 (4.23-4.92)	4.29 (3.86-4.71)	0.363	(-0.07 to 0.79)	0.102
	Proportion (95% CI)	**Proportion (95% CI)**	**Difference in proportions**		
Chest X-Ray	0.24 (0.17-0.31)	0.17 (0.11-0.28)	0.041	(-0.05 to 0.13)	0.374
Sputum smear	0.06 (0.02-0.01)	0.05 (0.00-0.10)	-0.001	(-0.06 to 0.056)	0.965
Xpert MTB/RIF	0.01 (0.00-0.03)	0.00 (0.00-0.00)	0.013	(-0.01 to 0.036)	0.285
Any medication	0.90 (0.85-0.95)	0.83 (0.75-0.90)	0.091	(0.012 to 0.17)	0.023
Antibiotics	0.48 (0.39-0.57)	0.55 (0.44-0.65)	-0.048	(-0.15 to 0.06)	0.384
Fluoroquinolones	0.16 (0.09-0.23)	0.01 (0.03-0.16)	0.074	(0.008 to 0.14)	0.027
Steroids	0.10 (0.04-0.15)	0.07 ((0.02-0.13)	0.032	(-0.032 to 0.096)	0.325
Anti-TB drugs	0.05 (0.01-0.85)	0.03 (0.00-0.07)	0.013	(-0.04 to 0.065)	0.626
Mentioned TB	0.24 (0.17-0.31)	0.32 (0.23-0.42)	-0.104	(-0.2 to -0.012)	0.027
Correct management	0.21 (0.14-0.28)	0.20 (0.12-0.28)	-0.018	(-0.12 to 0.09)	0.738
Patna Providers	**Male SPs (N=668)**	**Female SPs (N=453)**	**Difference in means**		
	Mean (95% CI)	**Mean (95% CI)**			
History Checklist %	0.48 (0.46-0.50)	0.52 (0.49-0.54)	-0.030	(-0.057 to -0.002)	0.034
Number of clinical exams	1.66 (1.56-1.76)	1.67 (1.55-1.80)	-0.096	(-0.20 to 0.015)	0.091
Number of medicines	3.09 (2.96-3.23)	3.04 (2.87-3.21)	-0.021	(-0.20 to 0.16)	0.818
	Proportion (95% CI)	**Proportion (95% CI)**	**Difference in proportion**		
Chest X-Ray	0.49 (0.45-0.54)	0.42 (0.37-0.47)	0.096	(0.045 to 0.15)	<0.0001
Sputum smear	0.19 (0.16-0.22)	0.20 (0.16-0.23)	0.031	(-0.014 to 0.075)	0.176
Xpert MTB/RIF	0.006 (0.00-0.01)	0.013 (0.00-0.025)	-0.004	(-0.015 to 0.007)	0.5

Any medication	0.88 (0.85-0.91)	0.82 (0.79-0.86)	0.037	(-0.002 to 0.075)	0.06
Antibiotics	0.70 (0.66-0.74)	0.67 (0.62-0.72)	0.018	(-0.03 to 0.066)	0.457
Fluoroquinolones	0.20 (0.17-0.23)	0.23 (0.19-0.27)	-0.028	(-0.075 to 0.019)	0.238
Steroids	0.09 (0.07-0.12)	0.12 (0.06-0.12)	-0.008	(-0.039 to 0.024)	0.639
Anti-TB drugs	0.02 (0.01-0.03)	0.05 (0.03-0.07)	-0.012	(-0.033 to 0.0088)	0.254
Mentioned TB	0.28 (0.24-0.31)	0.30 (0.26-0.34)	0.046	(-0.002to 0.094)	0.058
Correct management	0.40 (0.35-0.44)	0.34 (0.30-0.38)	0.049	(-0.005 to 0.103)	0.076
Mumbai	**Male SPs (N=1346)**	**Female SPs (N=290)**	**Difference in means**	**95% CI**	**P-value**
	Mean (95% CI)	**Mean (95% CI)**			
History Checklist%	0.51 (0.49-0.52)	0.47 (0.44-0.50)	0.018	(-0.014 to 0.05)	0.269
Number of clinical exams	1.55 (1.49-1.60)	1.48 (1.36-1.60)	0.034	(-0.09 to 0.16)	0.588
Number of medicines	4.07 (3.92-4.21)	3.62 (3.33-3.90)	0.015	(-0.268 to 0.299)	0.915
	Proportion (95% CI)	**Proportion (95% CI)**	**Difference in proportions**		
Chest X-Ray	0.39 (0.36-0.43)	0.46 (0.39-0.52)	-0.140	(-0.201 to -0.078)	0.031
Sputum smear	0.11 (0.10-0.13)	0.23 (0.18-0.28)	-0.063	(-0.11 to -0.017)	0.007
Xpert MTB/RIF	0.07 (0.05-0.09)	0.11 (0.07-0.15)	0.003	(-0.032 to 0.038)	0.869
Any medication	0.87 (0.85-0.89)	0.83 (0.79-0.87)	-0.040	(-0.085 to 0.0058)	0.087
Antibiotics	0.47 (0.43-0.50)	0.53 (0.47-0.59)	-0.081	(-0.147 to -0.016)	0.015
Fluoroquinolones	0.07 (0.05-0.08)	0.08 (0.05-0.10)	-0.014	(-0.048 to 0.021)	0.441
Steroids	0.04 (0.03-0.05)	0.04 (0.02-0.07)	0.007	(-0.019 to 0.034)	0.586
Anti-TB drugs	0.05 (0.04-0.06)	0.09 (0.06-0.13)	0.036	(0.006 to 0.066)	0.017
Mentioned TB	0.42 (0.40-0.44)	0.58 (0.52-0.63)	-0.069	(-0.129 to -0.009)	0.024
Correct management	0.35 (0.32-0.38)	0.52 (0.46-0.58)	-0.054	(-0.115 to 0.007)	0.084

***After adjusting for case type, provider qualification and individual provider random effects using linear mixed effects GLS regression**

Chapter 5: Summary & Conclusion

5.1 Summary of results

The overall goal of my PhD thesis was to describe the quality of TB care in India, the country with the highest TB burden and with a complex and poorly regulated health care system, which includes both qualified and unqualified providers offering medical care to patients.

To begin with, I defined quality as adherence to standards of TB care by health care providers. I then systematically reviewed studies that provided information on health care providers' knowledge and practices related to TB diagnosis and treatment, and benchmarked them against the 2nd edition of International Standards of Tuberculosis Care. Of the 47 studies included, 35 were questionnaire surveys and 12 used chart abstraction. None of the studies assessed actual practice using standardised patients. Due to considerable heterogeneity in study methodologies and results, I could not conduct a meta-analysis, and therefore did a narrative synthesis of the data. Of 22 studies evaluating provider knowledge about using sputum smears for diagnosis, 10 found that less than half of providers had correct knowledge; 3 of 4 studies assessing self-reported practices by providers found that less than a quarter reported ordering smears for patients with chest symptoms. In 11 of 14 studies that assessed treatment, less than one third of providers knew the standard regimen for drug-susceptible TB. Adherence to standards in practice was generally lower than correct knowledge of those standards. Eleven studies with both public and private providers found higher levels of appropriate knowledge/practice in the public sector. From this review, I concluded that the available studies provided a reasonable picture of provider knowledge (i.e., what they know) and, to some extent, providers' self-reported behaviour (i.e., what they say they do). However, these studies did not provide adequate information about the behaviour of providers in real-life (i.e., what they actually do).

For the next two studies, I used data from an on-going project in Delhi, Mumbai and Patna cities of India in which standardised patients (SPs) were being used to assess actual practices of health care providers. In the second study, I assessed how retail pharmacies (who are an important source of medical care in India) managed SPs. We used two case scenarios to study management of patients who presented with TB symptoms (Case 1) and of those who presented with a laboratory report indicating TB sputum smear positive pulmonary TB disease (Case 2). This methodology helped us to assess two important aspects: a) pharmacists' behaviour and drug-use for patients with complaints, but no prescription, and b) how case management and drug use differs when the diagnosis is unknown versus confirmed. In Delhi, Mumbai and Patna, 622 pharmacies were sampled. SPs presented each case

scenario once to every pharmacy between April 2014 and November 2015. ‘Ideal management’ for both cases was defined a priori as referral to a health care provider without dispensing antibiotics and/or steroids. The results showed that ‘ideal management’ was seen in 13% (95% CI: 11–16) of the Case 1 and 62% (95% CI: 58-66) of the Case 2 interactions. Antibiotic use was significantly lower in Case 2 (16%) than in Case-1 (37%). Anti-TB drugs were never dispensed in any city. The differences in antibiotic and/or steroid use and number of medicines dispensed between Case 1 and Case 2 were attributable to the difference in the information that patients presented with and the referral behaviour. These study results add to the growing evidence on antibiotic abuse, and also underscore that the use and misuse of antibiotics are strongly influenced by the information that patients present. Although antibiotic use is high and such use can delay diagnosis, none of the pharmacies dispensed first-line anti-tuberculosis drugs (a major positive finding of the study).

In the third study, I assessed the gender differences in quality of TB care by using standardised patients. Male and female SPs depicting four different TB case scenarios visited 1346 health care providers in Delhi, Mumbai and Patna. The correctness of case management was assessed using the STCI as a benchmark and we used mixed effects regression methods to estimate gender differences. There were 3007 SP visits to providers in 1346 health facilities in the three cities, of which 836 (28%) visits were by female SPs. Overall, 36% (95% CI: 34-38) of the SPs were correctly managed. There were no statistically significant differences in the correct management of male SPs and female SPs. Allopathic (MBBS) providers were more likely to manage cases correctly [52% (95% CI; 49-56)], when compared to providers of alternative systems of medicine [18%; 95% CI: 16-20)]. However, allopathic (MBBS) providers were more likely to correctly manage male SPs than female SPs (adj OR 1.51 times; 95% CI: 1.08-2.07). With the exception of this finding, stratified analysis across the three cities and across the four types of cases did not show any statistically significant gender differences in quality of care for male versus female SPs. We concluded that low levels of correct management for both male and female SPs and gender differences by allopathic providers should be a cause for major concern.

5.2 Strengths and limitations

The major strength of the thesis is the definition of 'quality' of TB care as adherence to established standards of TB care. This makes it 'acceptable' across a wide spectrum of stakeholders, 'measurable', 'reliable' (by providing consistent estimates within and between individuals by making it objective rather than subjective) and 'valid' (especially if we want to link it to patient and public health outcomes such as early diagnosis of TB or recovery from the disease). However, the major limitation of our definition of quality is that we have placed the primary onus of ensuring quality on the health care providers without considering the patient, health system or other market forces that can indirectly influence provider behaviour. Another major limitation of my studies is that I have been able to assess quality on a few standards and in a few health care providers groups. However, the methodology presented in my thesis can be developed further and used to assess various other aspects of relevance.

My systematic review is the first to summarise the results of studies on health care providers' knowledge and practices, benchmark them against standards of TB care and make inference on quality of TB care in India. Strengths of this study include the extensive search strategy, inclusion of a wide variety of designs and outcomes and the detailed assessment of quality of each study. However, the limitations were that the studies included in my review were quite heterogeneous in their methodologies, as were the types of health care providers studied. The studies also did not cover providers in some of the highly populated parts of India. Moreover, the criteria that I used for assessing the quality of each study were developed based on expert opinion opinion because there are currently no validated tools to do so. Most of the studies provided information on health care providers' self-reported knowledge and practices but not what they actually did in reality. Therefore, my inferences about quality from these studies may not actually reflect the quality of care that patients receive on the ground. Despite these limitations, my review provided a strong basis for further development of guidelines, interventions and recommendations for the research on quality of TB care in India.

In this second study, I assessed the medical advice and drug dispensing practices of pharmacies for patients presenting with pulmonary TB symptoms and disease. The strengths of this study include the SP methodology, usage of two different types of cases (to represent the spectrum of patients and also to assess how additional patient information changes the pharmacists' behaviour), two case visits to each pharmacy and conducting the study in three large cities located in different parts of India. The first limitation of this study is that the practice observed likely only reflects what pharmacists do when they come across a completely 'unknown' or 'new' patient seeking over the counter advice or medical care.

The practice may be different for those patients that frequently visit these pharmacists or health care providers for all types of ailments and are therefore 'known' to them. We believe that the pharmacists are more likely to dispense medications to such known patients, and therefore, our study may be an underestimation of actual dispensing practices. Second, we have assumed that at the individual level, the pharmacist practices are consistent for a particular patient/case presentation. If the performance is inconsistent, then our study design may not be able to identify characteristics of individual pharmacists who adhere to the guidelines and those who do not. In such a scenario, the average estimates for the group (or marginal estimates) are more likely to be consistent rather than at the individual level. Third, our analysis and interpretation of management are from a TB disease perspective. The management may or may not be appropriate for the patient population without TB disease, especially for Case 1 whose presentation overlaps with many other medical conditions such as pneumonia, asthma, and upper respiratory tract infection. Even if Case 1 SP had in fact a different medical condition- for example asthma- referring to a doctor and not dispensing antibiotics/steroids would have been the correct way to manage them. Fourth, although the behaviour change in Case 2 suggests that pharmacists substantially decrease the use of unnecessary drugs when the diagnosis is known, it is unknown why some pharmacists gave antibiotics and others did not, neither can we uncover the reasons why pharmacists are unwilling to follow regulations regarding drug use in these three cities. It is quite possible that in some pharmacies, the SPs may have interacted with two different persons working in these pharmacies. It is unclear whether the variation in our data is explained by the competence and qualification of the person providing advice in pharmacies, which we did not track in the study. Lastly, our study does not provide evidence on how pharmacists in rural areas manage patients with TB symptoms. Despite these limitations, we feel that the results of this study provide sufficient information to design interventions to engage pharmacies in TB control and antimicrobial stewardship.

In the third study, I assessed the gender differences in quality of care for patients presenting with pulmonary TB symptoms and disease. The strengths of the study include the SP methodology, the large number of SP-health care facility visits with at least two SP visits to most of the health facilities and data from three large cities located in different parts of the country. In our analysis, we assessed gender differences not only for correct management, but also on 12 different parameters and did not find any major differences. In addition, we also assessed and did not find the presence of unmeasured confounding and therefore the study results are reliable, valid and generalizable to private health care

provider in these cities. The first limitation of this study is that the overall larger SP study was not primarily designed to study the gender differences in health care providers' management practices, and different recruitment challenges existed across the cities in identifying and retaining female SPs in particular. Therefore, we may not have had adequate sample size/power to describe all the nuances of the gender differences in management. However, we had adequate power to assess whether the odds ratio of "correct management" was at least 1.75 at the aggregate level. We chose this odds ratio of 1.75 to denote public health significance warranting specific interventions. We believe that a larger sample size would have increased the precision but not the relative levels of central estimates of the odds ratios and therefore, from a public health point of view, we feel that the gender differences in health care providers are unlikely to be huge. Second, in this study, our methodology reflected what health care providers do when they come across a completely 'unknown' or 'new' patient seeking medical care. If their practices are different for those patients that frequently visit them for all types of ailments and are 'known' to them, then extrapolating our study findings to those patients may not be appropriate. Third, we assumed that at the individual facility level, health care provider practices are consistent for a particular case presentation. If the practice is inconsistent, then our study design may not be able to identify correctly the characteristics of individual health care facilities who manage correctly and those who do not. In such a scenario, the average estimates for the group are more likely to be consistent rather than at the individual level. Fourth, we assessed the correctness of case management from an allopathic medicine system's perspective. Nearly 55% of health care providers included in our study did not have a qualification in allopathic medicine and their systems of medicine may recommend an alternative way of managing TB. Therefore, assessing their management from an allopathic perspective may appear incorrect. However, a recent ethnographic study from Mumbai shows that more than 90% of non-allopathic qualified providers interviewed followed an allopathic system for diagnosis and treatment for TB and therefore, assessing their practice from an allopathic system's perspective does not appear to be unreasonable. Lastly, our study was entirely focused on urban private health care providers in India, and did not provide any insight into whether male and female patients are managed differently in the public sector or by health care providers in rural areas.

5.3 Implications

First, all three studies show that albeit some differences, the quality of TB care in India is in general low, especially in the vast unregulated private sector and therefore some dedicated measures are required to improve the situation. Second, my thesis also demonstrates that the SP methodology can be used to assess TB management practices of a variety of health care providers (pharmacies, qualified, unqualified providers, etc.). By using this methodology, public health policy makers and programme managers can determine the need and extent of investment required to improve quality in TB control programmes, and also assess the impact of any interventions aimed at changing their practices. This methodology can also be used to establish a surveillance system on suspected problems such as over the counter antibiotic abuse, adherence to regulations, etc. Third, antimicrobial resistance is a global health emergency, and, as the largest consumer of antibiotics, India is in the danger zone. In my studies, I provide an estimate of the misuse of antibiotics by pharmacies and also by health care providers. These findings can inform interventions to reduce their misuse and antimicrobial stewardship. Fourth, I have identified the strengths and limitations of the various methods that I have used in my thesis. This will be of particular interest to researchers, as they can build on these to develop ever more robust methodologies to overcome these limitations. Lastly, the results of my thesis will be shared with the on-going Government of India and Bill and Melinda Gates Foundation funded projects in Mumbai and Patna. These studies, along with other on-going ethnographic studies, will help in better designing targeted educational and care interventions. Beyond Delhi, Mumbai and Patna, our methods could be taken up by national (e.g. Indian TB Control Programme) and international bodies (e.g. WHO/Stop-TB) for auditing TB care in areas of concern, allowing authorities to develop and implement context specific interventions.

5.4 Directions for Future Research

Each of my thesis studies provides directions for future research. These include newer methods/approaches to summarise data and make inference on quality of care not just from studies on patients and health care providers, but also from studies on health systems and the socioeconomic environment in which care takes place.

In our SP studies, we used a few different TB case scenarios that provide an overview of adherence to a few standards of TB care. These r case scenarios do not capture the full spectrum of TB case presentations in the community. Future researchers may consider developing more case scenarios for

measuring different aspects of all TB standards, and also consider incorporating repeated follow-up visits by the same SP to see when a majority of health care providers suspect or diagnose TB and what care patients finally end up with.

Next, while the SP methodology provides information on what health care providers do, the reasons for their behaviour can only be identified by in-depth qualitative and ethnographic studies. The results from my thesis provide areas for further exploration such as why doctors do not suspect TB in all persons with cough of 2 weeks or more, why they do not order sputum tests immediately for all persons with presumed tuberculosis, gender differences by allopathic health care providers etc. Such additional qualitative information will aid in better understanding and designing strategies to overcome the deficiencies.

Finally, some other aspects for future research include – studies on behaviour of private providers to explore the reasons for know-do gap, studies on how regulations can be better implemented, studies on whether patient awareness about the types of providers to favour (i.e., direct them to better quality providers) is an effective intervention.

5.5 Conclusion

In conclusion, in this thesis, I define quality of TB care as adherence to standards, highlight the limitations of the methods that have been used previously to study health care providers TB management practices in India, demonstrate how standardised patients can be used to overcome these limitations, assess the strengths and limitations of the standardised patient methodology, describe some key aspects on how to analyse and interpret the data from SP studies and finally make some suggestions on how this method can be used to improve quality of TB care in India.

This study, along with many other previous studies examined in a recent systematic review (chapter 2), contribute to the growing body of evidence showing considerable deficiencies in health care providers' management of TB in India. The overall low levels of correct management by different types of health care providers (e.g. pharmacies, qualified, unqualified providers) partly explains the reasons for delayed diagnosis and increasing levels of antimicrobial resistance. These should be a matter of serious concern in India. Qualitative research aimed at understanding the reasons for low levels of correct management, antibiotic misuse by pharmacies, gender differences by allopathic providers and targeted interventions aimed at addressing these reasons are urgently needed to improve TB management in in

the country. Since, India is the country with the highest largest number of TB cases in the world, addressing these deficiencies and creating a health system environment that promotes optimal care, especially in the private sector, will have a major impact on global TB control.

Back Matter

Appendix

Thesis Appendix 1: **A comparison of the 3rd edition of International Standards for Tuberculosis Care (ISTC) to India's Standards for TB care in India (Key standards that are relevant to my thesis manuscripts in Chapter 3 and 4)**

ISTC (3rd Edition)	STCI
Standard 2: All patients, including children, with unexplained cough lasting two or more weeks or with unexplained findings suggestive of tuberculosis on chest radiographs should be evaluated for TB.	**Standard 1.1** Testing: Any person with symptoms and signs suggestive of TB including cough >2 weeks, fever >2 weeks, significant weight loss, haemoptysis etc. and any abnormality in chest radiograph must be evaluated for TB.
Standard 3: All patients, including children, who are suspected of having pulmonary tuberculosis and are capable of producing sputum should have at least two sputum specimens submitted for smear microscopy or a single sputum specimen for Xpert® MTB/RIF* testing in a quality-assured laboratory. Patients at risk for drug resistance, who have HIV risks, or who are seriously ill, should have Xpert MTB/RIF performed as the initial diagnostic test. Blood-based serologic tests and interferon-gamma release assays should not be used for diagnosis of active tuberculosis.	**Standard 2.1** Microbiological confirmation on Sputum • All patients (adults, adolescents, and children who are capable of producing sputum) with presumptive pulmonary TB should undergo quality-assured sputum test for rapid diagnosis of TB (with at least two samples, including one early morning sample for sputum smear for AFB) for microbiological confirmation. **Standard 2.2** Chest X-ray as screening tool: • Where available, chest X-ray should be used as a screening tool to increase the sensitivity of the diagnostic algorithm. **Standard 2.5:** CB-NAAT (cartridge-based nucleic-acid amplification test) is the preferred first diagnostic test in children and PLHIV.
Standard 8. All patients who have not been treated previously and do not have other risk factors for drug resistance should receive a WHO-approved first-line treatment regimen using quality assured drugs. The initial phase should consist of two months of isoniazid, rifampicin, pyrazinamide, and ethambutol.* The continuation phase should consist of isoniazid and rifampicin given for 4 months. The doses of anti-tuberculosis drugs used should conform to WHO recommendations. Fixed-dose combination drugs may provide a more convenient form of drug administration.	**Standard 7.1** Treatment of New TB patients: • All new patients should receive an internationally accepted first-line treatment regimen for new patients. The initial phase should consist of two months of Isoniazid (H), Rifampicin (R), Pyrazinamide (Z), and Ethambutol €. The continuation phase should consist of three drugs (Isoniazid, Rifampicin and Ethambutol) given for at least four months.
Standard 11. An assessment of the likelihood of drug resistance, based on history of prior treatment, exposure to a possible source case having drug-resistant organisms, and the	**Standard 4.2** Diagnosis of multi-drug resistant TB (MDR-TB): • Prompt and appropriate evaluation should be undertaken for patients with presumptive MDR-

community prevalence of drug resistance (if known), should be undertaken for all patients. Drug susceptibility testing should be performed at the start of therapy for all patients at a risk of drug resistance. Patients who remain sputum smear-positive at completion of 3 months of treatment, patients in whom treatment has failed, and patients who have been lost to follow up or relapsed following one or more courses of treatment should always be assessed for drug resistance. For patients in whom drug resistance is considered to be likely an Xpert MTB/RIF test should be the initial diagnostic test. If rifampicin resistance is detected, culture and testing for susceptibility to isoniazid, fluoroquinolones, and second-line injectable drugs should be performed promptly. Patient counseling and education, as well as treatment with an empirical second-line regimen, should begin immediately to minimize the potential for transmission. Infection control measures appropriate to the setting should be applied.	TB or Rifampicin (R) resistance in TB patients who have failed treatment with first line drugs, paediatric non-responders, TB patients who are contacts of MDR-TB (or R resistance), TB patients who are found positive on any follow-up sputum smear examination during treatment with first line drugs, diagnosed TB patients with prior history of anti-TB treatment, TB patients with HIV co-infection and all presumptive TB cases among PLHIV. All such patients must be tested for drug resistance with available technology, a rapid molecular DST (as the first choice) or liquid / solid culture-DST (at least for R and if possible for Isoniazid (H); Ofloxacin (O) and Kanamycin (K), if R-resistant/MDR). • Wherever available DST should be offered to all diagnosed tuberculosis patients prior to start of treatment.

Standardized Case 1: Classic case of suspected TB (with no antibiotics or x-ray)

स्टैन्डराईज्ड केस 1: क्लासिक केस ऑफ सस्पेक्टेड टी बी (बिना एन्टीबायोटिक या एक्स-रे)

Ravi (Male)

Ravi is a 35 year old male who has studied up to 10th standard. He is the owner of a small tea shop. Today, in the morning like any other day, when he leaves for his work, his wife Rekha, handing him his lunch box asks, "why are you not eating your lunch properly - you get most of it uneaten every day"? Ravi replies, "I have cough and seem to have lost my appetite". Ravi's family is small. It consists of his wife and two children, aged six (daughter) and four (son) and they live in a two room house which he owns. His business at the tea stall is doing well as he is able to earn on average rupees 8000 - 10000 per month. Generally Ravi keeps good health. He has not had any major health problems or any chronic Illness. His wife and children too are in good health. But since last 2-3 weeks he is suffering from cough which is more or less present during early morning and night, and it also has expectoration though that does not have any color in it and is clear. He also has low grade mild fever, on and off, which gets worse during the evening time. But since this problem started he feels a bit tired and also has lost some weight, as his clothes have got a bit loose. He does not suffer from any associated chest or body pain. Around 1 week ago, he had visited a local chemist who gave him a cough syrup and some pills for the fever. He smokes 4-5 *beedis* during the day since last 8-10 years and drinks alcohol once or twice in the month. His relationship with his wife is good. He loves her very much. He has a cheerful and an easy going personality but today his face bears a tense look as he is worried about his cough and fever and visits a doctor nearby.

रवि (पुरुष)

रवि एक 35 साल का व्यक्ति है जिसने 10वीं कक्षा तक पढ़ाई की है। रोजगार के लिये वह अपनी चाय की दुकान चलाता है। जिसे वह खोलने के लिये हर रोज की तरह आज भी अपने घर से निकलता है और निकलते समय उसकी पत्नी रेखा खाने का डब्बा देते हुये बोलती है कि ''क्या बात है आज-कल आप खाना ठीक से नहीं खा रहे हो''? रवि कहता है ''मुझे खाँसी है और भूख भी कम लग रही है''। रवि का छोटा परिवार है, जिसमें उसकी पत्नी और दो बच्चे है, लड़की की उम्र 6 साल और लड़के की 4 साल है। रवि दो कमरे के खुद के मकान में रहता है। रवि की चाय की दुकान ठीक चलती है जिससे वह औसतन 8 से 10 हजार रुपये महीना कमा लेता है।

आमतौर पर रवि का स्वास्थ्य अच्छा रहता है, उसे किसी भी तरह की तकलीफ और कोई लम्बी बिमारी नहीं है। उसकी पत्नी और बच्चों का स्वास्थ्य भी अच्छा है। लेकिन रवि को पिछले 2-3 हफ्तों से खाँसी है, जो सुबह और रात के समय ज्यादा होती है। उसकी खाँसी के साथ बलगम भी आता है जिसका कोई रंग नहीं है, वह साफ है। खाँसी के साथ उसे हल्का बुखार रहता है जो चढ़ता-उतरता है, लेकिन अक्सर शाम के समय ही ज्यादा होता है। जब से उसे यह तकलीफ शुरु हुई है तब से उसे थकावट महसूस हो रही है। उसे लगता है कि उसका कुछ वजन कम हो गया है क्योंकि उसके कपड़े ढीले हो गये है। उसे इस तकलीफ में किसी भी तरह का छाती का दर्द और बदन दर्द नहीं है। एक हफ्ता पहले रवि ने इस तकलीफ के लिये घर के नजदीक के कैमिस्ट से दवा ली थी। कैमिस्ट ने खाँसी का सीरप और बुखार के लिये कुछ गोलियाँ दी थी।

वह दिन में 4 से 5 बीड़ी पीता है और उसकी यह आदत पिछले 8-10 सालों से है। महीने में एक या दो बार शराब का सेवन भी कर लेता है। उसके अपनी पत्नी के साथ अच्छे सम्बन्ध है। वह उसे बहुत प्यार करता है। वह हंसमुख और मिलनसार स्वभाव का व्यक्ति है, लेकिन आज उसके चेहरे पर अपनी खाँसी और बुखार को लेकर थोड़ी परेशानी है जिसको लेकर वह नजदीक के डॉक्टर के पास गया है।

Rekha (female)

Rekha is a 35 year old female who has studied up to 10th standard. She supplements her family income by stitching clothes at home. She is a little worried today as she has cough and running mild fever and thus does not feel like doing work. Her husband suggests that she should go and see a doctor to day about it. He leaves for work at his tea stall. Rekha's is a small family unit with her husband and two children aged six (daughter) and four (son) and they live in a two room house. She has been stitching clothes since a few years as her husband's work does not generate enough income and with her work she is able to earn an extra 2000 -3000 rupee in a month. Generally Rekha has been in good health and has not had any major health problems or any chronic Illness. Her husband and children too have had good health. But since last 2-3 weeks she has been having cough which is more or less present during early morning and night, and also has expectoration that does not have any color in it and is clear. She is also running low grade mild fever, on and off, which gets worse during the evening time. But since this problem started she feels tired and also has lost some weight, as her clothes have got bit loose. She does not suffer from any associated chest or body pain. Around 1 week ago, she had visited a local chemist who gave her a cough syrup and some pills for the fever. Rekha has a cheerful nature and she abstains from alcohol and smoking. Her relationship with her husband is good and she loves him very much but today she is worried about her cough and fever and visits a doctor nearby

रेखा (महिला)

रेखा पढ़ी–लिखी दसवीं पास 35 साल की महिला है। वह अपने घर के खर्च को पूरा करने के लिये घर में कपड़े सिलाई का काम करती है। आज रेखा का मन काम करने का नहीं कर रहा था क्योंकि आज भी उसे खाँसी, हल्का बुखार और कमजोरी महसूस हो रही थी। यह बात उसने अपने पति को बताई तो उसके पति ने कहा कि तुम आराम करो और आज किसी डॉक्टर को जरुर दिखा लेना। यह कह कर उसका पति अपनी चाय की दुकान पर चला गया।

रेखा के घर में उनके पति और दो बच्चे है। लड़की की उम्र 6 साल और लड़के की 4 साल है। रेखा दो कमरे के खुद के मकान में रहती है। रेखा कुछ सालों से घर पर सिलाई का काम कर रही है ,क्योंकि उसके पति की चाय की दुकान से इतनी कमाई नहीं हो पाती और वह अपने काम से महीने में 2 से 3 हजार रूपये कमा लेती है।

आमतौर पर रेखा का स्वास्थ्य अच्छा रहता है, उसे किसी भी तरह की तकलीफ और कोई लम्बी बिमारी नहीं है। उसके पति और बच्चों का स्वास्थ्य भी अच्छा है। लेकिन रेखा को पिछले 2–3 हफ्तों से खाँसी है, जो सुबह और रात के समय ज्यादा होती है। उसकी खाँसी के साथ बलगम भी आता है जिसका कोई रंग नहीं है, वह साफ है। उसे हल्का बुखार रहता है जो चढ़ता–उतरता है लेकिन अक्सर शाम के समय ही ज्यादा होता है। जब से उसे यह तकलीफ शुरु हुई है तब से उसे थकावट महसूस हो रही है। उसे लगता है कि उसका कुछ वजन कम हो गया है क्योंकि उसके कपड़े ढीले हो गये है। उसे इस तकलीफ में किसी भी तरह का छाती का दर्द और बदन दर्द नहीं है। एक हफ्ता पहले रेखा ने इस तकलीफ के लिये घर के नजदीक के कैमिस्ट से दवा ली थी। कैमिस्ट ने खाँसी का सीरप और बुखार के लिये कुछ गोलियाँ दी थी।

रेखा हंसमुख और मिलनसार स्वभाव की महिला है और वह किसी भी प्रकार का कोई नशा नहीं करती। उसके अपने पति के साथ अच्छे सम्बन्ध है। वह उसे बहुत प्यार करती है। लेकिन आज उसके चेहरे पर अपनी खाँसी और बुखार को लेकर थोड़ी परेशानी है जिसको लेकर वह नजदीक डॉक्टर के पास गयी है।

Opening statement: "Doctor, I have cough and fever that is not getting better"

ओपनिंग स्टेटमेंट : डॉक्टर साहब, "मुझे खाँसी बहुत हो रही है और साथ में बुखार भी है, जो ठीक ही नहीं हो रहा है"

History questions asked by the provider and their answers

प्रोवाइडर द्वारा पूछे गये हिस्ट्री सवाल और उनके जवाब

Q 1: What is the duration of cough?
प्रश्न 1: खाँसी कब से हो रही है?
Ans1 : 2-3 weeks, more during early morning and night
उत्तर 1: 2–3 सप्ताह से, यह सुबह–सुबह और रात को ही ज्यादा होती है।

Q 2: Are you producing sputum (bulgam)?
प्रश्न 2: क्या आपको बलगम बनती है?
Ans 2: Yes
उत्तर 2: हाँ।

Q 3: Does the sputum contain blood?
प्रश्न 3: क्या आपके बलगम में खून आता है?
Ans 3: No
उत्तर 3: नहीं।

Q 4: How long have you had fever?
प्रश्न 4: आपको बुखार कब से है?
Ans 4: Since 2-3 weeks
उत्तर 4: 2–3 हफ्ते हो गये।

Q 5: What type of fever do you have?
प्रश्न 5: बुखार कैसा रहता है?
Ans 5: Low grade (mild), on and off, more during evening times.
उत्तर 5: हल्का बुखार चढ़ता उतरता रहता है, लेकिन ज्यादातर शाम को होता है।

Q 6: Have you taken any medicines for your illness?
प्रश्न 6: क्या आपने इस तकलीफ के लिये कोई दवाई ली है?
Ans 6: Went to a local chemist who gave cough syrup and some pills for fever.
उत्तर 6: नजदीक के कैमिस्ट के पास गया था उसने मुझे खाँसी का सिरप और बुखार के लिये कुछ गोलियाँ दी थी।

Q 7: Do you get any chest pain?
प्रश्न 7: क्या आपकी छाती में दर्द होता है?
Ans 7: No
उत्तर 7: नहीं।

Q 8: Any loss of appetite?

प्रश्न 8: भूख में कोई कमी?
Ans 8: Yes, loss of appetite.
उत्तर 8: हाँ, भूख तो कम लगती है।

Q 9: Have you lost weight?
प्रश्न 9: क्या वजन कम हुआ है?
Ans 9: I think so; my clothes have become a bit loose.
उत्तर 9: हाँ, मुझे लगता है क्योंकि मेरे कपड़े ढीले हो गये हैं।

Q 10: Any wheezing or difficulty in breathing?
प्रश्न 10: साँस लेने में कोई तकलीफ/सीटी जैसी आवाज?
Ans 10: No
उत्तर 10: नहीं।

Q 11: Do you smoke?
प्रश्न 11: क्या आप बीड़ी/सिगरेट पीते हैं?
Ans 11: Yes, I smoke beedis. [in case of male SP]
उत्तर 11: हाँ, मैं बीड़ी पीता हूँ। (मेल SP के लिये)
No [in case of females SP] नहीं (फीमेल SP के लिये)

Q 12: How many beedis in a day?
प्रश्न 12: एक दिन में कितनी पीते हो?
Ans 12: 4-5 beedis, I guess
उत्तर 12: अंदाजन, 4 से 5 बीड़ी।

Q 13: Since when have you been smoking beedis?
प्रश्न 13: कब से बीड़ी पी रहे हो?
Ans 13: Since the last 8 or 10 years
उत्तर 13: पिछले 8 या 10 सालों से।

Q 14: Do you drink alcohol?
प्रश्न 14: क्या आप शराब पीते हैं?
Ans 14: Yes [in case of male] No [in case of female SP]
उत्तर 14: हाँ (मेल SP के लिये), नहीं (फीमेल SP के लिये)

Q 15: How often do you drink?
प्रश्न 15: कितनी बार पी लेते हो?
Ans 15: Once or twice in a month. [in case of male] No [in case of female SP]
उत्तर 15: महीने में एक–दो बार। (मेल SP के लिये), नहीं (फीमेल SP के लिये)

Q 16: Have you been treated for TB in the past?
प्रश्न 16: क्या आपने पहले कभी टी बी का इलाज कराया है?
Ans 16: No
उत्तर 16: नहीं तो।

Q 17: Anyone in your family has TB?
प्रश्न 17: क्या आपके घर में किसी को टीबी है?
Ans 17: No
उत्तर17: नहीं।

Q 18: Do you have diabetes?
प्रश्न 18: क्या आपको शुगर है?
Ans 18: I do not know
उत्तर 18: जी, पता नहीं।

Q 19: Do you have hypertension?
प्रश्न 19: क्या आपको हाईपरटेंशन है?
Ans 19: I do not know
उत्तर 19: जी, पता नहीं।

Q 20: Do you have HIV-AIDS?
प्रश्न 20: क्या आपको HIV-AIDS है?
Ans 20: I do not know
उत्तर 20: जी, पता नहीं।

Q 21: Have you ever been tested for these diseases?
प्रश्न 21: क्या आपने कभी इन बिमारियों कि जाँच या टेस्ट करवाया है?
Ans21: Not been tested
उत्तर 21: कभी टेस्ट नहीं करवाया।

Q 22: Have you ever been tested for these diseases?
प्रश्न 22: क्या आपको किसी दवाई से एलर्जी है?
Ans22: No.
उत्तर 22: नहीं।

Important instructions to be remembered by SP

महत्वपूर्ण बातें जो एस पी को याद रखनी है

1.	SP must remember if the provider carried out any of the following examination? SP को याद रखना है कि प्रोवाइडर ने निम्नलिखित में से कोई परीक्षण किये? • Pulse rate नब्ज़ की दर • Respiratory rate साँस की दर • Auscultation of Chest हृदय, फेफड़ों की गति को सुनना • Blood Pressure ब्लड प्रेशर • Temperature बुखार मापना – थर्मामीटर • Throat examination गले का परीक्षण • Weight वजन मापना
2.	Did the provider recommend any investigations? क्या प्रोवाइडर ने निम्नलिखित जाँच कराने को कहा? (If yes, SP should ask provider to write the name of the test and the laboratory. And hand over the document to an ISERDD staff.) *Write the specific name of lab given by the provider and if no put (-99).* (यदि हाँ, तो SP को प्रोवाइडर से टेस्ट और लैब का नाम लिखित में लेना है और उस पर्चे को ISERDD स्टॉफ को सौंप देना है) *अगर प्रोवाइडर ने किसी विशेष लैब का नाम दिया है तो वह लिखें, यदि नहीं तो (-99) भरें।* • Chest X-Ray छाती का एक्स–रे • CT Scan सी टी स्केन • Blood- Total count, differential count- ESR रक्त–टोटल काउंट, डिफरेंशियल काउंट–ई एस आर • Blood- HIV test रक्त–एच आईवी टेस्ट • Blood- Diabetes test रक्त–शुगर टेस्ट • Blood- TB Gold रक्त – टी बी गोल्ड • Blood-TB ELISA रक्त – टी बी ऐलाइजा • Sputum smear examination (Sputum AFB) स्पूटम स्मियर एक्जामिनेशन • Sputum GeneXpert test स्पूटम जीनएक्सपर्ट टेस्ट • Sputum culture स्पूटम कल्चर • Mantoux Test मॉनटुक्स टेस्ट • Drug susceptibility test ड्रग स्सेप्टिबिलिटी टेस्ट
3.	ISERDD staff to mark which of the following tests was recommended. जो भी टेस्ट करवाने के लिए बोला गया है उसे ISERDD स्टॉफ को फार्म में मार्क करना है।
4.	SP must collect prescription and/or any medicines given by the provider SP को प्रोवाइडर द्वारा दी गयी दवाई या दवाई का पर्चा अवश्य लेना है।
5.	SP must remember if the provider gave any diagnosis. SP को प्रोवाइडर द्वारा दिये गये डाइग्नोसिस को याद रखना है।
6.	Prescriptions and pills given must be preserved for analysis. SP को प्रोवाइडर द्वारा दिया गया पर्चा और दवाईयाँ एनालिसिस के लिये संभाल कर रखना है।
7.	SP must remember if the provider recorded the information he took from you. SP को यह ध्यान रखना है कि प्रोवाइडर ने आपसे जो जानकारी ली उसको कहीं लिखकर रखा।
8.	SP Should get the prices, brand and generic names of the prescribed medicines from the chemist. SP को प्रोवाइडर द्वारा पर्चे पर लिखी दवाईयों का सही मूल्य, ब्रॉन्ड और जेनेरिक नाम कैमिस्ट से पता करना है
9.	ISERDD staff will identify the provider clinic/chemist for the SP, where the SP will present his case alone. ISERDD स्टाफ फील्ड में SP को प्रोवाइडर का क्लीनिक/कैमिस्ट बतायेगा जहाँ SP को अकेले अपना केस करना है।
10.	SP should refuse any injections/ invasive tests performed by the provider during this encounter but note down details of what was offered/suggested. SP को इस बात चीत के दौरान किसी भी तरह का इन्जेक्शन/इन्वेसिव टेस्ट लेने से इन्कार करना है लेकिन ऐसे किसी भी सुझाव को नोट करके बताना है।

Appendix-2

SP1_ EXIT QUESTIONNAIRE: "Ravi/Rekha"

Provider ID : ☐☐☐☐☐☐☐ Form No: ☐☐☐

1	City Name **शहर का नाम**	**दिल्ली DELHI**	2	City **शहर की** ID	☐
3	Clinic Name & Address क्लीनिक का नाम और पता	*English*			
4	Clinic ID क्लीनिक आई डी	☐☐☐☐☐☐☐			
5	Provider Qualification प्रोवाइडर की डिग्री	No Degree=01, RMP=02, BAMS=03, BIMS=04, BUMS =05, BHMS/DHMS=06 BEHMS/BEMS=07, MBBS=08, MBBS+MD=09, Chemist=10 Other (*Specify*) =11			☐☐
6	Provider Name प्रोवाइडर का नाम	*English*			
7	Provider ID प्रोवाइडर की ID	☐☐☐☐☐☐☐			

Visits विज़िट्स्		**Visit-1 पहला विज़िट**		**Visit-2 दूसरा विज़िट**		**Visit-3 तीसरा विज़िट**	
8	Date of survey for each visit सर्वे की तारीख हर विजिट के लिये	☐☐☐☐☐☐☐☐ *DD /MM/YYYY*		☐☐☐☐☐☐☐☐ *DD/MM/YYYY*		☐☐☐☐☐☐☐☐ *DD/MM/YYYY*	
9	SP Name SP का नाम	----------		----------		----------	
10	SP ID आई डी	☐☐		☐☐		☐☐	
11	Total time spent at the Provider Clinic In time (Railway time) प्रोवाइडर के क्लीनिक में बिताया गया कुल समय (रेलवे समय)	In time अन्दर जाने का समय	Out time बाहर आने का समय	In time अन्दर जाने का समय	Out time बाहर आने का समय	In time अन्दर जाने का समय	Out time बाहर आने का समय
		☐☐ Hrs घंटे ☐☐ Min मिनट	☐☐ Hrs घंटे ☐☐ Min मिनट	☐☐ Hrs घंटे ☐☐ Min मिनट	☐☐ Hrs घंटे ☐☐ Min मिनट	☐☐ Hrs घंटे ☐☐ Min मिनट	☐☐ Hrs घंटे ☐☐ Min मिनट
12	Completion of the case. केस पूरा हुआ *Yes=1, No=2*	☐		☐		☐	
12a	If no, give reason. यदि नहीं, कारण दीजिए।	☐		☐		☐	
	Reason for non- Completion of the case:- यदि केस पूरा नहीं हुआ तो कारण बतायें :- Waited 3 hrs. 3 घंटे इन्तजार किया = 1; Provider in town but not coming to clinic प्रोवाइडर शहर में है लेकिन क्लीनिक में नहीं आया=2 Provider out of town प्रोवाइडर शहर से बाहर है = 3; Clinic locked क्लीनिक बन्द था = 4; Provider no longer practicing प्रोवाइडर ने प्रैक्टिस छोड़ दी =5; Provider migrated प्रोवाइडर ने एरिया छोड़ दिया =6						

13	Do you know if you saw the sampled Provider? क्या आपको पता है कि आपने सेम्पल प्रोवाइडर को ही दिखाया?	☐ *Enter 1=Yes; 2= No; 3=don't know*			
14	Interviewer Name साक्षात्कारकर्ता का नाम		14a	Interviewer ID साक्षात्कारकर्ता की आई डी	☐☐
15	जब आप क्लीनिक में पहुँचे तब कितने रोगी इन्तजार कर रहे थे?	How many patients were waiting when you reached the clinic?			☐☐
16	जब आप क्लीनिक से बाहर निकले तब कितने रोगी बाकी थे?	How many patients were in the clinic when you left?			☐☐

Provider ID : | | | | | | | | Form No: | | | |

NO.	QUESTION (HINDI)	QUESTION (ENGLISH)	*Asked*- YES (1) NO (2)	If not *asked*- given by SP? YES (1) NO (2)
SECTION 1:	**ESSENTIAL HISTORY INFORMATION TAKEN BY THE PROVIDER**			
H1	क्या प्रोवाइडर ने खाँसी की अवधि के बारे में पूछा?	Did the provider ask about duration of cough?		
H2	क्या प्रोवाइडर ने पूछा कि बलगम बनता है?	Did the provider ask whether sputum is produced?		
H3	क्या प्रोवाइडर ने पहले कभी आपको टी बी हुई है इसके बारे में जानकारी ली?	Did the provider ask if you had TB in the past?		
H4	क्या प्रोवाइडर ने परिवार में किसी को टी बी है इसके बारे में जानकारी ली?	Did the provider ask about history of TB in the family?		
	RECOMMENDED INFORMATION TAKEN BY THE PROVIDER			
H5	क्या प्रोवाइडर ने थूक में खून के बारे में पूछा?	Did the provider ask about Blood in the sputum?		
H6	क्या प्रोवाइडर ने पूछा कि आपकी खाँसी सारा दिन रहती है?	Did the provider ask that do you have cough throughout the day?		
H7	क्या प्रोवाइडर ने बुखार के बारे में पूछा?	Did the provider ask about Fever?		
H8	क्या प्रोवाइडर ने बुखार का प्रकार (हल्का या तेज) पूछा?	Did the provider ask about type of fever (low grade vs high grade)		
H9	क्या प्रोवाइडर ने परिवार के सदस्यों की जानकारी और परिवार में किसी को इस तरह के लक्षण के बारे में पूछा?	Did the provider ask about family members and similar symptoms in the family		
H10	क्या प्रोवाइडर ने छाती में दर्द के बारे में पूछा?	Did the provider ask about chest pain?		
H11	क्या प्रोवाइडर ने भूख में कमी के बारे में पूछा?	Did the provider ask about any loss of appetite?		
H12	क्या प्रोवाइडर ने वजन के कम होने के बारे में पूछा?	Did the provider asked have you lost weight?		
H13	क्या प्रोवाइडर ने साँस लेने में सीटी जैसी आवाज के बारे में पूछा?	Did the provider ask about any wheezing?		
H14	क्या प्रोवाइडर ने साँस लेने में कोई तकलीफ के बारे में पूछा?	Did the provider ask about any difficulty in breathing?		
H15	क्या प्रोवाइडर ने बीड़ी/सिगरेट के बारे में पूछा?	Did the provider ask about anything about smoking?		
H16	क्या प्रोवाइडर ने शराब के बारे मे पूछा?	Did the provider ask anything about alcohol history?		
H17	क्या आपने इस तकलीफ के लिये कोई दवाई ली है?	Have you taken any medicines for your illness?		
H18	क्या प्रोवाइडर ने शुगर के बारे मे पूछा?	Did the provider ask anything about Diabetes?		
H19	क्या प्रोवाइडर ने एच आई वी-एड्स के बारे मे पूछा?	Did the provider ask anything about HIV-AIDS?		
H20	क्या प्रोवाइडर ने हाई ब्लड प्रेशर या हाईपरटेंशन के बारे में पूछा?	Did the provider ask anything about high blood pressure or hypertension?		

Provider ID : | | | | | | | | Form No: | | |

H21	क्या प्रोवाइडर ने आपकी उम्र पूछी?	Did the provider ask your age?	☐	☐
H22	प्रोवाइडर ने आपसे जो जानकारी ली उसको कहीं लिखकर रखा। *हाँ=1, नहीं=2*	The provider recorded the information he took from you. *Yes=1, No=2*	☐	

SECTION 2 : CLINICAL EXAMINATION CONDUCTED BY THE PROVIDER			**Yes (1) No (2)**
E1	नब्ज़ की दर	Pulse rate	☐
E2	हृदय, फेफड़ों की गति को सुनना	Auscultation	☐
E3	बुखार मापना – थर्मामीटर	Temperature - thermometer	☐
E4	गले का परीक्षण	Throat examination	☐
E5	ब्लड प्रेशर मापा	Blood Pressure	☐
E6	वजन मापना	Weight	☐
RECOMMENDED INVESTIGATIONS ORDERED BY THE PROVIDER			
अगर प्रोवाइडर कोई टेस्ट करवाने के किसी पैथ लैब का नाम बताता है तो उसका नाम लिखें, यदि किसी पैथ लैब का नाम नहीं बताता है तो –99 भरें *Write the name of the path lab from where the provider recommended the test, if no name was given put -99.*			
E7	छाती का एक्स–रे Chest X-Ray		☐
E8	सी टी स्केन CT Scan		☐
E9	स्पूटम स्मियर एक्जामिनेशन Sputum smear examination (Sputum AFB)		☐
E10	स्पूटम जीनएक्सपर्ट टेस्ट Sputum-GeneXpert test		☐
E11	स्पूटम कल्चर और ड्रग स्सेप्टिबिलिटी टेस्ट Sputum culture test and Drug susceptibility test		☐
E12	रक्त – टोटल काउंट, डिफरेंशियल काउंट–ई एस आर Blood -Total Count, Differential Count- ESR		☐
E13	रक्त – एच आईवी टेस्ट Blood- HIV test		☐
E14	रक्त – शुगर टेस्ट Blood- Diabetes test		☐
E15	रक्त – टी बी गोल्ड Blood-TB Gold		☐
E16	रक्त – टी बी ऐलाइज़ा Blood-TB Elisa		☐
E17	मॉनटूक्स टेस्ट Mantoux test		☐

Provider ID : ☐☐☐☐☐☐☐ Form No: ☐☐☐

SECTION 3 : DIAGNOSIS			**Yes (1) No (2)**
D1	क्या प्रोवाइडर ने बातचीत में टी बी होने की शंका जताई?	Did the provider mention about suspicion of TB in the whole conversation?	☐
D2	क्या प्रोवाइडर ने खुद से कोई पर्चा लिख कर दिया? यदि हाँ, तो D2a & D2b भरें। यदि नहीं, तो D3 पर जायें	Did the provider give a prescription on his/her own? If yes, fill D2a & D2b. If no, go to D3	☐
D2a	क्या वह पर्चा दवाईयों के लिये था?	Was the prescription for medicines?	☐
D2b	क्या वह पर्चा डायग्नोस्टिक जाँच के लिये था?	Was the prescription for diagnostic test?	☐
D3	प्रोवाइडर ने क्या डायग्नोसिस दिया?	Did the provider give a diagnosis?	☐
D3a	यदि हाँ, तो डायग्नोसिस क्या था? (यदि, डायग्नोसिस एक या एक से अधिक दिये गये तो सभी को लिखें) If yes, what was the diagnosis? (if, one or more diagnosis given then write all of them)	_____	

Provider ID : ☐☐☐☐☐☐☐ Form No: ☐☐☐

SECTION 4: TREATMENT (In case to be taken SOS code -66 in frequency)										
T1	Total time taken by Provider प्रोवाइडर द्वारा लिया गया कुल समय			**HH** ☐☐ : **MM** ☐☐ : **SS** ☐☐						
T2	Did the provider dispensed/prescribed any medicine? If yes, fill T3, if no go to T4 क्या प्रोवाइडर ने आपको दवाई दी/लिखकर दी? यदि हाँ, तो T3 भरें। यदि नहीं, तो T4 पर जाये									☐
T3	Medicines दवाईयाँ *Dispensed* दवाई दी = *1* *Prescribed* दवाई लिखी *=2*	(a) Name नाम If provider has prescribed/Dispensed less than 6 medicines than write -99 in the medicine name. यदि प्रोवाइडर ने 6 से कम दवाईयाँ दि है तो मेडिसिन नाम में -99 भरें	(b) Types of Medicine दवाईयों का प्रकार Tablets गोली=1, Capsules केप्सूल=2, Syrups सिरप=3, Injectables इंजेक्टेबल=4 Powder चुरण=5	(c) Dose खुराक	(d) Frequency दिन में कितनी बार	(e) Duration कितने दिनों तक	(f) How many days in week हफ्ते में कितनी बार	(g) How many weeks कितने हफ्ते	(h) Drug classification code दवा का कोड refer to annex	(i) Price for full course of prescribed medicine? पर्चे पर लिखी दवाई की कीमत
	1. ☐	ब्रॉन्ड Brand जेनेरिक Generic	☐	☐☐:☐☐	☐☐	☐☐	☐	☐☐	☐☐	☐
	2. ☐	ब्रॉन्ड Brand जेनेरिक Generic	☐	☐☐:☐☐	☐☐	☐☐	☐	☐☐	☐☐	☐
	3. ☐	ब्रॉन्ड Brand जेनेरिक Generic	☐	☐☐:☐☐	☐☐	☐☐	☐	☐☐	☐☐	☐
	4. ☐	ब्रॉन्ड Brand जेनेरिक Generic	☐	☐☐:☐☐	☐☐	☐☐	☐	☐☐	☐☐	☐
	5. ☐	ब्रॉन्ड Brand जेनेरिक Generic	☐	☐☐:☐☐	☐☐	☐☐	☐	☐☐	☐☐	☐
	6. ☐	ब्रॉन्ड Brand जेनेरिक Generic	☐	☐☐:☐☐	☐☐	☐☐	☐	☐☐	☐☐	☐

Annex to T3 (h) Drug classification code :- Unlabelled Tablets/Syrup खुली/बिना नाम की गोलियाँ/सिरप=1; Unlabelled injections खुली या बिना नाम का इंजेक्शन =2; IV bottles/glucose drip आई वी बोतल/ग्लूकोस ड्रिप =3; Ayurvedic medicines आयुर्वेदिक दवाईयॉ =4; Homeopathic medicines होम्योपेथिक दवाईयॉ =5; Antibiotics ऐन्टिबायोटिक दवाईयॉ =6; Analgesics ऐनालजेसिक दवाईयॉ =7; Anti-ulcer medication ऐन्टी-अल्सर दवाईयॉ =8; Steroids (NSAIDS) स्टेरॉयड्स =9; Anti-allergy medicines ऐन्टी-अलर्जिक दवाईयॉ =10; Cardiac medication कारडियक दवाईयॉ =11 ; Psychiatric/ neural medicines साईकाईट्रिक दवाईयॉ =12; Identified as anther type of medication =13; Household remedies घरेलू दवाईयॉ =14; Drugs not classified दवाई जो क्लासिफाइड नहीं है = 50

Provider ID : ☐☐☐☐☐☐☐ Form No: ☐☐☐

T4	आपने प्रोवाइडर को कुल कितने पैसे दिये? How much money did you give at end of consultation?	Rs. ☐☐☐☐	
T5	क्या प्रोवाइडर ने कोई इंजेक्शन लेने के लिये कहा?	Did the provider offer any Injection?	☐
T6	क्या प्रोवाइडर ने आई वी लेने के लिये कहा?	Did the provider offer an IV?	☐
T7	क्या प्रोवाइडर ने कोई अन्य इनवेसिव जाँच के लिये कहा, जैसे कि ब्लड ग्लूकोज़ टेस्ट? यदि हाँ तो T7a भरें, यदि नहीं, तो T8 पर जायें।	Did the provider offer any other invasive exams, such as blood glucose test? If yes go to T6a. if no, go to T7	☐
T7a	यदि हाँ, तो प्रोवाइडर ने कौन सा इनवेसिव टेस्ट किया/सलाह दी? If yes, what invasive test was offered/suggested?	_____	
T8	क्या प्रोवाइडर ने बीमारी के किसी खतरे के निशान के बारे में बताया?	Did the provider inform about any danger signs of the disease?	☐
T9	क्या प्रोवाइडर ने दवाई के साईड इफैक्ट (मिचली, उल्टी, पेशाब का लाल होना) के बारे में बताया?	Did the provider inform about any side effects of drugs? (nausea, vomiting, red discoloration of the urine)	☐
T10	क्या प्रोवाइडर ने खाँसते समय किसी प्रकार की सावधानी बरतने के बारे में बताया?	Did the provider speak about cough hygiene?	☐
T11	क्या प्रोवाइडर ने धूम्रपान बंद करने की सलाह दी?	Did the provider speak about smoking cessation?	☐
T12	क्या प्रोवाइडर ने वापस आने की सलाह दी? यदि हाँ, तो T12a से T12f भरे। यदि नहीं, तो T13 पर जायें।	Did the provider ask the patient to come back? If yes, mark from T12a to T12f and if no, go to T13	☐
T12a	लक्षणों में कोई सुधार नहीं	If the symptoms persist	☐
T12 b	लक्षण और बिगड़ जायें	If the symptoms become worse	☐
T12c	दवाई लेने के लिये	To get medicines	☐
T12d	टेस्ट रिपोर्ट दिखाने के लिए	To show the test results	☐
T12e	अन्य	Other	☐
T12f	विवरण_____	Specify_____	

T13	Any other questions asked that were not on the previous list? ऊपर दिये गये सवालों के अलावा कोई नये सवाल आपसे पूछे गये? ☐ *1 =Yes* हाँ, *2 =No* ना	1	*हिन्दी* *English*
		2	*हिन्दी* *English*
		3	*हिन्दी* *English*
		4	*हिन्दी*

Provider ID : ☐☐☐☐☐☐☐ Form No: ☐☐☐

SECTION 5: REFERRAL			**Yes (1) No (2)**
R	क्या प्रोवाइडर ने रोगी को आगे की देखभाल के लिए कहीं जाने की सलाह दी? यदि हाँ तो R1 से R4a भरें। यदि नहीं, तो सेक्शन 6 पर जायें।	Did the provider ask the patient to go anywhere for further management? If yes fill R1 to R4a, If no, go to section 6.	☐
R1	प्राइवेट प्रोवाइडर/प्राइवेट अस्पताल	Private Provider/ Private Hospital	☐
R2	सरकारी अस्पताल	Government Hospital	☐
R3	डॉट्स सेन्टर	DOTS Centre	☐
R4	अन्य	Other	☐
R4a	विवरण _____	Specify _____	

SECTION 6: GLOBAL ASSESSMENT SCALE			
G1	Did you like this doctor? क्या आपको डॉक्टर अच्छा लगा ?	*1 =Yes* हाँ, *2 =No* ना	☐
G2	Would you go to this doctor again? क्या आप इस डॉक्टर के पास दोबारा जाओगे?	*1 =Yes* हाँ, *2 =No* ना	☐
G3	Did the doctor create an environment in which you could convey your symptoms and concerns easily? क्या डॉक्टर ने ऐसा माहौल बनाया कि आप उसे अपनी तकलीफ आसानी से बता सकें?	Definitely निश्चित रुप से =3 Somewhat थोड़ा सा =2 Not at all बिल्कुल नहीं =1	☐
G4	Did the doctor appear to be knowledgeable about your illness? आपको क्या लगा क्या यह डॉक्टर अच्छे जानकार हैं। क्या आप समझते है कि उन्हें आपकी बीमारी की जानकारी है?	Very knowledgeable अच्छी जानकारी है =3 Somewhat knowledgeable सामान्य जानकारी है =2 Not at all बिल्कुल नहीं =1	☐
G5	Did the doctor address your worries seriously? क्या आपकी चिन्ता पर डॉक्टर ने पूरा ध्यान दिया?	Very seriously पूरा ध्यान दिया =3 Somewhat seriously थोड़ा ध्यान दिया =2 Not at all बिल्कुल नहीं =1	☐
G6	Did the doctor explain anything about your illness? क्या डॉक्टर ने आपको बीमारी के बारे में समझाया?	Very well बहुत अच्छी तरह से =3 Cursorily थोड़ा सा =2 Not at all बिल्कुल नहीं =1	☐
G7	Did the doctor explain your treatment plan? क्या डॉक्टर ने आपको इलाज के बारे में समझाया?	Very well बहुत अच्छी तरह से =3 Cursorily थोड़ा सा =2 Not at all बिल्कुल नहीं =1	☐
G8	The SP will give a rank to the provider from 1-10, where 10 is the highest and 1 the lowest. SP प्रोवाइडर को 1 से 10 रेंक दे जिसमें 10 सबसे अधिक और 1 सबसे कम है।		☐☐

Provider ID : ☐☐☐☐☐☐☐ Form No: ☐☐☐

SECTION 7: ***Errors and Detection*** *गलतियाँ और पहचाना गया*			
1.	क्या आपको लगता है कि केस प्रेजेंट करने में आपसे कोई गलती हुई? यदि हाँ, तो कौन सी गलती हुई। उनको नीचे लिखें। *हाँ=1, नहीं=2*	Did you think you made any mistakes in the presentation of the case? If yes, what mistakes you made please note them down. *Yes=1, No=2*	☐
2.	क्या आपको प्रोवाइडर ने एक एस पी के रूप में पहचान लिया? यदि हाँ, तो आप कैसे पहचाने गये? *हाँ=1, नहीं=2*	Did the provider detect you as an SP? If yes, how were you detected? *Yes=1, No=2*	☐

Supervision Check सुपरवाइजर चैक			
Supervisor's Name सुपरवाईजर का नाम		Supervisor ID सुपरवाईजर की ID	☐☐
Form checking date फॉर्म चैक करने की तारीख	☐☐/☐☐/☐☐☐☐ *DD/MM/YYYY format*		
Recorder No रिकार्डर नम्बर			☐

Provider ID : | | | | | | | | Form No: | | | |

Comments/ टिप्पणी **:**

End