Associations between client experience and technical care quality: A standardized patient study for tuberculosis in urban India

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Montreal, Quebec,

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মা, বাবা এবং ভাইয়ের জন্য

(To Maa, Baba & Borda)

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Abstract

INTRODUCTION

Quality in healthcare systems is integral to achieving universal health coverage. Healthcare quality should not only focus on adherence to technical standards but must also include measurement of the degree of patient-centredness and care-seekers' perceptions of care. But how do client experience and satisfaction correlate with technical quality? Authentic patients' medical data and their subjective impressions poses fundamental issues for making inferences as the true cause of health conditions remains unknown and provider selection is limited. We attempt to solve these limitations by using standardized-patient (SP) data from a large-scale study, whereby SPs acting as people with tuberculosis (TB) symptoms or known TB visited a representative random sample of providers. Although SPs are aware that they are portraying TB and thus differ from real patients, their impressions about their client-provider interactions remain valid and can be leveraged. This data is therefore well suited to estimate the association between technical care (defined as adherence to standards of care), subjective quality or client experience (defined as adherence to patient-centred standards) and SPs' subjective assessment of providers.

METHODS

We performed secondary data analyses on 2,602 SP-provider interactions across 1,203 primary-care facilities in urban Patna and Mumbai between 2014 and 2015. Analyses for correct management compared with Standards for TB Care in India were previously studied for four TB conditions. When SPs were debriefed on the same day as their visits, they were asked to report clinical details and to record their impressions using a global assessment scale. Questions from this tool cover a repertoire of subjective measures and include the following: "Did you like this doctor?", "Would you go to this doctor again?", "Provide a 1-10 ranking of the provider", etc. We compiled descriptive analyses and examined the association between correct care and quality measures using odds of correct management from generalized estimating equations. We then performed principal component analyses to derive a three-item index for SPs' subjective assessment which retained 82.4% of the original variance. We applied mixed-effects linear regressions using this index as the dependent variable to quantify the change in SP-attributed

provider scores for objective and subjective forms of quality, as well as for interactional demographics.

RESULTS

From the 2,602 total interpretable interactions that were completed between November 2014 and August 2015, 954 interactions were correctly managed (35%, [95% CI 32%–37%]). SPs reported they were likely to return to their provider in 2,053/2,602 interactions (79%, [95% CI 78%-81%]. Their average 1-10 ranking of providers was 6.27 [95% CI 6.18 – 6.36]. Using adjusted odds ratios (aOR) for correct management, we found that subjective quality or SPs' client experience was associated with correct care. This was visible when SPs reported providers appeared knowledgeable (aOR 4.87 [95% CI 4.01 – 5.91]), addressed their worries seriously (aOR 3.17 [95% CI 2.65-3.80]), clearly explained illnesses (aOR 2.40 [95% CI 1.80–3.20].

In our simple to multiple linear regressions, we report that when adjusting for correct care, the change in SPs' subjective assessment weakened for markers related to client experience. For instance, this was observed when providers addressed SPs' concerns seriously (1.36 vs. 0.60 unit-change in subjective assessment scores) and gave clear explanations on illness (1.02 vs -0.01). In this connection, objective quality markers also decreased, as seen when providers posed all essential history questions (2.56 vs 1.21).

CONCLUSION

Our study suggests that interactions in which SPs' provider assessments were positive also seem to result in SPs being appropriately managed by providers. Patient-centred elements of quality may therefore serve as signals for providers' technical practice and their inclusion in providers' practice consistently resulted in positive subjective assessments.

SPs also recognized the value of accessible communication which is particularly note-worthy given that they were knowledgeable of the medical cases they were presenting.

Résumé

INTRODUCTION

Pour assurer la qualité des soins de santé, il importe d'évaluer, dans un premier temps, à quel point les services sont bel et bien axés sur le patient même, mais aussi sur la perception des soins chez les demandeurs de soins. Dans cette optique, par contre, on se veut de s'interroger comment l'expérience et la satisfaction des clients seraient, elles, liées à la qualité technique ? Des données médicales authentiques de patients et les impressions subjectives qui en découlent posent des problèmes fondamentaux si l'on veut s'en servir pour en arriver à des conclusions qui auraient une portée plus large, car la véritable source des problèmes de santé reste toujours inconnue, de même que l'éventail des choix de prestataires de soins demeure restreint. Nous tentons de remédier à ces limites par le biais d'une utilisation de données de patients standardisées (PS) provenant d'une étude réalisée à grande échelle, où les PS se présentant comme des personnes atteintes de tuberculose (TB) ont visité un nombre de prestataires provenant d'un échantillonnage aléatoire représentatif. Même si les PS sont conscients qu'ils ne font qu'incarner des personnes atteintes de la TB et qu'ils sont ne soient pas de véritables patients, leurs impressions quant à leurs interactions client-prestataire demeurent valables et peuvent être mises à profit. À cette lumière, ces données sont bien pertinentes si l'on veut mesurer l'association entre les soins techniques (ainsi définis comme le respect des normes afférentes aux soins), la qualité subjective ou l'expérience client (ainsi définie comme le respect des normes axées sur le patient) et l'évaluation subjective des prestataires.

MÉTHODES

Nous avons effectué des analyses de données secondaires sur 2 602 interactions entre prestataires et PS dans 1 203 établissements de soins primaires dans les villes de Patna et de Mumbai entre 2014 et 2015. Précédemment, en Inde, des analyses de la prise en charge appropriée par rapport aux normes pour le traitement de la tuberculose avaient déjà été étudiées pour quatre types de tuberculose. Lors des interrogations (débriefages) des PS le jour même de leurs visites, on leur a été demandés de communiquer aussi bien les détails cliniques que leurs impressions à selon une échelle d'évaluation globale. Les questions de cet outil couvraient un

répertoire de mesures subjectives, telles que : « Avez-vous aimé ce médecin ? », « Iriez-vous consulter à nouveau ce médecin ? », « Fournissez un classement de 1 sur 10 du médecin ».

Nous avons compilé des analyses descriptives et examiné l'association entre la prise en charge appropriée et les mesures de qualité selon les probabilités de prise en charge appropriée à partir d'équations d'estimation généralisées. Nous avons ensuite effectué des analyses en composantes principales afin d'établir un indice à trois éléments pour en arriver à une évaluation subjective des PS qui conservait 82,4 % de la variance originale. Nous avons appliqué des régressions linéaires à effets mixtes en utilisant cet indice comme variable dépendante pour quantifier le changement dans les évaluations des prestataires attribuées par les PS pour les formes objectives et subjectives de qualité, ainsi que pour les données démographiques interactionnelles.

RÉSULTATS

Sur le total des 2 602 interactions qui se sont avérées interprétables parmi ceux qui ont eu lieu entre novembre 2014 et août 2015, un total de 954 interactions a été pris en compte de façon conforme (35 % [IC à 95 % 32 %-37 %]). Les PS ont déclaré qu'ils étaient aptes à retourner chez leur prestataire dans 2 053/2 602 interactions (79 % [IC à 95 % 78 %-81 %]. Le classement moyen, de 1 à 10, qu'ont ils ont fourni des prestataires, s'élevait jusqu'à 6,27 [IC à 95% 6,18 - 6,36]. En utilisant les rapports de probabilité ajustés (« aOR ») pour une prise en charge appropriée, nous avons trouvé que la qualité subjective ou bien l'expérience client des PS était associée à une prise en charge appropriée. Ceci a été observé lorsque les PS ont communiqué que les prestataires semblaient être bien informés (4,87 [IC à 95% 4,01 - 5,91]), ont abordé leurs inquiétudes sérieusement (3,17 [IC à 95% 2,65-3,80]), ont expliqué clairement les maladies (2,40 [IC à 95% 1.80-3,20]).

Dans nos régressions linéaires simples et multiples, en ajustant pour des soins appropriés, le changement dans l'évaluation subjective des PS a baissé en ce qui a trait aux marqueurs liés à l'expérience du client. Par exemple, cela s'est observé lorsque les prestataires ont abordé les préoccupations des PS avec sérieux (1,36 vs 0,60 unités de changement dans les évaluations des prestataires) et ont mené à des explications claires sur la maladie (1,02 vs -0,01). Dans ce contexte, les marqueurs objectifs de qualité ont également baissé, comme on l'a vu lorsque les prestataires ont posé toutes les questions primordiales sur leur histoire (2.56 vs 1.21).

CONCLUSION

En conclusion, les évaluations positives des prestataires par les PS sembleraient avoir une relation avec une prise en charge appropriée des PS par les prestataires. Ainsi, les divers éléments qui contribuent à assurer la qualité d'une prestation des soins axée sur le patient peuvent servir de points de repère dans les pratiques professionnelles des prestataires de soins, comme leur présence dans les pratiques des prestataires de soins s'est, de manière systématique, traduite par une évaluation subjective positive.

Également, les PS ont reconnu la valeur d'une communication accessible, ce qui est à bien noter, étant donné que ces acteurs connaissaient bel et bien le contexte médical qu'ils doivent dépeindre.

Front matter

Preface

Quality is a multifaceted metric and, ideally, within the healthcare setting, providers' commitment to deliver medically-sound care should be accompanied by affective behaviours characterized by trust, empathy, effective communication, inter alia. Recently, the TB community has attributed renewed value to patient experience, and patient-centeredness in general. India currently holds the highest nationwide tuberculosis (TB) burden and is the top contributor of missed TB cases.[1] While the road towards universal health coverage is long, the country is working with the end in sight. India has, among other actions, introduced new health reforms, increased its health expenditures, and further expanded public-private capacity and coverage of health services.[2-4] However, shortcomings in quality of care can cripple health systems and, ultimately, derail advances. As the TB patient community has raised its voice against care that is rightfully deemed of poor quality,[5] our study's objective to determine the association between technical care and health users' experiences is timely. Our findings also provide unique insight that can benefit the patient community not only from a medical perspective but from a human one. We present these findings as a manuscript in Chapter 4: Sen P, Daniels B, Sulis G, Kwan A, Benedetti A, Das J, Pai M. *Associations between client experience and technical care quality: A standardized patient study for tuberculosis in urban India*. Unpublished.

Preliminary results from this thesis were previously presented on international platforms as well as internally within McGill:

1) The Union Conference – North American Region. February 2021. British Columbia, Canada. Poster presentation.
2) EBOSS Graduate Research Day. March 2021. Montreal, Quebec – Canada. Poster presentation.
3) McGill Global Health Night. November 2020. Montreal, Quebec – Canada. Poster presentation

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I would also like to thank the original implementers not directly linked to this analysis study. To the members of QuTUB and ISERDD who designed and completed the fieldwork to conduct this large standardized-patient study, thank you for your efforts and for ensuring data quality.

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Author contributions

This thesis covers secondary data analyses of standardized-patient data from India collected between 2014 and 2015. The aim of this analysis was formulated by MP, JD, BD, GS, AK, and PS. Data manipulation, compilation of descriptive statistics, and computation of regression analyses were completed by PS with guidance from BD, AK, and GS. Subsequently, the analyses received critical appraisal from MP, JD, and AB, and were then revised by PS. The initial manuscript draft was written by PS with support from BD. All other authors, MP, JD, AB, GS and AK shared constructive feedback, which enabled PS to finalize the manuscript.

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List of key abbreviations

AYUSH	Ayurveda, Yoga, Unani, Siddha, or Homeopathy
DS-TB	Drug-sensitive tuberculosis
GRS	Global rating scale
ISERDD	Institute of Socio-Economic Research on Development and Democracy
LMIC	Low- and middle-income country
MBBS	Bachelor or Medicine, Bachelor of Surgery
MDR-TB	Multi-drug-resistant tuberculosis
NSP	National Strategic Plan
PPIA	Private Provider Interface Agency
QOC	Quality of care
QuTUB	Quality of Tuberculosis Care (Team)
RNTCP	Revised National Tuberculosis Control Programme
STCI	Standards for Tuberculosis Care in India
SP	Standardized patient
TB	Tuberculosis
UHC	Universal Health Coverage
WHO	World Health Organization
Xpert	GeneXpert MTB/RIF (Cepheid Inc., CA)

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Chapter 1: Introduction

Quality in healthcare systems is integral to achieving universal health coverage (UHC), as the Lancet Commission on High-Quality Health Systems (HQHS) highlights.[6] Studies on quality care should not only focus on adherence to technical standards but must also seek to understand whether care is patient centred. As the measure of quality is inherently multidimensional, it is well acknowledged that user (client) input contributes to a distinct dimension of quality in its own right.[7] Furthermore, their experiences need to be positive so that healthcare systems and institutions are trusted by users.[6] Yet, the extent to which objective measures of quality correlate or associate with whether patients feel they have received appropriate care and whether their concerns were adequately addressed remains unclear and is unknown for certain disease areas such as for tuberculosis (TB).

TB is a bacterial disease responsible for 1.4 million deaths, with close to 4 million missed cases worldwide in 2020.[1] The focus that TB programs put on coverage of services did not prevent the high occurrence of patient mortality rates, missed cases, and patient loss to follow-up which continue to persist.[1,8] Presently, India is managing the largest TB epidemic with 100% TB service coverage; yet, patients continue to fall through the cracks in the continuum of care.[1,8] In its public sector, fewer than 1 in 2 individuals successfully completes treatment,[9] and city-representative findings from standardized patient (SP) studies have shown that the quality of private-sector TB care is sub-standard.[10] Furthermore, primary providers' practice of empirical treatment results in diagnostic delays and promotes other consequences, such as the occurrence of antimicrobial resistance.[11] Findings of such studies underscore the prevalence of low-quality TB care in India and provides a motivation to study the association between subjective and objective measures within the clinical setting to potentially inform future Indian health reforms.

Typically, studies examining this association have been limited by their inability to measure technical quality, as patients' underlying conditions remain unknown or the studies fail to report patient accounts across various providers for the same clinical case. Moreover, patients' subjective impressions are inherently biased as studies generally recruit patients who have self-selected their own provider.

The use of standardized patient (SP) data attempts to remedy these limitations: SPs are operating on behalf of the research team and are trained to repeatedly portray distinct TB

presentations across many providers, accurately recount clinical details that can be benchmarked with standards of care, and report on their subjective experiences. Therefore, SP studies can collect data on both technical quality as well as subjective quality. For these reasons, among others, the use of SP data allows for a robust assessment of whether determinants of patient-centredness and patient experience parallel hard outcomes such as correct management.

Chapter 2: Literature review

2.1. High-quality health systems are a requisite to achieve universal health coverage

"Treating patients as you would like to be treated – with dignity, respect and confidentiality. This is the fundamental basis to ensure high-quality care" -Ashna Ashesh, TB Survivor, presented at the Union World Conference on Lung Health, 2020

In 2015, target 3.8 of the 2030 Sustainable Development Goals defined universal health coverage (UHC) as an ideal to ensure the availability and delivery of essential health services without imposing financial hardships on patients or users.[12,13] In other words, UHC deems health as a human right. The World Health Organization (WHO) endorsed this definition of UHC, which purported to revolutionize the entire continuum of care. It was also suggested that the realization of this ideal would benefit national economies.[12] Thus to achieve UHC long term, ongoing international support and funding have been lent to the cause of increasing widespread user utilization and participation in the healthcare systems of low- and middle-income countries (LMICs).[14]

Widespread access to health services is insufficient, however, if the quality of care is lacking – a reality the global health community has increasingly acknowledged,[14-17] notably through observing the situation in countries like India. The nationwide Janani Suraksha Yojana programme is a telling example. The programme sought to reduce neonatal and maternal deaths by granting mothers cash transfers if they chose to deliver their child in either public or private health institutions.[18,19] Shortly after its implementation, impact evaluation reports showed that India experienced an upsurge in institutional births, but its maternal mortality rate remained relatively the same.[19] On a similar note, India's full coverage treatment service for tuberculosis (TB)—direct-observed treatment, short course (DOTS)— has proven insufficient to mitigate persistent rates of patient mortality, missed cases, as well as patient loss to follow-up (LTFU).[8,20] Another indicator of the absence of quality-corrected services is absenteeism among healthcare providers, as is observed in Bangladesh and Uganda, for example.[21] Evidence from India, Vietnam, and China suggests there is a concerning discrepancy between providers' clinical knowledge and the quality of their clinical practice, a reality which poses an additional challenge.[21,22] Therefore, UHC does not automatically imply that health services necessarily offer *quality* care.

In reality, quality care –or even high-quality care—is highly variable across LMICs. While local definitions of health care quality can change, the WHO defines quality care as "*the degree to which health services for individuals and populations increase the likelihood of desired health outcomes*."[23] Translated in terms of pillars, quality health care is safe, effective, people or patient-centred, timely, equitable, integrated, and efficient.[24] In contrast, the 2018 Lancet commissioners on High-Quality Health Systems defined *"a high-quality health system [to be] one that optimises health care in a given context by consistently delivering care that improves or maintains health outcomes, by being valued and trusted by all people, and by responding to changing population needs."*[6] High-quality health systems, in lieu of poor quality, could annually avert an estimated 8 million deaths in LMICs across health conditions,[6] including 469,956 TB deaths in 2016 alone.[25] Three critical reports on the quality of healthcare published in 2018 have set the precent by declaring a clear message: the delivery of quality care, which includes patient-centredness, must form the backbone of health systems and should be integrated into the holistic aim of UHC.[6,17,26,27] For health systems to succeed and adequately address patients' needs, knowledge of both objective and subjective metrics of quality is therefore needed to capture a full picture. While standardized metrics exist, such measures are not comparable across settings. The added challenge, then, is to measure quality care in a context-specific manner that responds to local needs and is culturally in-tune. In other words, the "one-size-fits-all approach" is inappropriate, a familiar theme in global health.

In the pre-COVID-19 world, the trajectory of health outcomes was weighted towards an increase in non-communicable diseases, conditions that would generally require prolonged use of health systems.[6] Pandemic-related lockdowns, curfews, and social distancing measures have contributed to disruptions in routine health services and led to an inevitable rise in communicable diseases.[28] Put simply, health quality research is essential and has only become more so during the pandemic.

One area where quality of care has been a long-standing concern is tuberculosis (TB), a disease that continues to kill nearly 1.5 million people each year, despite TB being a curable, bacterial infection.[1,8]

2.2. Global and Indian tuberculosis epidemiology

Even before COVID-19, TB was –and continues to be—a major public health issue. TB is a bacterial disease caused by *Mycobacterium tuberculosis,* which primarily affects the lungs, although extra-pulmonary, subclinical, and latent forms can manifest as well.[29] Transmission usually occurs in the form of a cough or sneeze and disease prevalence overwhelmingly impacts marginalized populations and those living in poverty.[1]

In 2020, there were almost 10 million people who developed TB disease and 1.2 million HIV-negative persons who died of the disease, with men disproportionately accounting for more than half of the TB burden.[1] To date, South-Asian and South-East Asian regions account for the majority (43%) of new global infections, with the continent of Africa being second (25%).[1] Of the 10 million people who fell ill with TB, nearly 4 million were either not diagnosed, or not reported in notification systems (**Figure 2.2.1**). Due to the COVID-19 pandemic, for the first time, TB deaths actually increased during 2020, and the number of missing patients increased from 3 to 4 million.[1] This large number of "missing patients" with TB, combined with the high TB mortality, raises major concerns about quality of TB care.

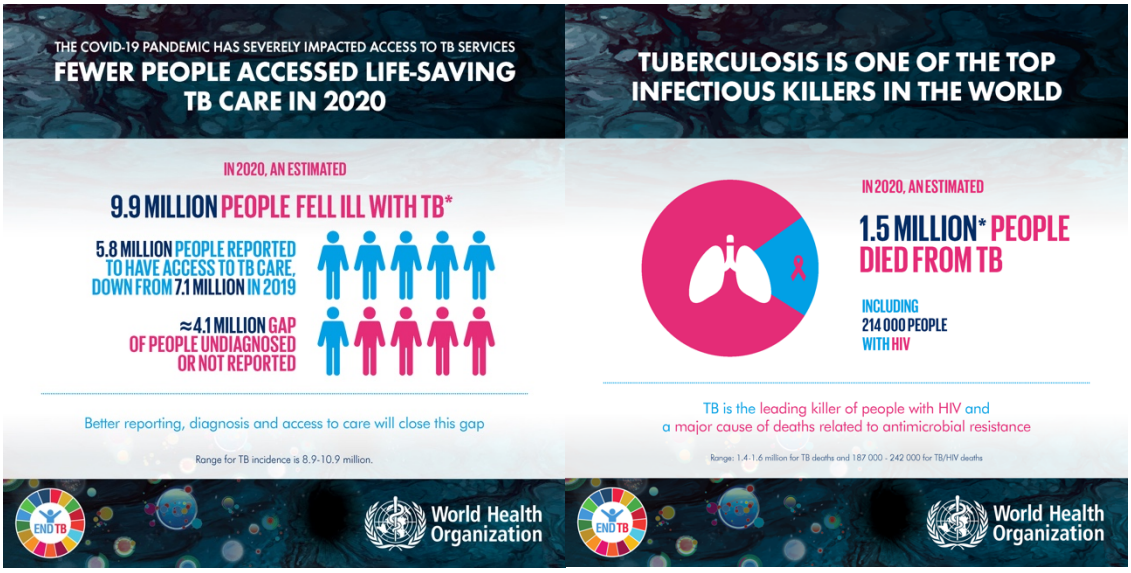

FIGURE 2.2.1. Global snapshot of tuberculosis burden. *Infographics taken from the World Health Organization.*

As COVID-19 spread globally, attention and funding were channeled into reinstating normalcy, even at the cost of setting back gains made in other areas of health. A noteworthy example is seen in the management of TB.[28,30-32] Accounts from civil societies show that retractions in TB testing capacity (and thereby notifications), treatment delivery, and closure of service platforms were widespread.[33] Whereas the cumulative number of COVID-related deaths accrued to 2.74 million on 11 March 2021,[34] one year after the WHO declared the outbreak of COVID-19 a pandemic, annual TB-related deaths reach about 1.5 million, a persistent global fact for the last five years (**Figure 2.2.2**).[1,8,35] Consequently, TB is among the top ten leading causes of death globally in LMICs.

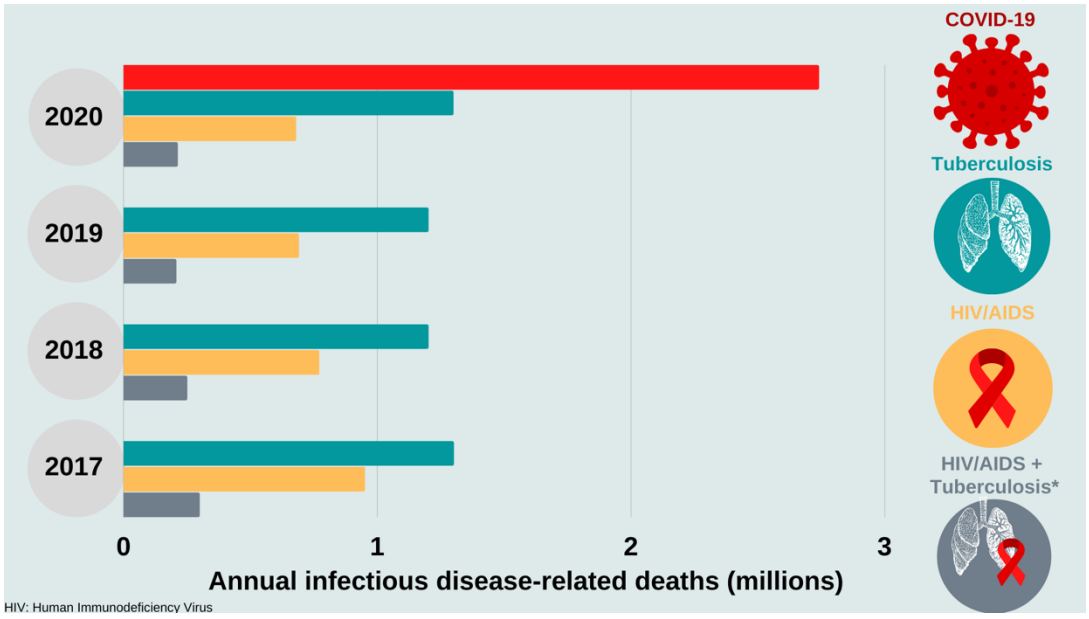

FIGURE 2.2.2. Global total mortality caused by infectious agents: COVID-19, Tuberculosis and HIV/AIDS.

**The grey bar reports the number of deaths ultimately caused by TB among people living with HIV/AIDS.*
Sources:
All tuberculosis and tuberculosis-caused deaths among those living with HIV/AIDS are reported from Global Tuberculosis Reports published yearly by the World Health Organization. Likewise, HIV/AIDS deaths were pulled from webpages from the World Health Organization and UNAIDS.org.

In the Indian context, absolute TB incidences have led WHO to list India on the drug-sensitive (DS) TB, HIV/TB, as well as multi-drug-resistant (MDR) TB high-burden lists.[1] Indeed, in 2020, India observed 188 clinically-evident TB cases per 100,000 persons for its 1.38 billion inhabitants, an incidence rate that excludes HIV-comorbid and drug-resistant cases. These facts push the country into the position of leading contributor of TB cases among the top eight countries that collectively account for nearly 66% of all global incidences.[1]

Figure 2.2.4. illustrates India's TB burden in 2019, 0.1 million persons were diagnosed with drug-resistant (DR) TB, and approximately 0.4 million persons died from TB. On the treatment front, success rates are imperfect and treatment coverage still remains below the 90% target. Subbaraman et al. (2016) have developed care cascades using public health sector data from 2013. Overall, from diagnosis to treatment and treatment to cure, large numbers of patients exit the pathway without reaching treatment completion (**Figure 2.2.3**).[9]

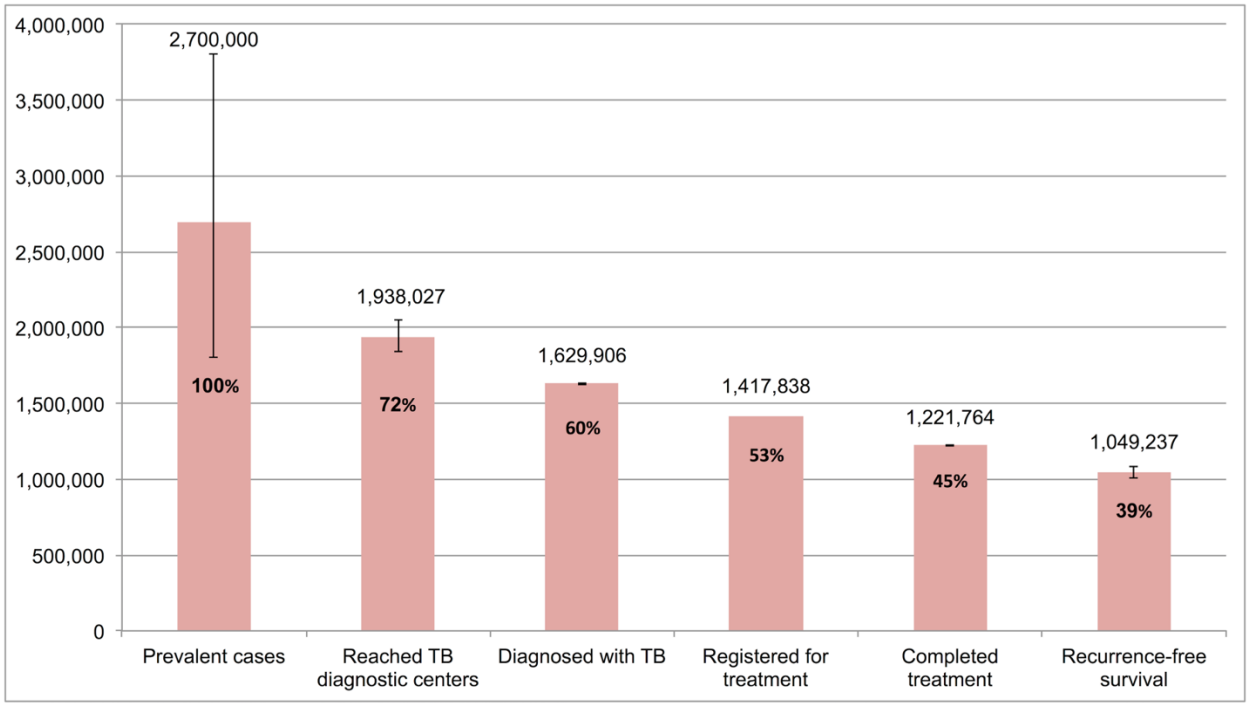

FIGURE 2.2.3. The cascade of care for all forms of tuberculosis in India's Revised National Tuberculosis Control Programme (RNTCP) in India, 2013. *Figure and caption taken directly from Subbaraman et al. (2016).*[9]

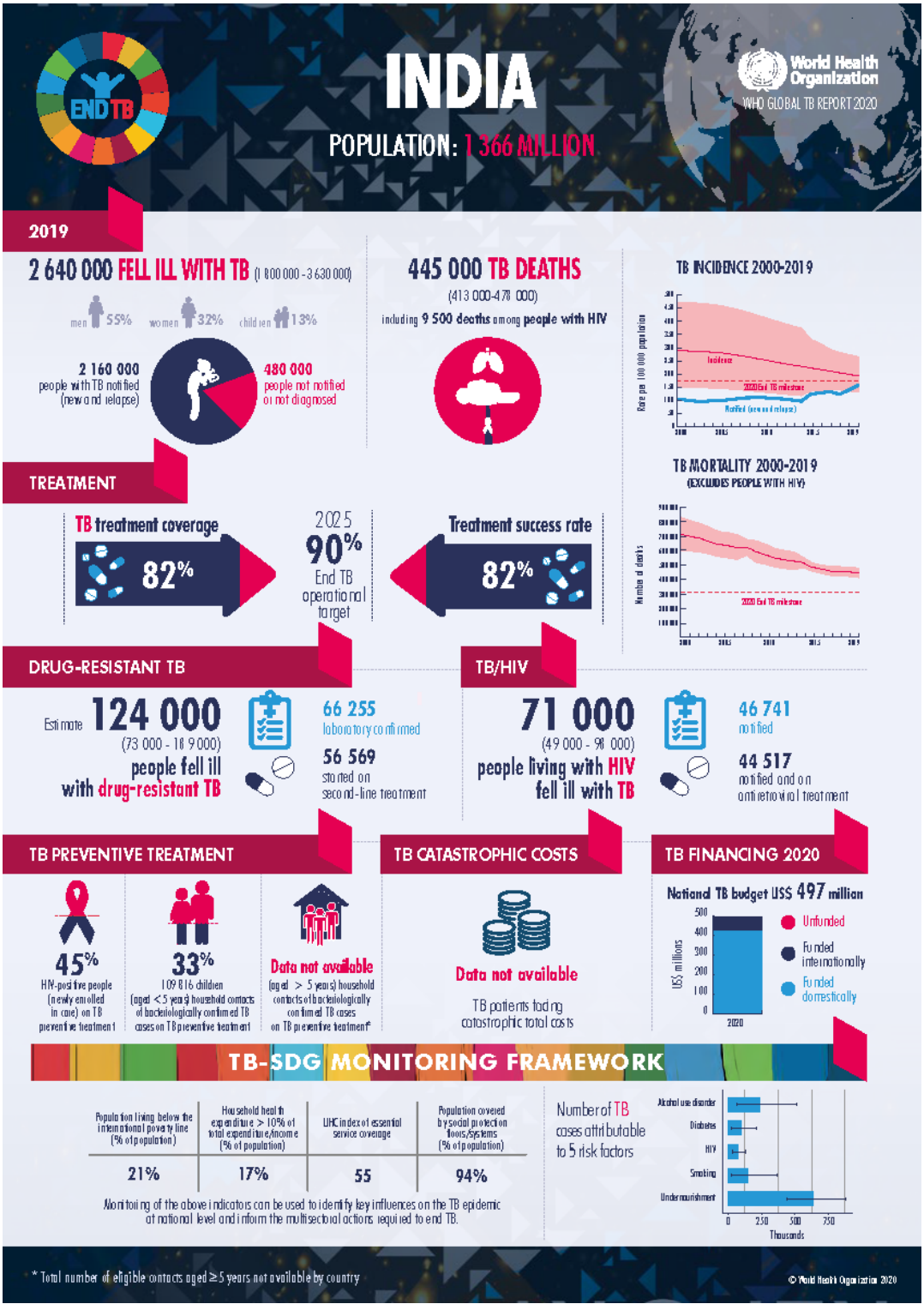

FIGURE 2.2.4. 2019 tuberculosis profile for India as depicted by the World Health Organization.
*NB: The population should read 1.366 *billion*, instead of million.*

2.3 Tuberculosis care in India's urban-private healthcare sector

The Indian health system constitutes two main divisions: the public and private healthcare sectors (which also includes informal sectors). The public sector includes the Revised National Tuberculosis Control Programme (RNTCP), a government-led national TB program whereby patients' progress is routinely captured.[36] This public-sector data is filtered into the online Nikshay platform, along with private data.[a] Despite efforts to bolster the public health sector, people often seek other forms of health care or services as a first resort.[37-39] In fact, 80% of the Indian population first consults with private providers,[40] including presumptive TB patients, as recent drug sale studies support.[39,41,42] Furthermore, more than half of healthcare teaching facilities are privately affiliated.[36] With the private sector responding to such a large clientele of TB patients,[43] various studies have aimed to characterize its dynamics.

Frequently cited in TB literature are standardized patient (SP) studies that attest to providers' inability to align their practice with evidence-based technical guidelines. The authors[b] spearheading this methodology for healthcare research report the scarcity of quality care: only a weighted 35% [95% CI 32%‑37%] of SP-provider interactions in India's private sector resulting in appropriate care according to national and international standards of TB care.[10] The same data also showed that providers' practice was overall neutral to SP gender, age, and other biometric factors.[44,45] The only exception was seen in the practice of Bachelor of Medicine, Bachelor of Surgery (MBBS)-qualified providers, i.e., allopathic physicians, where the odds of correct management were 1.51 [95% CI 1.08 - 2.07] times greater among men SPs than women. However, the same authors considered this slight difference insufficient to justify the implementation of interventions from a gendered lens.[c] [46] Moreover, providers – private and public – generally prescribed broad-spectrum antibiotics before ascertaining diagnosis.[10,47] First, this inappropriate stewardship fuels antimicrobial resistance, a WHO-recognized global threat.[11,48,49] Second, and unsurprisingly, diagnostic delays, i.e., the length of time between the patient's first visit within the health system and their confirmed diagnosis, are widespread within

[a] The Nikshay platform also registers data from patients visiting private-sector health facilities; however, it is widely understood that private sector notification is not what it should be. As such, finding the 'missing TB patients' remains a high priority on the Indian agenda to eliminate TB.
[b] The authors are the Quality of Tuberculosis Care (QuTUB) team.
[c] The authors' informed threshold was set to 1.75, which would result in a worrying 10-12 percentage or proportion difference in how men and women patients would be clinically managed.

India. In fact, other studies show that the average total delay ranged from 1.5 to 2 months and required consultations with nearly three providers.[43] Deo et al.(2020) note that provider qualification further characterized average delay, with less-qualified providers prolonging the duration.[50] What's more? Fluroquinolones, which are medicines that can mask TB symptoms, are among the first medicines prescribed.[10] Such negligence results in close to a 10-day delay and promotes the likelihood of resistance selection.[51] Furthermore, 11 of 14 studies found private providers to be ill-equipped to manage DS-TB, compared to those occupying public positions.[52]

All in all, these examples illustrate how medical performance in TB screening and diagnosis falls short of Standards for TB Care in India (STCI). [11,53] On the treatment front, Subbaraman et al. (2019) report that in 2013, only half (43%) of those receiving care for DS-TB completed the care cascade, a trend which only worsened when looking at MDR-TB patients, who completed 7% of the cascade.[54]

Further impediments to eliminating TB in India are the government's overly ambitious targets and its parsimonious expenditure towards health.[3] In 2014, the WHO devised its END TB strategy, which pledges to eliminate TB by 2035 through attaining a 95% reduction in deaths, a 90% reduction in incident cases, and safeguarding families from incurring catastrophic costs from TB care.[55] In alignment with this initiative, the Government of India instated the 2017-2025 National Strategic Plan (NSP). The NSP's objectives foreshadowed ideas that would later be put forward by the Heads of State during the 2018 UN High Level Meeting on tuberculosis such as greater political commitment to eliminate TB and adoption of more patient-centric solutions.[56] However, India's continued underinvestment in health (< 2.5% of its GDP)[3] forecasts that many of its objectives for the private sector are short-sighted, including the aim of attaining a tenfold increase in detection, i.e., 0.2 to 2 million notifications by 2025.[4]

The variation and overall low quality could cloud our understanding as to why TB patients decide to frequent and remain loyal to the private sector. Of course, patients may be encouraged to visit private providers because of their high stature, their (profit-motivated) retention schemes,[57] their facilities' degree of accessibility, among other factors; however, providers may show distinct qualities that lead to a favourable patient experience. This theory could provide India with the necessary knowledge to inform its future TB strategies.

2.4 Need to apply the patient-centred agenda set for tuberculosis

"Blame and shame culture towards TB patients. Particularly with drug-resistant TB patients. Often times TB patients get blamed for being 'lazy,' for not complying, or not taking their medications on time. It seems that there [is] a lack of understanding and empathy from the system where there is a socioeconomic broader context that needs to be considered before anything else." -Handaa Enkh-Amgalan, TB Survivor, TB-PPM Webinar, 2021

As proposed by the WHO, patient-centred care includes *"providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions*."[58] This intention equally resonates with the first pillar of the END TB Strategy that advocates for *"integrated, patient-centred care and prevention."*[55] The WHO's patient-centred approach to TB care also set forth recommendations that celebrate patient choice and needs, such as giving the option to select between community-based treatment support or digital adherence technologies to enable treatment monitoring by health staff [58]

Movements within the TB research community have resulted in a slew of publications aiming at shedding light on the successes and on the missed opportunities in healthcare quality. Most recently, a compendium of 20 articles on TB quality (including a summary article) was compiled by Pai and Temesgen as an eBook.[59] Of particular relevance to this section is a 35-study systematic review that aimed to characterize TB patients' perception of quality care across LMICs. Importantly, to garner knowledge strictly from patients, the review omitted studies where caregivers or treatment teams gave their account. The authors found that while measurement of user experience was heterogenous, studies commonly found high rates of satisfaction,[60] despite quality of care being verifiably poor shown by SP studies, for instance.[61] The authors suggest the need to further study this seemingly inverse relationship by implementing better measurement approaches with well-defined subjective and experience-related metrics.

In an attempt to address the absence of patient contributions, recent efforts spearheaded by TB survivors rightfully argued the place of patient-led definitions in assessing quality of care. This resource is also included in the eBook and described high-quality care as that which: 1) Is evidence-based and best in class; 2) Efficient; 3) Transparent; 4) Addresses the mental health of patients; 5) Protects patients' privacy; and 5) Respects patients' dignity.[5] Suffice to say, aligning with TB patients' rights,[62] the global TB community must continue to re-imagine user-focused

health services and actively cater to the developing needs of the patient community.[63,64] To measure integrations of patient-centric values in health systems, clear metrics will unequivocally be required.

2.5 Quality of care conceptual frameworks

Quality conceptual frameworks are suitable tools to display and organize quality metrics. The most recent global framework was published in the 2018 Lancet Commission on High-Quality Health Systems (HQSS) (**figure 2.5.1**). This framework draws partly on Avedis Donabedian's seminal framework for quality of medical care (1966). The three pillars of Donabedian's conceptual framework include healthcare *structures*, *processes, and outcomes*.[65] Healthcare structures constitute physical resources (e.g., medical supplies), healthcare workforce, and the organizational relationships that enable the functioning of the system. Processes consist of actions relevant to the patient-provider interaction as well as to the patient's journey throughout the health system. Lastly, outcomes encompass patients' health trajectory, engagement, and user experience while frequenting the system.

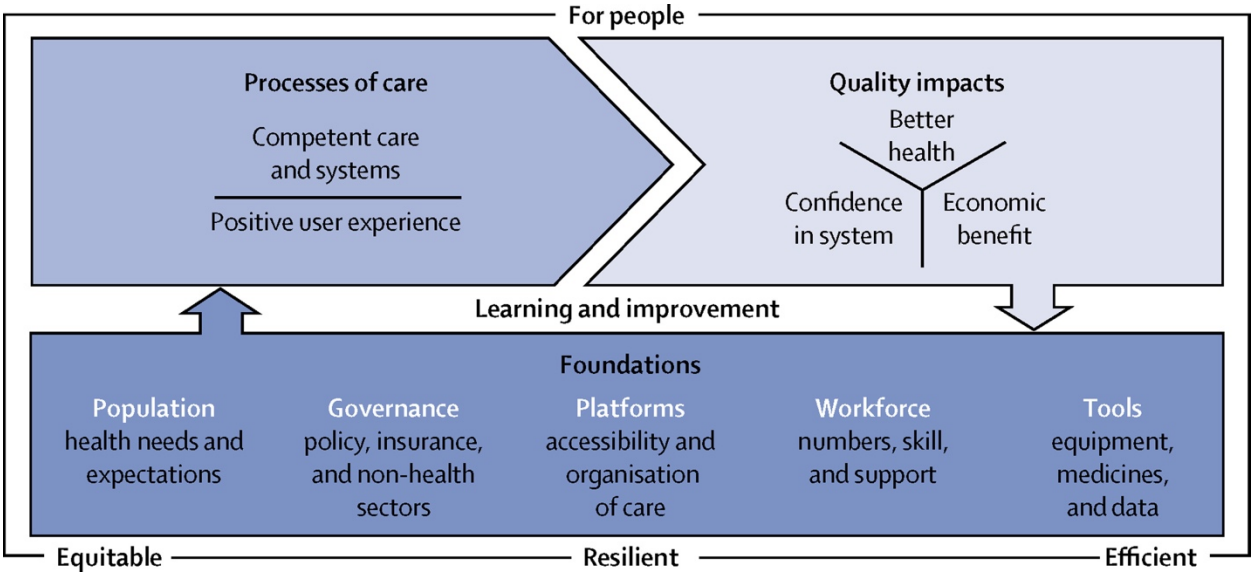

FIGURE 2.5.1. Framework for high-quality health systems, as devised by the 2018 Lancet commissioners of High-Quality Health Systems.[6]

The 2018 Lancet HQSS framework equally borrows from several other resources and frameworks.[6] It expands on Donabedian's definitions of health quality metrics and stresses that high-quality care should be *for people*, *equitable*, *resilient*, and *efficient* (**figure 2.5.1**). It is grouped by *foundations*, *processes of care, and quality impacts*; all of which are further subdivided. Foundations include government-supported health structures that are tailored to individual-level and population-level needs. Processes of care require the joint delivery of evidence-based and patient-centred care. Finally, quality impacts should ensure the following for patients: 1) Patient-reported positive health outcomes; 2) Confidence in providers and health systems; and 3) Financially accessible care that permits continued participation in society.[6]

The TB-adapted framework illustrated in the 2019 Lancet Tuberculosis Commission (**figure 2.5.2**), which mirrors the 2018 diagram (**figure 2.5.1**), is most pertinent in addressing the TB epidemic in high-burden countries such as India.

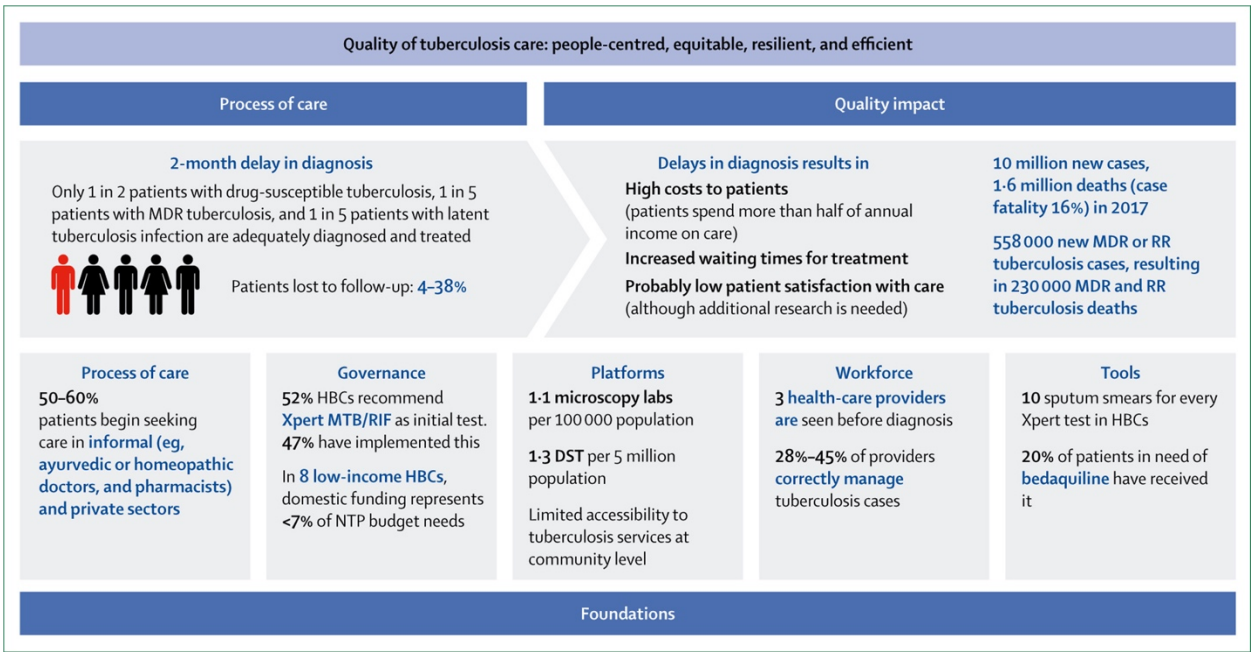

FIGURE 2.5.2. Tuberculosis-specific high-quality health system framework, published in the 2019 Lancet Commission on Tuberculosis.[66] Health gaps and disparities are identified, unique to this framework.

Figure 2.5.2. depicts some key facts that further emphasize the importance of seeking patient or client perspectives in determining quality care. First, the framework literally underscores the

need for additional research to assess patient satisfaction. Second, on a global scale, there continues to be a large number of new TB cases and deaths; yet, diagnostic delays are prevalent, and there are high rates of patients lost to follow-up (LTFU). Alongside delineating why health providers cannot ascertain diagnosis early in the patient pathway, it is equally important to determine why patients choose to leave care, which is sometimes made available free of charge. Third, the framework notes that 50% to 60% of patients seek care from informal or private-sector providers; therefore, drawing inferences from such providers is critical. Fourth, from the quality domain titled foundations, there is a general call for improvements in having an adequate workforce and equipment.

To conclude this section, a short discussion of the quality domains that will be discussed or used in greater detail in the chapters that follow is called for.

1. Focussing on foundations of care in the 2018 HQHS framework (or Donabedian-defined 'structures'), we have workforce, and tools to consider.
2. Focussing on 'process of care', we have two items for consideration from the 2018 HQHS framework:
    - Competent care. Medical competence or technical care fall under this umbrella term.
    - User experience. This term includes measures for subjective quality or client/patient experience.

2.6 Instruments used to assess clinical competence and global ratings

This section reports on processes of care, specifically on 'competent care' from the high-quality health system framework.

Table 2.6.1 below provides an overview of the methods that are typically used to judge competent care:

TABLE 2.6.1. Overview of common methods used to judge clinical competence in healthcare research

MEASURE OF QUALITY (COMPETENT CARE)	Measures Knowledge	Measures Practice	Accounts for Case-Mix	Accounts for Patient-Mix	Hawthorne Effects*	Illnesses Covered
VIGNETTES	Yes	No	Yes	Yes	By design: Vignettes measure the maximum a provider can do	All
CLINICAL OBSERVATION	No	Yes	No	No	Yes: Leonard and Masatu (2007) show big Hawthorne effects begin to decline with the time spent observing	Limited in two ways. 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	No	Yes	No	No	No	Similar to clinical observation, but providers rarely keep patient charts. Even when they exist, charts tend to be incomplete and don't accurately reflect patient-provider interactions.
STANDARDIZED PATIENTS	No	Yes	Yes	Yes	No	Limited to (A) adults only; (B) diseases that don't have any obvious physiological symptoms (which cannot be mimicked) and (C) conditions that don't require invasive exams—particularly in low-income countries.

Note: Information was either replicated or distilled from Kwan et al.'s (2019) Use of standardized patients for healthcare quality research in low – and middle-income countries.

*The Hawthorne effect describes a phenomenon whereby providers' clinical practice changes when they are being observed or monitored. Typically, providers behave more cautiously and adhere better to medical standards and codes of conduct.

The measure of clinical competence is generally done by benchmarking providers' actions in managing patients with technical standards or guidelines of care. To this end, Kwan et al. (2019) stipulate that in the context of healthcare quality research in LMICs, the use of standardized patients offers a robust modality to collect valid measures:

The authors support their claim by refuting the use of:

1. *Clinical vignettes.* Vignettes are limited by being focussed on clinical knowledge which may or may not be applied in a clinical setting. To report on care quality, measures of providers' clinical practice are thus more valid.

2. *Direct or clinical observation*. This method can report on clinical practice; however, it still poses problems for validity. First, the underlying cause of the medical complaint cannot be determined with certainty. Therefore, providers' medical recommendations or diagnoses cannot be definitively categorized as correct. Second, there is the likelihood of the Hawthorne effect. Third, as observations occur for select interactions, certain clinical cases, and patient groups will not be represented.
3. *Chart abstraction.* Generally, in LMICs, patient records are incomplete thereby limiting the scope of information that can be collected or used for inferences.

The measure of provider performance is not limited to competence, but there is an equal emphasis on interpersonal factors, or "soft skills". To this end, global ratings may be used. Global ratings are common in objective structured clinical examinations (OSCEs), a medical education assessment tool for medical trainees. **Table 2.6.2** provides a crude comparison between methods typically used to assess medical students.[67]

TABLE 2.6.2 Comparisons between typical structured examinations for medical trainees.

EXAMINATION ASSESSMENT TOOL	Explanation	Clinical knowledge	Practical knowledge	Patients' underlying condition	Main disadvantage(s)	Standardized patient
SHORT CASE	Trainees are required to briefly clinically examine patients and deliver findings.	Yes	Yes	Unknown	Clinical presentations of patients are not consistent across trainees, making it difficult to compare performances. Susceptible to the Hawthorne effect. *	No
VIVA VOCE	Trainees must orally respond to questions posed by examiners after studying pre-prepared clinical evidence.	Yes	No	Unknown	Only knowledge is assessed, physical performance is not.	No
LONG CASE	Trainees are assessed on their history-taking abilities and ability to examine a selected patient.	Yes	Yes	Unknown	Examination is limited to the patient selected and cannot be reproduced across candidates. Comparisons between candidates is difficult. Susceptible to the Hawthorne effect. *	No
OBJECTIVE STRUCTURED CLINICAL EXAMINATION	A station-based examination whereby both knowledge tasks and practical tasks can be assessed. Patient cases are standardized.	Yes	Yes	Predetermined	Resource intensive.	Yes

Note: Information was either replicated or distilled from Khan et al.'s (2013) The Objective Structured Clinical Examination (OSCE): AMEE Guide No. 81. Part I: An historical and theoretical perspective. *The Hawthorne effect describes a phenomenon whereby providers' clinical practice changes when they are being observed or monitored. Typically, providers behave more cautiously and adhere better to medical standards and codes of conduct.

Unique to the OSCE, a standardized station-based format is applied to assess examinees. Importantly, some stations may require medical professionals or trained patients (or in some cases volunteers) to repeatedly portray a specific ailment to prospective physicians, thereby allowing each examinee to receive an identical situation to manage clinically. Such individuals are also called standardized patients (SPs). Other stations may require the examinee to perform a routine procedure, and so forth. Therefore, by virtue of being station-based, this form of examination yields objective scores.[68] The OSCE is also a valid method. As the clinical cases enacted by SPs are pre-determined and tailored to a specific condition, they allow for fair evaluations.[69] The OSCE is marked in two parts: 1) A checklist and 2), A global rating scale (GRS). The latter item being most being most important for this thesis work.

Briefly, the checklist component includes binary questions that reflect whether the examinee performed a given action or task. In this way, the individual's clinical performance is evaluated.[70] On the other hand, the GRS is holistic and measures practice quality, or as Ilgen et al. (2015) put it, "capture[s] nuanced elements of [medical] expertise,"[71] i.e., *how well* the task was performed.[70,71] Other advantages of the GRS are higher inter-item reliability as suggested by a 45-study systematic review.[71] The GRS's construct validity has also been supported.[72] From the standpoint of SPs, the GRS is most useful to take record of subjective assessments of providers. Global ratings typically include conceptually-tied categories with an optional overall score that is comparable to the structure of the global assessment tool used in SP studies. **Table 2.6.3** provides some examples of previously established GRSs.

Since the OSCE's conception by Harden et al. in 1975,[68] there has been increased commitment among teaching institutions to refine, adapt, and employ this tool.[67] With studies reporting that there is agreement between physicians' scores and those of non-experts trained as standardized patients,[70] this further validates the feasibility of using SPs to fill GRSs in global health research. To avoid repetition, Chapter 2, section 2.8, as well as the methods section of the manuscript provide more insight on the application of SPs and adapted GRS, known as the global assessment scale, to measure healthcare quality.

TABLE 2.6.3 Composition of global ratings.

	Examinee	Categories and definitions	Authors (Year)
OTTAWA GLOBAL RATING SCALE	Canadian medical residents	Five categories of crisis resource management. Each category is marked using a seven-point ordinal scale. 1. **Leadership** 2. **Problem solving** 3. **Situational awareness** 4. **Resource utilization** 5. **Communication** 6. **Overall**	Kim et al. (2009)[73]
ANALYTIC GLOBAL RATING	Canadian medical students	Four component subscales: 1. **Empathy**: response to the patient's feelings and needs 2. **Coherence**: degree of coherence in the interview 3. **Verbal communication**: verbal expression 4. **Non-verbal communication**: non-verbal expression	Hodges et al. (2003)[72]
OBJECTIVE STRUCTURED CLINICAL EXAMINATION: GLOBAL RATING SCALE	Canadian pharmacy students	Five categories. Detailed rubric provides scores from 1-5 (highest). 1. Overall **knowledge** and **skills** 2. **Empathy**: response to patient's feelings and needs 3. Degree of **Coherence** 4. **Verbal-expression** 5. **Non-verbal expression**	Sibbald et al. (2001)[69]
STANDARD 5-POINT RATING SCALE	American medical students	Two categories and an overall score 1. **Communication** (two items): • Clarity and thoroughness • Ability to summarize findings and [manage] options 2. **Professional service** (two items): • Professional manner or thoroughness, carefulness, and competence in dealing with the patient's problems • Competence in dealing with patient's problems and [. . .] the demonstration of their courtesy, respect, and sensitivity toward the patient 3. [Standardized] patient's **overall satisfaction**, trust and anticipated compliance with the student's recommendations	Vu et al. (1990)[74]

2.7 Metrics used to assess patient, user, or client experience

"I will, in general shy away from thinking of those we serve as 'consumers', 'customers', or 'clients' of healthcare and instead refer to them as 'patients', 'partners' or 'participants' in care. Call me old-fashioned, but I think the latter "p-words" better capture than the former what healthcare is all about." – Dr. Philip C. Hébert, Author and Physician[75]

This section provides a broad synthesis of the variables typically used to measure user experience, the second determinant in the 'processes of care' category. This term comprises both satisfaction measures and experience-related measures. Patient centredness and client perceptions of the quality of medical care delivered by health care providers have gained prominence for several reasons, notably since Donabedian's seminal work on medical quality in the late 20th Century.[76-78] First, individual care-seekers use their perception of the quality of various providers to make informed decisions about where to seek care;[79,80] and second, the

experience of feeling respected for the individual is an important component of care in its own right.[76,81]

First, clarifications must be made regarding the different terms used to label healthcare seekers: patients, clients, users, consumers, inter alia. Although studies from the literature commonly use terms other than 'patient,' a scoping review has shown that service users prefer the term patient.[82] In practice however, these terms may diverge in meaning. For the purposes of this thesis, standardized patients (SPs) are referred to as 'clients' frequenting the health system. 'Client' can be used to describe a broader group of individuals who do not require urgent medical resources; it is more inclusive. For instance, a woman seeking services from a fertility clinic can be viewed as a 'client', whereas a woman requiring immediate medical attention during delivery could be viewed as a 'patient.'[83] The term 'client' is equally fitting for SPs involved in studies in India,[10] who, conforming to the Indian private sector's business scheme,[84] are ultimately purchasing health services. SPs have knowledge of the medical case they are presenting and are different from traditional healthcare users; however, their appraisals of provider care are valid and can still be used.

Second, another distinction must be made between patient 'experience' and patient 'satisfaction;' the former captures measures tied to patients' interactions with health services, while the latter provides insight on measures benchmarked against patients' expectations.[81,85] Evidently, both indicators report on patient-centredness and are related, but with this WHO-supported division, experience measures offer more insight on the quality of care. Specifically, patient experience includes *effective communication*, *respect and dignity, and emotional support*.[81] Again, some areas of the literature use 'satisfaction' and 'experience' synonymously which could be misleading. Hereafter, we use the term 'experience' on the same grounds as Larson et al. (2019); [81] however, in our synthesis, we report the original terms and metrics used by authors, despite the terminological variability that this may produce. We also select for themes that parallel variables from our study's dataset.

Naturally, to assess patient experience we must rely on patient-reported measures. Therefore, the following studies—in part or in full—report from the patient perspective. Santana et al. (2020) enumerate 26 indicators to assess patient-centred quality.[d] The authors first distilled the literature and subsequently cross-referenced their findings with how patients, caregivers,

[d] Most studies from the literature use terms from Avedis Donabedian's foundational framework.

providers, community members, and quality improvement experts valued and defined quality care. Of the 26 quality indicators, seven were structural, such as *providing an accommodating and supportive person-centred care environment;* 16 were process indicators, such as *timely access to a primary care provider*, *communication between patient and healthcare provider*, *information about taking medicine, and communicating test results*; two were outcome indicators, *affordability and overall experience;* and finally, one was a global indicator reporting on whether the patient would recommend this service to individuals within their social network.[86]

Evidence from a systematic review, which aggregated findings from 109 studies published between 1980 and 2014, suggests that *interpersonal care* largely determines patient satisfaction. Specifically, when providers used affective behaviours, respected patient privacy, and effectively communicated patients' course of disease and treatment plan, satisfaction was augmented. Other influential items that predicted high patient satisfaction included the following: 1) *Technical care*, specifically perceived competency, as well as duty of confidentiality; and 2) *Access,* particularly short wait times and long consultation times. Importantly, 91 studies were cross-sectional, e.g., reporting a one-time interaction, which matches the nature of our data.[87] Building on this work, a 26-study systematic review equally reported nearly identical predictors to explain patient satisfaction; however, this time, the majority of studies (n=19) captured perception of quality in a longitudinal manner.[88]

Specific to the United States, efforts to create standardized tools have led to the conception of the 8-item Client Satisfaction Questionnaire for mental health.[89,90] While it is concise, a body of research supports its content validity and reliability.[91] In particular, this tool uses a question which aligns with our global assessment scale: *"If you were to seek help again, would you come back to our program?"*

Content from the global assessment scale also overlaps with multiple tools used to collect patient-related experience measures (PREMs), as suggested by a 109-study systematic review. Measurement tools overwhelmingly originated from high-income countries and included the following overlapping themes: Communication, privacy, timeliness, wait times, for instance.[92] Another relevant tool applied in five high-income contexts, with satisfactory reliability and validity, is the 15-item Picker Patient Experience questionnaire which collected related themes

pertaining to information and education, coordination of care, emotional support, and overall impression.[93]

Across LMICs, the Service Provision Assessment (SPA)'s section titled 'the client exit interview' is highly pertinent and shares similarities with our global assessment scale.[94] Advantageously, the SPA is country-specific and is standardized. Despite the comprehensiveness of the SPA, Macarayan et al.'s (2018)10-country analysis across 7,049 health facilities, accounting for nearly 64, 000 patient visits, showed that data is largely lacking for indicators relevant to patient experience.[94] Across maternal health services in developing countries, as captured by 54 studies, patient satisfaction was predominantly determined by providers' interpersonal behaviors, respect of privacy, (perceived) competency, and supportive nature.[95] Obviously, many tools exist and this literature review by no means claims to offer an exhaustive list.

Generally, most studies conducted in India on patient satisfaction or experience are filled with high-satisfaction rates across many health conditions.[96-98] For the TB context, there is no reliable tool to collect patient experience or more generally, patient input. Collaborative efforts with patients in Uttar Pradesh, led to the development of a valid and reliable tool for out-patient care. The tool included several items that captured medical counselling, the doctor's receptiveness towards patients' questions, how easy it was to procure medicines, and so forth.[99] Quantitative TB studies, including two from Cazabon et al.'s search results, show a general discontentment with the public health sector's provision of DOTS.[100] As for private patients, opinions are less well understood. As noted by Subbaraman et al. (2020), the *"notable paucity of qualitative research evaluating [patient loss to follow-up],"* may help explain the recent gaps in knowledge.[45]

An important limitation of studies that have sought to evaluate patient satisfaction and/or experience is that they rely on questionnaires with positively-framed questions that introduce biases, e.g., acquiescence bias.

- Example of a positively-framed question:
    - The waiting time was appropriate. Agree/Disagree

Dunsch et al.(2018) caution against the use of such questionnaires and have supported their assertion through randomly assigning patients with either positively or negatively-framed questions. They observed up to a 19 percentage-point difference which has important

ramifications for quality care research.[101] In particular, this finding may help explain the baseline prevalence of high patient-reported satisfaction scores. The authors propose developing questionnaires with questions framed both ways to limit this bias.

2.8 Concordance between patient experience and desired health outcomes

Systematic reviews show a growing consensus that there is concordance between desired health outcomes and positive patient experience. In fact, varying study designs have shown that this holds true across different clinical settings, illnesses, and populations.[102,103] Although Cazabon et al. (2020) report TB patients valuing the appearance of technical competence, as an aspect of patient-provider rapports, this systematic review generally contained lower-quality studies.[60] To our knowledge, such work remains largely opaque in the field of TB research and must be undertaken to further elucidate patient pathways and, more generally, quality of care. There is currently one such effort from Boffa et al. (BMJ GH 2021), who are studying this relationship in SPs who presented TB cases to South African private providers.

As identified by Manary et al. (2013), critics challenge patients' input on quality by claiming that (1) patients are poorly equipped to judge medical competence, (2) that their health status confounds their testimonies, and (3) that they might be tempted to respond more favourably if their providers comply with their requests (e.g., if providers prescribe the desired medicine). The authors refute this by offering the following counterarguments: 1) Patient-reported measures reflect a dimension of care that is correlated with health outcomes and patient adherence to guidelines, which suggests that patients capture a measure of quality that would otherwise be missed; 2) If patients do truly evaluate their experience based on their health outcome, then we would not observe a correlation with treatment adherence; 3) finally, patient satisfaction may actually result from increased patient engagement but not necessarily from increased medical services ordered. In addition, the complexity and heterogeneity that characterize the definition and measurement of patient satisfaction and experience warrant the search for conclusive results, rather than the assumption that such measures are obsolete.[7] In our efforts to use SPs to measure the association between objective and subjective forms of quality, we must continue to counter the criticism outlined above in a context-informed, socio-culturally appropriate manner.

As proclaimed by the WHO, the standard treatment regimen for DS-TB, which accounts for most infectious cases, is six months long.[104] This implies that the TB patient's journey throughout health systems is resource intensive; thus, we reviewed studies in LMICs wherein patients require substantial use of health services. For pediatric care across seven Sub-Saharan African countries, communication was a quality component that significantly affected caregivers' likelihood to return to the health facility, thereby facilitating follow-up of pediatric patients.[105] In Pakistan, gestation-related distress felt among women receiving antenatal care was soothed when providers showed affective behaviours characterized by empathy.[106] More generally, studies from many disease areas (including TB) show that stigma experienced within the health system leads to poorer health outcomes.[107]

For India, TB studies reporting alignment between favourable health outcomes and user experience measures is scarce. We found one recent study in West Bengal that suggests that high client satisfaction was commonly seen among those who completed treatment.[108]

2.9 The standardized patient methodology for quality of tuberculosis care research

In the field of quality care research, there is growing acknowledgment that patients should be ensured quality care as well as a positive experience. Measuring these two metrics is difficult. Traditionally, researchers used data collected from real patients to measure clinical management and user experience; however, this approach compromises the validity of the conclusions drawn. Patients seek care because they do not know what ails them and are not in a position to accurately judge whether their provider delivered appropriate care. The record of their clinical experience, therefore, is compromised.

With regards to analyzing subjective measures, there are also pitfalls. Patients choose their health providers for many reasons: habit, personal referral, availability, proximity, affordability, etc.[109,110] These choices introduce biases in the assessment of patient experience; for example, an individual might respond more positively to an exit questionnaire if they deliberately *chose* their own provider. Furthermore, using overly standardized survey tools, that are primarily derived in high-income settings, may render quantitative data so foreign to local contexts that findings cannot be remedially contextualized by qualitative work. Clearly, the scientific community must use a different methodology to appropriately measure both metrics. This methodology relies on the use of standardized patients.[111]

As alluded to, the standardized patient methodology was first applied to evaluate medical trainees[67] but gradually earned a new purpose in research: to serve as the gold standard methodology for measurement of correctness in care.[111] SPs are called 'simulated' or 'mystery' patients –among other terms. All actors are visibly healthy individuals who are trained to portray a given illness and to avoid receiving any harmful medical interventions, e.g., invasive injections. This is a similar concept to a 'mystery' shopper rating a given store, or to an incognito food critic reviewing a restaurant.

The benefits of the SP methodology span the design, implementation, and data collection phases. Researchers employing this technique can create credible scripts, carefully tailored to the social context, to train local recruits. As such, objective quality measures, e.g., correct clinical management, can be deduced by benchmarking against country-specific guidelines as disease presentation is predetermined. In this way, valid metrics are obtained. Given that SPs are trained to be 'standardized' by repeatedly enacting the same medical scenario, their ability to present a consistent clinical case is reliable.[111] Lastly, as SPs may be assigned to a representative random sample of providers, the findings drawn from the data can be generalizable. Importantly, research ethics boards can grant researchers permission not to seek consent from providers on grounds to safeguard the validity of the study. Consent was waived for Indian SP studies; however, this was not sought in South Africa. Following this argument, since research efforts remain hidden, providers behave as they routinely would and a phenomenon known as the Hawthorne effect, a bias whereby providers' behavioural changes in response to being observed or studied, are prevented. **Table 2.9.1** provides a detailed comparison between real patients and SPs. Evidently, a limitation of this method is that SPs must present conditions that can be reasonably simulated and where physical signs (e.g., skin lesions) are not required.[111] The SP method is not feasible for assessing quality of care for children. The methodology is not validated across multiple visits using the same SP as inevitably, unique trajectories in care would break standardization.

Previous studies employing this technique have been applied in many LMIC contexts, including in India,[10,112] China,[113] Kenya,[61] Uganda,[114] among others,[111] for a variety of qualified providers, including pharmacists.[115] To date, no SP studies have published the agreement between global assessment scale measures and hard clinical outcomes (i.e., medical correctness) or objective experience.

TABLE 2.9.1 Advantages gained from using standardized patients rather than real patients in healthcare quality research (selected).

	Patient Type		
	Real Patient (RP)	**Standardized Patient (SP)**	**Explanations**
PATIENT - MEASURABLE CONFOUNDERS	Likely	No	**RP** – Although analyses could be adjusted for patient-related confounders, there is still the possibility that residual confounding remains. In addition, limited sample sizes between strata of a given confounder may prevent full-depth analyses. As such, heterogeneity between patients, or patient sorting, is a common limitation.[116] **SP** – As SPs' identities are predetermined, patient-related confounders are fully known by the research team.
PROVIDER – SELECTION BIAS	Extremely likely	No	**RP** – Discounting financial considerations, the process of provider selection is entirely subjective. As such, studies using real patients struggle to encapsulate a representative sample of providers to draw conclusions from. In addition, other studies may require the consent from the providers, in which case, systematic differences between providers may compromise the generalizability of inferences. **SP** – Ethics boards can exempt research groups from requiring to seek provider consent. As former SP studies have compiled a "universe" list of providers, a representative random sample of providers is possible.[10]
PATIENT – SELECTION BIAS	Extremely likely	No	**RP** – For real patients, the opportunity to provide feedback is entirely optional i.e., is on their own accord and time. As there are systematic differences between those who opt to partake in research versus not, selection bias is easily introduced. Furthermore, the time at which patients' opinions are solicited, affects the quality and validity of data collected.[7] **SP** – SPs are employed by the research team and have the same objectives. To date, the SP methodology has been designed for a one-time interaction; thus, comparisons between first-contact providers can be made.
RECALL BIAS	Yes	No/Negligible	**RP** – Real patients are not trained to accurately remember their interactions and may forget important details. **SP** – As validated by Das et al.'s (2015) Delhi pilot study, SPs' ability to recall interactions were close to recordings.[112] In addition, for interactions in which a chaperone accompanied the SP, there was agreement between the SP's recount and the chaperone's.[111]
INTERVIEWER BIAS	Like	No	**RP** - For studies where patients are interviewed, there is a possibility that interviewers will sway patients' responses. **SP** – With the exception of some qualitative SP work done in South Africa by Boffa et al. (Unpublished), most SPs are familiar with the structured exit questionnaire and were trained on how to thoroughly complete it, thereby eliminating interviewer bias.
SERVICE FEES	Will deter results	Will not deter results	**RP** – The literature reports on how out-of-pocket fees lead to dissatisfaction and an unpleasant user experience.[117] **SP** – On the SPs' end, service fees would be provided by the research team i.e., costs cannot deter an SP's ability to perceive quality care as studies with real patients have demonstrated.
PROVIDER - RANDOMIZATION	Likely	No	See "Provider – Selection Bias" above.
USER EXPERIENCE	Yes	No	**RP** – User experience can be measured. However, response biases such as social desirability bias, whereby patients' responses fit to what is socially accepted or by what others will want to hear compromise the validity of their answers. **SP** – In this work, client experience is distinct and unique to SP methodology. It is clinically useful, but it should not be considered as a proxy measure for user or patient experience. (Chapter 2; section 2.7)
	RP: real patient; SP, standardized patient NB: Ideas were drawn and expanded from Kwan et al.'s (2019) "Use of standardized patients for healthcare quality research in low- and middle-income countries. *BMJ Global Health*.		

Chapter 3: Description of data source

To improve TB programs in Patna and Mumbai, the Indian private health sector participated in pilot programs from 2014-2017. Under this initiative, a team from the McGill TB Centre and the World Bank (principal investigators: Madhukar Pai and Jishnu Das) were funded by the Bill and Melinda Gates Foundation to evaluate the quality of TB care provided by private providers in these cities, before, during and after the implementation of pilot programs. This team evaluated the impact of programs that aimed to aggregate private providers, and train them to manage TB better, and provide free diagnostics and drugs. The baseline data from this project, published in PLOS Medicine,[10] formed the dataset for this thesis research. Correct management was extensively studied in previous work[10,44] and for this thesis, will be contrasted with client experience.

To situate readers, a concise description of the context in which the primary study was coordinated is befitting. This chapter describes the following: 1) City demographics and severity of the TB epidemic in India from 2014-2015; 2) The role of the Private Provider Interface Agency; 3) SPs recruitment, narrative development, and training; 4) The variations in provider qualification; and finally, 5) A brief discussion on ethics.

3.1 City demographics and tuberculosis burden at the time of study

SPs first visited providers in the city of Patna, Bihar, which is a relatively an underdeveloped city, with an approximate net district domestic product of $2,000 USD (2009-10 value).[118] As per 2011 census data, Patna has a population of 2 million and an average literacy rate of 83%. SPs then went onto visit practitioners based in Mumbai, Maharashtra, one of India's more developed cities, which accounted for 2% of India's national GDP (2003-04).[119] In 2011, Mumbai had a population of 12 million and a literacy rate of 90%.[120]

Table 3.1.1 provides the TB incidences and state-level populations in the settings where SPs visited providers. In Bihar, 628 persons were newly infected on average with TB per 100,000 persons between 2014 and 2015. In Maharashtra, the value was 233 persons per 100,000 within the same timeframe. Despite the prevailing TB epidemic within India's borders, the severity of underreported TB cases is of particular concern, especially in the private health sector.[84] Moreover, because TB is a transmissible disease, primarily facilitated through adult carriers, its detection by the health system needs to be timely.

TABLE 3.1.1	Select state tuberculosis (TB) burden and population between the years 2014 and 2015.		
CITY	State	State population (2011)[i]	State TB incidence per 100,000 persons (2014 - 2015)[ii]
PATNA	Bihar	104 million	628 [95% CI 593 - 663]
MUMBAI	Maharashtra	112 million	233 [95% CI 206 - 259]
NATIONWIDE	-	1.20 billion	304 [95% CI 298 - 310]

[i] *The last government-led census occurred in 2011, three years before the commencement of QuTUB's study. Another census is scheduled for 2021; however, reporting values from 2011 is applicable in our case.*
[ii] *Self-reported TB incidence rates from the National Family Health Survey – Round 4 (NFHS-4) computed by Mazumdar et al. (2019) were used.*[121]

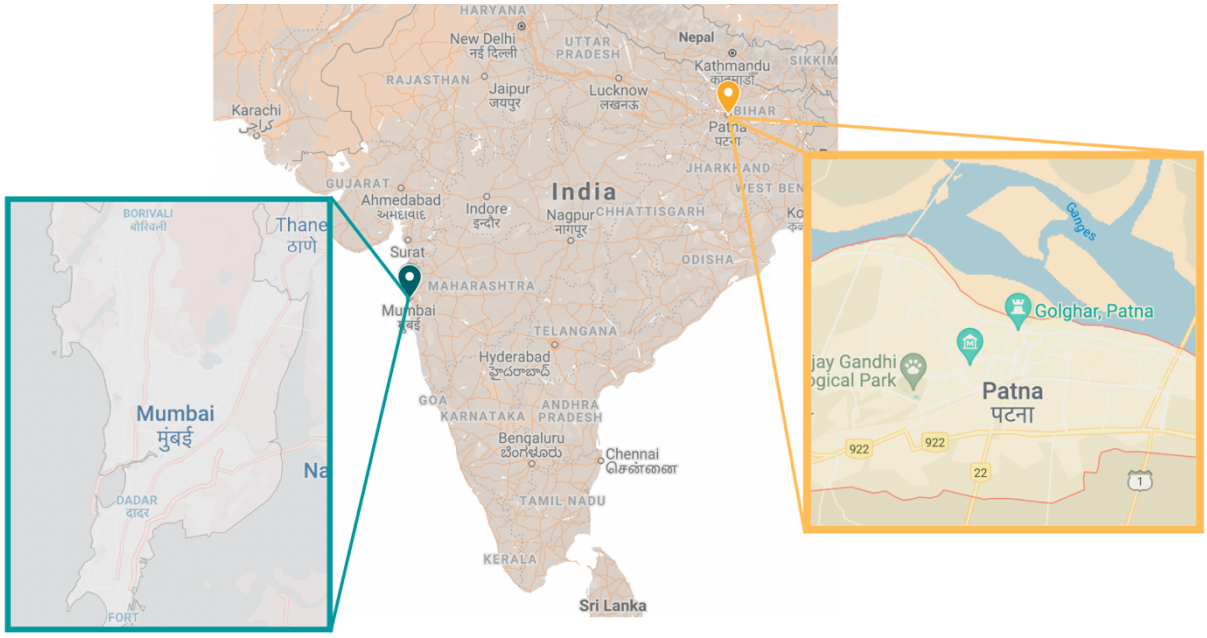

Figure 3.1.1. City-specific geographical location of where standardized patient-provider interactions took place in India. *Image generated using Google Maps.*

3.2 Role of the Private Provider Interface Agency

The original study occurred in the context of national efforts to expand the engagement of the private healthcare sector toward eliminating TB. Recognizing the importance of the private health-care sector[42] and informed by optimistic findings from previous public-private mix (PPM) studies,[122] the Indian government set forth to further bridge the divide between public and private health-care sectors through its National Strategic Plan (NSP) for TB Control (2015-2017);[123] a message that would later be echoed in its NSP designed for TB Elimination (2017-2025).[4] Municipal and external parties (e.g., the Bill & Melinda Gates Foundation who partly funded the

primary study) saw the value of such efforts, which led to the creation of the Private Provider Interface Agency (PPIA). Thus far, the PPIA has been piloted in three cities: Patna, Mehsana, and Mumbai. The primary healthcare (PHC)-led fabric of the PPIA uses patient vouchers or subsidies to engage private providers, incentivizing both diagnosis and treatment, and safeguarding patients from incurring damaging costs.[124]

The synergy of national and local initiatives facilitated the collaborative efforts of Quality of Tuberculosis (QuTUB) Team and their local partner, the Institute for Socio-Economic Research on Development and Democracy to quantify the quality of medical care delivered by urban-private health providers. This objective was first validated in New Delhi,[112] and then studied on a larger scale in two PPIA cities: Patna and Mumbai.[10] Since the PPIA's conception, recent studies continue to support its ongoing value.[125,126]

3.3 Standardized patient recruitment, narratives, and training

The following text paraphrases Kwan et al. (2018):[10]

Over the November 2014-August 2015 study period, 24 trained adult SPs were recruited to enact four "clinical scenarios" capturing distinct TB presentations (presented in detail in Chapter 4). SPs are local recruits who were screened *a priori* for underlying health conditions that could potentially mislead providers. In Patna, 13 SPs were hired to visit providers, whereas in Mumbai, 17 SPs were hired. Some SPs were hired for the entire duration of the study period and some even had prior experience from the New Delhi validation study.[112]

The development of SP narratives was contingent on drafting credible patient personas and presenting medically-sound cases. Scripts were carefully developed by QuTUB's multi-disciplinary Technical Advisory Group (TAG) consisting of experts from various fields, including anthropology, medicine, epidemiology, economics, etc., some of whom were knowledgeable in national and international TB guidelines. Importantly, SPs also shared their local expertise in contextualizing the SP narratives.

The authors designed the training phase to achieve four objectives: 1) Standardized presentation of TB cases; 2) Accurate recollection of the interaction; 3) Successful presentation of cases such that providers cannot detect SPs as being actors; and 4) SPs remaining safe from harms.

3.4 Medical providers in India

Our dataset comprises clinical data from the Indian urban-private health sector. This primary study broadly investigated the practice of Bachelor of Medicine, Bachelor of Surgery (MBBS) and non-MBBS providers.[e] For the Indian context, the MBBS degree is a 5.5-year curriculum, after which graduates may practice as allopathic providers. A second, salient group of practitioners are known as AYUSH providers, who practice alternative forms of medicine such as Ayurveda, Yoga, Unani, Siddha, or Homeopathy. Finally, informal providers possessing minimal to no qualifications also offer medical services. Despite the 1946 Bhore Committee Report discouraging non-qualified providers from practising,[127] India adopted a framework similar to other LMICs where multiple practitioners with varying qualifications regularly diagnose and treat populations.[128]

Within each city, SPs first visited non-MBBS-qualified providers, before visiting their more qualified counterparts. **Figure 3.4.1** shows the trajectory that SPs took from city to city and from provider to provider. Because visits were sorted by city and provider qualification, SPs were only asked to appraise like providers in each phase of the study, thereby limiting the likelihood of overinflating or undervaluing provider practice based on previous visits.

In general, after visits with providers, SPs were asked to recount information on the following: 1) provider characteristics such as estimate of age, presenting sex, etc.; 2) providers' technical competence, namely the nature of examinations conducted, types of medical recommendations or diagnoses etc.; 3) history questions posed by providers; 4) their subjective impressions of the providers' soft skills, and so forth. The final appendix in Das et al.'s pilot study in New Delhi indexes case-specific SP narratives and presents the exit questionnaires completed by SPs and the research staff from the Institute of Socio-Economic Research on Development and Democracy (ISERDD).[112]

[e] The rationale behind grouping Ayurveda, Yoga, Unani, Siddha, or Homeopathy (AYUSH) providers and informal health-care providers together is that both have similar medical practice for TB, as shown by Das and colleagues (2015). The only glaring exception is the general reluctance among AYUSH providers to refer their TB patients to receive appropriate care, which makes them less favourable options.

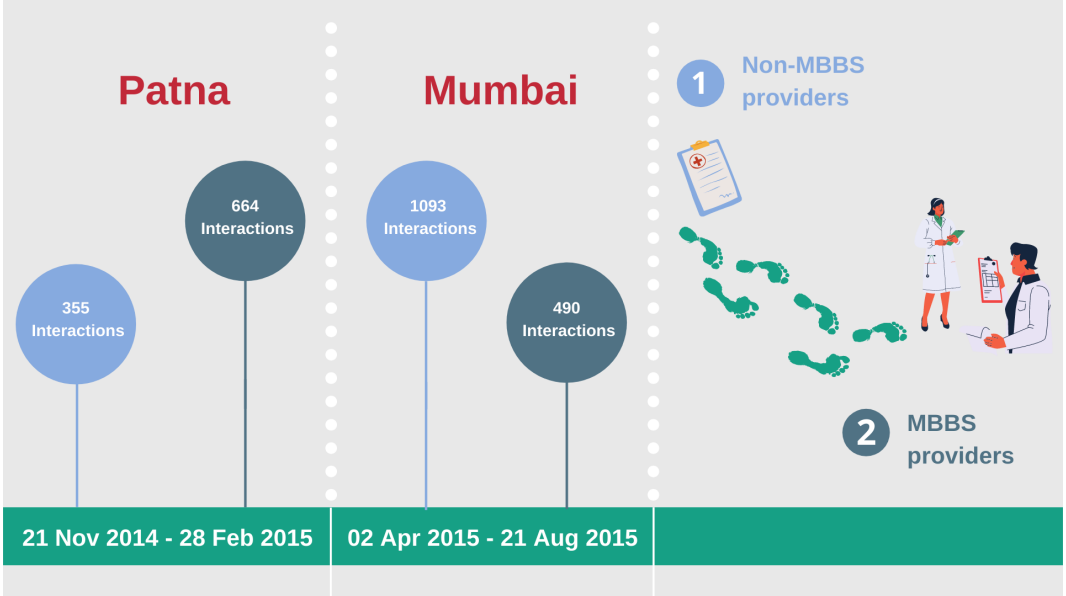

Figure 3.4.1. City-specific timelines and number of interactions stratified by provider qualification. MBBS: Bachelor of Medicine, Bachelor of Surgery.

3.5 Ethics

The following text is taken verbatim from Kwan et al. (2018):[10]

Ethical approvals for this study were granted by the McGill University Health Centre in Montreal, Canada (REB No. 14-137-BMB) and the Subcommittee for the Ethical Approval of Projects at the Institute for Socioeconomic Research on Development and Democracy in Delhi, India. […] For this study, a waiver of provider informed consent was sought with particular attention to the research ethics provisions under the Government of Canada Panel on Research Ethics, as well as a recent study by Rhodes and colleagues (2012) on ethical aspects of simulated patient studies commissioned by the US Department of Health and Human Services.[129] Supported by findings from the validation of the SP method for TB in urban India as reported in Das and colleagues (2015),[112] both ethics committees approved a waiver of provider informed consent in Mumbai and Patna because (1) the combination of informed consent and congregation of providers during association meetings and in the implementation of TB interventions that occurred during the study period posed threats to the scientific validity of the study objectives as well as to the risk of SP detection and (2) there is no more than minimal risk of participation to the SPs or providers.[112]

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Chapter 4 – Manuscript

Associations between client experience and technical care quality: A standardized patient study for tuberculosis in urban India

4.1 Introduction

Quality has been acknowledged as a key component in achieving high-quality health systems (HQHS) and by extension, in achieving universal health coverage.[1] The study of quality inherently requires a multidimensional approach and cannot be simplified to measuring only adherence to objective technical guidelines or standards of care. Rather, patient-centredness and patient input, such as measures for client experience and satisfaction, provide unique insight and report on whether health users have confidence in health systems and would continue to seek care.[2] This is of particular interest in the area of tuberculosis (TB) research, where quality is known to be highly variable or suboptimal.[3]

TB is currently the second leading infectious disease killer. In 2020, there were 1.4 million TB deaths and close to 10 million newly-infected persons.[4] TB patients are also persistently lost to follow-up throughout the continuum of care.[4-7] Furthermore, progress toward reaching global targets, such as the need for patient-centred care set by the World Health Organization's (WHO) END TB Strategy,[8] has been slow, especially given disruptions that have occurred due to the ongoing COVID-19 pandemic.[4,9] Due to the pandemic, for the first time in many years, annual TB deaths have increased.[4]

A recent 20-article compendium on quality of TB care highlighted the missed opportunities in TB health-service delivery, which include the continual delivery of subpar care by private health sectors that manage large volumes of TB patients;[10] the absence of patient-led definitions and input in health systems;[11] and the lack of standardized approaches to measure patient satisfaction and experience.[12] Patient engagement and trust both merit inclusion as considerations within the healthcare sphere and patient-centered care is needed to end TB.

To date, India manages the highest TB burden worldwide,[4] with a fragmented and highly unregulated private health sector;[13,14] making India an ideal starting point to study care quality, which includes both technical care and patient perceptions.

However, direct measurement of patient experience and satisfaction by interviewing actual patients poses problems for inferences. Two observable patterns have called into question the value of patient satisfaction to report on quality: 1) patients generally report high rates of satisfaction; 2) providers' demeanor (which includes communication style) greatly contribute to the limited variation observed in satisfaction. Multiple systematic reviews and studies corroborate such patterns.[12,15-17]

Even with efforts to improve patient questionnaires, such as by reframing[18] or specifying questions[19] to limit biases such as the social desirability bias, studies are still subject to profound limitations, a few of which we list: First, patients have already selected the provider who they believe is most appropriate for the care they need; therefore, we cannot compare across providers using patients who have chosen to visit them. Second, because it is not generally possible to determine the underlying diagnosis for most care-seekers, researchers cannot judge the medical appropriateness of the care they received. Third, patients who choose their provider are also more likely to give a positive review. Fourth, patients are unaware of what actually ails them, and, as a result, they may attribute more value to their user experience than to whether they received medically-competent care.

This paper attempts to address these problems by using unique data from a large-scale standardized patient (SP) study for TB in the Indian private health sector. In this study, the same individuals attended various providers, presenting the same complaints, allowing us to compare across providers. Because these case scenarios and underlying conditions were fixed and standardized in advance by the research team, we are able to judge the technical quality of care, various elements of subjective quality, and also ask SPs about their subjective impressions. This approach allows us to disentangle provider choice from objective and subjective measures of quality and to report on concordances between them.

As numerous sources caution against the interchangeable use of patient satisfaction and patient experience,[19-21] we take this opportunity to clarify that patient experience captures whether or not events in healthcare have occurred. A related yet distinct concept is patient satisfaction, which measures health users' response to care based on their initial expectations. Between the two measures, patient experience is better framed to address gaps in quality.[19]

Accordingly, we conducted secondary data analyses on SP data from urban Indian[22] to assess associations between objective and subjective forms of quality. From that study, we used

multidimensional measures of (a) appropriateness of care (defined as adherence to standards of care); (b) subjective quality or client experience (defined as adherence to patient-centred standards); and (c) SPs' subjective assessment or ratings of providers. Although SPs are aware of the ailment they are presenting and therefore have more knowledge than real patients, their perceptions as clients remain valid and provide an opportunity to understand the relationship between technical competence and subjective quality or SPs' client experience.

4.2 Methods

Study design, data measures, and definitions

We obtained representative data from a study conducted in the urban areas of Patna and Mumbai, India from 21 November 2014 to 21 August 2015.[22] In that study, 24 SPs (8 women; 16 men) received training on how to portray cases, recall clinical interactions, and protect themselves from potential harms e.g., injections. Data were collected from the SPs using exit questionnaires completed by SPs and staff. Additional study details are presented in the primary publication,[22] the appendix, and in past secondary analyses.[23] Data collection tools are also available,[24] along with a detailed manual and toolkit on how to conduct SP studies.[25]

Four TB cases were used in the study. Case 1 was presumptive TB; Case 2 was presumptive TB, after use of broad-spectrum antibiotics failed to alleviate symptoms; Case 3 was active TB with positive sputum smear test results the SP claimed to have obtained from a government health facility; Case 4 was presumptive TB, and, when asked, the SP explains previously starting and discontinuing a TB treatment regimen (thus, suggestive of recurrent TB, likely multi-drug resistant TB). Complete case definitions and expected management are presented in **Table 1**.

We conducted secondary analyses on 2,602 SP-provider interactions across these four distinct TB case scenarios. The exit questionnaire was partly based on the objective structured clinical examination (OSCE), which is commonly used to assess prospective physicians in North America.[26] The primary study's data collection tool was subdivided into two components: a checklist reporting clinical actions performed by providers, and a global assessment scale used to capture interpersonal skills and overall performance.

To measure objective technical quality, we used the definition of correct management agreed upon *a priori* by a Technical Advisory Group (TAG) ahead of SP deployment at the time

of the study. The TAG consisted of experts in the TB field in India and internationally. We also considered the percent completion of the essential history checklist and whether providers suspected the likelihood of TB as an indication for medical correctness.

Three variables representing SPs' subjective assessment of providers were taken directly from the global assessment scale (**Figure 1**). These included: 1) Whether SPs liked the provider; 2) their inclination to return to seek additional medical care with the same provider; and 3) a crude 1-10 ranking that captures an overall impression of the provider. The first two questions were binary and the final measure (i.e., the ranking) was continuous.

To measure subjective quality or client experience, we used whether the provider had taken specific actions related to patient-centered standards of care. These included: 1) Whether the provider ensured a private environment for the consultation; 2) the degree to which SPs' concerns were addressed seriously; 3) whether the provider seemed knowledgeable 4) whether the provider explained the illness to the patient; 5) whether the provider explained the treatment to the patient; and 6) whether the provider limited the presence of any environmental disruptions or distractions (e.g., including a TV being on, provider using their cellphone, or others being present in the consultation room). The first five actions were from the global assessment scale and used a Likert-type scale, while the sixth measure was binary (appendix). Daniels et al. (2019) have also demonstrated that although the primary study's design did not intend to randomly allocate SP gender, women and men SPs were distributed as good as random to providers.[23] We can thus interpret provider assessment scores to stem in equal parts from each gender group (measured as binary).

Other elements of quality affecting SPs' clinical visits were the following: 1) Whether the provider was observed to make a record of the interaction; 2) the presence of a clinical assistant; 3) the duration of consultations in minutes; and 4), the number of other people waiting in line at the clinic.

Provider sampling

Informed by a street-by-street mapping census, the QuTUB study team derived a representative sample of private providers, details of which have been previously reported.[22] SPs were randomly sent to general healthcare practitioners involved in adult care from pre-selected health facilities located in low-to middle-income settings. Some providers received visits from

multiple SPs portraying different TB cases. For the Indian context, providers holding a Bachelor of Medicine, Bachelor of Surgery (MBBS) degree are higher-qualified than informal or AYUSH providers practicing alternative forms of medicine (Ayurveda, Yoga, Unani, Siddha or Homeopathy). The breakdown of TB case presentations across these two broad categories of providers are presented in **Table 2**.

Statistical analysis

We first tabulated descriptive statistics with bootstrapped 95% confidence intervals for the distribution of quality measures across all SP-provider interactions for objective quality, SPs' subjective assessment and subjective quality, and other elements of care quality. To explore the association between objective and subjective forms of quality, we compiled descriptive statistics stratified by appropriateness of clinical management, again with bootstrapped 95% confidence intervals. To evaluate the association between correct clinical management and quality, we report odds of correct clinical management by exponentiating the results obtained from generalized estimating equations with a logit link and standard errors clustered at the provider level. We accounted for provider-level clustering, as observations for correct management are unlikely to be independent. The following quality categories were investigated: objective quality, subjective quality (or client experience), subjective assessments of providers, and other elements of quality. For each predictor presented in the left most column of **Table 6**, we consistently controlled for TB case presented and the city where the interaction took place. All predictors were binary except for the following three measures which were continuous: Proportion completion of essential questions, duration of medical consult (minutes), and number of other patients present.

Quality is inherently multidimensional; therefore, we chose to inform our analyses by two composite indices for subjective measures: (1) SPs' subjective assessment of providers and (2) subjective quality (or client experience). We created index measures using principal components analysis (PCA) on a correlation matrix taking the first principal component of variance for all of the items in each section.[27] Both indices are continuous and we graphically represented the relationship between both indices stratified by medical correctness. Missing data were limited, and therefore, filling data gaps (e.g., with multiple imputation) was not necessary.

We then performed a set of mixed-effects linear regressions with a random intercept for SP identity in addition to accounting for provider-level clustering using robust standard errors.

These regressions were used to assess the association across all quality measures and demographics using the subjective assessment index as the dependent variable. SP-level clustering was additionally accounted for under the assumption that observations within each SP are likely to be correlated. We first regressed each interactional measure in **Table 9** on the subjective assessment index, controlling for TB case and city, and denoted these as simple analyses. We then estimated expected changes in the subjective assessment index using all measures together. This full multiple linear regression comprised the following binary or dummy predictors: Clinical management (correct vs. not correct); provider suspected the onset of TB (yes vs. no); provider created a private environment (definitely vs somewhat/not at all); provider appeared knowledgeable about SPs' illnesses (definitely vs somewhat/not at all); provider addressed SPs' concerns seriously (very vs somewhat/not at all); delivery of explanation pertaining to illness (very well vs somewhat/not at all); delivery of explanation pertaining to treatment (very well vs somewhat/not at all); provider physically recorded information (yes vs no); presence of environmental disruptions defined as either the TV being on, the provider using their cellphone, or other individuals being present in the consultation room (yes vs no); presence of a clinical assistant (yes vs no); provider qualification (MBBS vs non-MBBS); provider's presenting sex (male vs female); and SP's self-reported gender (man SP vs woman). The following continuous measures were included in the model: Share of essential history questions asked by the provider (0% - 100%); duration of consultation in minutes; and, the number of other patients waiting. Lastly, the multiple regression model had a categorical measure: Provider's estimated age (less than 30 years, between 30-50 years, older than 50 years)

The supplementary appendix reports how each predictor (binary/dummy, categorical or continuous) was represented and determined from the primary study. It also presents additional support for model selection and fit, including residual analysis. All statistical analyses were computed using R, version 4.1.1.

Ethics

Ethical clearance for the primary study was provided by the Institute for Socio-Economic Research on Development and Democracy and McGill University (REB No. 14-137-BMB). A waiver of provider informed consent was granted by both committees. This study used only de-identified and publicly-available data and therefore, did not require additional IRB approval.

4.3 Results

We performed secondary analyses on 2,602 SP-provider interactions in urban India from a previously published large-scale study. We first present patterns for objective and subjective dimensions of quality, followed by associations between the different dimensions of quality with medical correctness. We then describe variations in providers' clinical practice and their contribution to SPs' subjective assessment of providers, followed by how subjective quality measures serve as signals of technical quality. Lastly, we assessed which aspects of care are valued and undervalued by SPs irrespective of correct medical care.

Technical quality

Table 3 reports measures on technical quality. Providers correctly managed TB cases, according to research definitions, in 959/2602 interactions (37%, [95% CI 35% - 39%]) across all cases. For Case 1, providers correctly managed SPs in 543/1377 interactions (39%, [95% CI 37% - 42%]). For Case 2, 254/385 interactions (66%, [95% CI 61% - 71%]) resulted in correct management. For Case 3, 106/354 interactions (30%, [95% CI 25% - 35%]) were correctly managed. Lastly, 56/486 Case 4 interactions (12%, [95% CI 9% - 15%) were deemed medically correct. Providers on average asked 50% [95% CI 21% - 78%] of the predetermined history questions and mentioned a suspicion of TB in 987/2602 interactions (38%, [95% CI 36% - 40%]) to the SP.

Patterns of subjective measures

Table 4 reports subjective measures and ratings by the SPs. For SPs' subjective assessment of providers, in 2146/2602 interactions (82%, [95% CI 81% - 84%]), the SP said that they personally liked the doctor, and in 2053/2602 interactions (79%, [95% CI 78% - 81%]) the SP said they would personally go to the doctor again. On a scale of 1 to 10 (highest), standardized patients on average rated their subjective experience with the provider as 6.27 [95% CI 6.18 - 6.36]. In terms of subjective quality (or client experience), in 1887/2602 interactions (73%, [95% CI 71% - 74%]), the SP agreed that the provider created a private environment; in 1224/2602 interactions (47%, [95% CI 45% - 49%]) that the provider appeared very knowledgeable about the illness; and in 1223/2602 interactions (47%, [95%CI 45% - 49%]) that

the providers addressed their worries seriously. In 209/2602 interactions (8%, [95% CI 7% - 9%), the SP reported that the provider explained the illness clearly; in 601/2602 interactions (23%, [95% CI 22% - 25%]) that the provider explained the treatment plan clearly; and that one or more environmental disruptors were present in 663/2602 interactions (26%, [95% CI 24% - 27%]).

Other elements of quality

Table 5 shows other elements of quality. As noticed by the SP, providers recorded information in 276/2602 interactions (11%, [95% CI 9% - 12%]) and had a clinical assistant present in 63% [95% CI 61% - 65%] of interactions. During those interactions, the SP was seen by the provider for 6.29 [95% CI 6.11 - 6.47] minutes and on average, there were 2.10 [95% CI 1.95 - 2.25] other patients waiting at the clinic.

Associations between subjective measures and technical quality

Table 6 shows the estimated associations between elements of quality and technical quality as defined by correct management. For objective quality, history-taking of essential questions was associated with correct care: moving from asking none of the checklist questions to asking them all predicted an increase in correct management (aOR = 5.03 [95% CI 3.54 – 7.14]). Lastly, providers who mentioned a suspicion of TB to the patient were more likely to manage the case correctly (aOR=4.58, 95%CI 3.72 - 5.64).

Measures reflecting subjective assessment of providers were positively associated with the correct management of SPs. For interactions where SPs reported liking the provider, the provider was more likely to correctly manage the patient (aOR 3.84 [95%CI 2.88 – 5.14]); results were similar when SPs reported being willing to return to that provider (aOR 3.46 [95%CI 2.67 – 4.48]). Likewise, SPs' overall appraisals of providers, as determined by the 1-10 ranking, strongly predicted the technical quality of care. Each 1-unit increase in the SP's numerical ranking was associated with more correct care (aOR of 1.50 [95%CI 1.42 – 1.57]).

With regard to subjective quality or SPs' client experience, a higher proportion of interactions were determined to be correct when SPs responded that providers 'definitely' created a private environment (aOR 2.12 [95% CI 1.73 – 2.59]); that they seemed 'very knowledgeable' about their patients' medical cases (aOR 4.87 [95%CI 4.01 – 5.91]); or when

they appeared to address worries 'very seriously' (aOR 3.17 [95%CI 2.65 – 3.80]). Providers who provided clear explanations of the illnesses and of treatment plans showed higher rates of correct management (aOR=2.40 [95%CI 1.80 - 3.20] and aOR=2.07 [95%CI 1.70 – 2.48], respectively). Lastly, the presence of environmental disruptions was negatively associated with correct care (aOR = 0.81 [95% CI 0.67 – 0.99]).

Other elements of quality were also positively associated with correct management of the standardized patients. Taking a physical record of medical information predicted correct management (aOR =1.29 [95%CI 1.01 – 1.65]); as did the presence of a clinical assistant (aOR =1.94 [95% CI 1.61 – 2.34]). Providers who spent more time on average with SPs were more likely to correctly manage them, as each additional minute spent was associated with an aOR of 1.05 [95%CI 1.03 -1.08]. The aOR for each additional patient in the wait-room was 1.05 [95% CI 1.03 – 1.08].

Subjective quality or client experience as a signal for technical quality

Figure 3 illustrates the change in SPs' assessment as a function of the index for subjective quality or client experience, stratified by correct management. SPs who were correctly managed consistently reported higher provider assessment scores at the same level of subjective quality. However, SPs who were incorrectly managed reported similar provider assessment scores as SPs who were correctly managed, if their client experience was approximately 0.25 standard deviations higher. We investigated these potential trade-offs using regression analysis.

Table 9 reports the results of a set of regressions using the subjective assessment index as the dependent variable. In the first column, we report simple linear associations with the assessment index for measures capturing objective quality, various subjective measures, and demographic information. These regressions controlled for TB case presented and city. In the second column, we report estimates from a multiple linear regression model in which all the predictors were included. The final column reports the absolute differences between the point estimates.

First, we report the association between correct management and subjective assessments of providers or global scores. In the simple model, SPs who were correctly managed scored providers positively (0.65 [95% CI 0.56 – 0.73]-unit increase in the subjective assessment index). When client experience was controlled for, the association between technical quality and

assessment scores was lower (0.06 [95% CI -0.03 – 0.15] units). Similarly, history-taking of all essential checklist questions resulted in SPs positively valuing providers (3.89 [95% CI 3.64 – 4.14] units); when adjusting for objective quality, this association decreased by nearly half (2.09 [95% CI 1.83 – 2.34] units). In the simple model, providers who mentioned TB to the SPs obtained higher assessment scores (0.85 [95% 0.75 – 0.94] units); when controlling for client experience, the relationship was observed to be about one-third as strong (0.23 [95% CI 0.13 – 0.33] units).

Second, we report the association between subjective quality (or client experience) and the provider assessment scores. Generally in the full model, across all markers, we observed a simultaneous decrease in the expected change in SPs' subjective scores for providers. Drawing from the simple model, SPs subjective assessment was greater when providers created a safe and private environment (1.17 [95% CI 1.08 – 1.26] units); when adjusting for medical correctness, this association was reduced by more than half (0.51 [95% CI 0.41 – 0.61] units). When providers were judged to appear knowledgeable, SPs' assessment of providers underwent a positive increase (1.24 [95% CI 1.16 – 1.32] units); when controlling for correctness in care, their provider scores decreased by more than half (0.46 [95% CI 0.35 - 0.57] units). This same trend was observed with SPs' subjective assessment scores when providers seriously addressed their concerns; in the simple model the value was 1.36 [95% CI 1.27 – 1.44] units, which shifted to 0.60 [95% CI 0.49 – 0.70] units in the fully adjusted model. SPs reported greater provider scores when they received clear explanations on illnesses (1.02 [95% CI 0.86 – 1.17] units); when controlling for medical correctness, this association reduced completely (-0.01 [95% CI -0.18 – 0.16] units). Likewise, receiving clear explanations on treatment plan was originally 0.95 [95% CI 0.85 – 1.04] units; when adjusting for technical care, this value was reduced by nearly 1/3rd (0.26 [95% CI 0.15 – 0.37] units). In the simple model, SPs reported a negative experience when at least one environmental disruptor (TV being on, provider using a cellphone, or others being present in the room) arose (-0.43 [95% CI -0.52 - -0.33]); when adjusting for technical quality, SPs response to disruptions remained in the negative direction (-0.15 [95% CI -0.24 - -0.05] units).

Third, we report how other elements of quality predicted changes in SPs' subjective assessment. Providers physical notetaking of SPs' medical information resulted in a positive change in assessment scores (0.46 [95% CI 0.33 – 0.59] units); when controlling for objective

and subjective quality, this shifted downwards to 0.06 [95% CI -0.06 – 0.19] units. The presence of a clinical assistant caused SPs' assessment to increase (0.43 [95% CI 0.35 - 0.51] units); when controlling for all other markers, this decreased by more than half (0.13 [95% CI 0.05 – 0.22] units). In the simple model, with each one-minute increase in time spent with providers, SPs subjective assessment shifted by 0.06 [95% CI 0.05 - 0.07] units; in the full model, their assessment scores shifted by 0.01 [95% CI 0.00 – 0.02] units. Finally, with each additional patient in the wait room, SPs' subjective scores changed by 0.02 [95% CI 0.01 – 0.03] units in the simple model; when adjusting for all predictors, the observed change remained consistent 0.02 [95% CI 0.00 – 0.03] units).

Fourth, we report how interactional demographics shifted between simple and fully adjusted models. In the simple model, SPs who visited MBBS-qualified providers reported higher subjective scores (0.64 [95% CI 0.56 – 0.73] units); when adjusting for all forms of quality, this association decreased to 0.04 [95% CI -0.06 – 0.14] units. Subjective impressions were also explained by providers' presenting sex and age. Viewing the simple model, SPs perceived interactions with male-presenting providers to be more negative than female providers (-0.10 [95% CI -0.21 – 0.02] units); in the multiple model, this negative association persisted (-0.09 [-0.21 – 0.03] units). In the simple model, the medical practice of providers aged between 30 and 50 years changed SPs' subjective assessment of providers by 0.16 [95% CI -0.03 – 0.35] units and that of providers older than 50 was of 0.28 [95% CI 0.08 – 0.48] units. In the adjusted model, these values changed to 0.05 [95% CI -0.13 – 0.23] units and 0.06 [95% CI -0.14 – 0.25] units, respectively. We lastly observed men SPs to report a superior level of subjective provider scores than their women counterparts in the simple model (0.10 [95% CI -0.51 - 0.71] units); in the adjusted model, this trend persisted (0.18 [95% CI -0.26 – 0.62] units).

4.4 Discussion

The SP study design is recognized as the gold-standard method for healthcare quality research[25] and has been widely used to report on technical quality across various LMIC contexts.[28] Further expanding on the scope of SP-provider data, we explored associations between objective and subjective forms of quality; the former being verifiable, and the latter, bias-free from personal preferences in provider selection, as SPs were assigned to visit a random

sample of providers. In this way, we can assess what subjective measures imply in the context of patient-provider rapports.

Accordingly, we characterized which patient-centred aspects of provider practice served as signals of medical correctness, as we are positioned to control for technical quality. To draw parallels between subjective quality (or client experience) and objective (or technical) quality, two polar cases can be illustrated: (1) If an association between both measures exists (technical and experience), then, with the inclusion of medical correctness in the model, we would observe the change in SPs' subjective assessment for client experience signals (i.e., variables for patient-centeredness) to decrease to zero, since correctness would fully explain subjective quality; (2) If the reverse is true, and no such association exists, then we anticipate no difference to be observed in the change in SPs' provider scores for subjective predictors when information on technical quality is added to the regression. For all other cases, we would observe an in-between effect.

Our results demonstrate that subjective quality is a strong predictor of correct care, but this association is imperfect. First, elements of patient-centredness do function as signals to SPs about the medical quality of the provider. Specifically, we see that providers appearing knowledgeable (1.24 vs 0.46 unit change in subjective assessment) and explaining the illness (1.02 vs -0.01 units) work as proxies for objective quality: they are strong predictors of subjective assessment in simple linear analyses but are less significant controlling for technical quality. Likewise, when examining the complimentary interpretation, the expected change in SPs' subjective assessment for objective quality markers weakened with the addition of subjective measures, supporting the association between both quality measures. This was evidenced when providers clinically managed SPs (0.65 vs 0.06 units) and when providers posed all essential history questions (2.56 vs 1.21 units).

Secondly, and conversely, we identify that there are elements affecting patient-centredness that remain unchanged from simple to multiple analyses and are therefore, separate dimensions of quality to value (or disvalue) in their own right. Specifically, we see that avoiding disruptions (-0.43 vs -0.15 units) remain important even after controlling for technical quality and other markers.

To our knowledge, this is the first analysis of healthcare-seeker perceptions (defined as SPs' subjective assessment of providers) in which clients possess comprehension of correct care, in this case for TB. The supporting evidence for this claim is manifold: to begin with, SPs were

asked to repeatedly complete an extensive seven-section exit questionnaire chronicling details of providers' practice; thus, SPs had extensive exposure to what the research team was looking for. At the very least, because SPs knew that they were presenting cases curated for TB, practitioners' suspicion of TB would be seen as a proxy for correct management and thus lead to noticeable changes in subjective assessment relative to other markers, which our results support (0.85 and 0.23 units). Furthermore, some SPs were hired for the entire study period. Even though SPs were not explicitly required to learn clinical definitions and retain them, they worked closely with the research staff spearheading this methodology. Through conversation, elements of what constituted technical quality were likely to be shared.

Taken together, our results recognize that healthcare users value aspects of care other than technical care. In fact, items requiring accessible communication were consistently associated with positive changes in SPs' subjective assessment of providers. This was seen most strongly with history-taking of essential questions, as well as when providers created a safe space for communication (1.17 vs. 0.51) and responded to SPs' concerns with sincerity (1.36 vs. 0.60). In the South African context regarding private practitioners, Boffa et al. (BMJ GH 2021) also showed that client actors valued features of care other than correct diagnosis, such as the time spent with providers, providers' attentiveness to address comorbidities like HIV, providers' ability to show respect, demonstrate physical touch, and, lastly, communicate. Communication was demonstrated by way of allowing shared-decision making, of making medical knowledge accessible to client actors, for instance.

Effective communication is a cardinal aspect of care taught widely across medical institutions.[29] It is a process indicator commonly acknowledged in systematic reviews[15,30-32] to be an essential component of patient-provider rapports and an enabler of treatment adherence for multiple disease areas.[33] A study looking at telehealth also recognized how telecommunication leads to positive patient satisfaction scores.[34] These findings are particularly relevant given the increased utilization of telehealth modalities with the COVID-19 pandemic. In fact, transparent communication was also demanded by TB survivors.[11] Furthermore, the WHO patient-centred approach for TB promotes the use of different modalities for communication (digital and in-person), so as to make things easier for patients.[35]

However, counselling should be receptive to the needs of the patient; otherwise, it is unlikely to be effective. For instance, nationally-representative surveys from 56 countries

showed that patients frequenting hospitals had greater difficulty with therapeutic explanations and sharing their concerns than those who received services in health centers.[36] This highlights the inconsistencies between types of services. Furthermore, a TB study in the Philippines found large discrepancies between the level of information on TB illness, treatment, and side effects thought to be communicated by providers and the level of actual understanding among clients, which was substantially lower.[37] A possible explanation for substandard patient-provider communication may be due to the opportunity to counsel patients being constrained by the length of consultation, which varies across countries.[38]

Study limitations and strengths

We also note some limiting factors imposed by our methodology. First, we were limited by what was originally collected during the primary study; however, expanding the scope of measures can be easily integrated in future SP efforts. Second, the measures of the global assessment scale tool were all positively worded. A study which randomly assigned positively-worded versus negatively-worded surveys found that differences up to 19 points were possible in responses;[18] therefore, our subjective measures are likely to have been inflated towards higher ratings. This is still acceptable, however, as high patient scores are widely seen in the literature where studies may have also mistakenly framed questions in the positive direction. Third, we only have information on SPs' first-contact with a given provider, and cannot infer estimates on SPs' client experience throughout the continuum of care (e.g., repeat visits and longer term follow-up), which have important implications on how to retain TB patients in care. Correspondingly, healthcare users' experiences are not limited to the patient-provider interaction; in fact, interactions with other members of the health team are also important.[39] For our particular objective, this was acceptable, as we were interested in the weight of technical quality. However, to gain a more holistic understanding of experience can be to expand the collection of interactional data.

Nevertheless, our study had a number of strengths. We used data from a large private-sector study from two cities with a high incidence of TB, all of which are meaningful to address India's TB epidemic. SPs are trained to reliably portray TB cases and are able to accurately recall clinical details from consults. We also did not require provider consent, thereby limiting the possibility of the Hawthorne effect, i.e., when providers behave differently when they are

being observed versus not.[25] Our inferences are also generalizable, as the SP recruits mirrored some notable demographic features of the actual population, such as age and education;[40] this was also identified in previous work.[23] Education level is especially important, as studies report that expectation levels, which ultimately determine satisfaction or subjective scores, are associated with educational achievement.[41] This earlier work also demonstrated that SP gender was randomly allocated to providers; thus, we captured subjective data from both men and women SPs. We also used a composite measure to capture SPs' subjective assessment, rather than relying on a single measure. As with any form of quality, subjective perceptions are also multidimensional; therefore, our approach to use an aggregate was most appropriate.

4.5 Conclusions

To conclude, our study suggests that interactions in which SPs' provider assessments were positive also seem to result in SPs being appropriately managed by providers. Patient-centred elements of quality may therefore serve as signals for providers' technical practice and their inclusion providers' practice consistently resulted in positive subjective assessments. SPs also recognized the value of accessible communication which is particularly note-worthy given that they were knowledgeable of the medical cases they were presenting.

Potential exists to expand the SP methodology to enable a greater collection of measures related to objective and subjective quality in order to address the lack of standard patient-centred measures and advance the agenda for patient-centred care set forth by the End TB Strategy.

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4.6 Figures and Tables

TABLE 1. SP case descriptions, patient presentations, and correct management definitions.

	Case Description	Presentation of Patient	Expected Correct Case Management
CASE 1	Classic case of presumed TB with 2–3 weeks of cough and fever.	Presents with presumptive tuberculosis, for the first time, to a private health-care provider, saying "Doctor, I have cough that is not getting better and some fever too"	Recommendation for sputum testing, chest radiograph, or referral to a public DOTS center or a private provider or specialist.
CASE 2	Classic case of presumed TB in a patient who has had 2–3 weeks of cough and fever. The patient has taken a broad-spectrum antibiotic (amoxicillin) given by another health-care provider for 1 week with no improvement. He also carries an abnormal CXR suggestive of TB.	Presents after an initial, failed (empirical) treatment for symptoms with broad-spectrum antibiotics and a diagnostic CXR, saying "I have cough and fever which is not getting better. I went to a doctor and took the medicines he gave me and have also had an X-ray done." The CXR and blister pack for the antibiotics are shown if the provider asks	Recommendation for sputum testing, chest radiograph, or referral to a public DOTS center or a private provider or specialist.
CASE 3	Chronic cough with a positive sputum smear report for TB from a public health facility.	Presents with evidence of microbiologically confirmed TB, saying "I am having cough for nearly a month now and also have fever. I visited [the local government hospital] and they gave me some medicines and did a sputum test." The sputum report is shown if the provider asks.	Either referral to a public DOTS center, a qualified provider or specialist, or (in the case of a qualified private provider) initiation of treatment with standard, 4-drug, first-line anti-TB therapy (HRZE regimen)
CASE 4	Chronic cough and, if asked, elaborates a history of previous, incomplete treatment for TB, which would raise the suspicion of MDR TB.	Presents as a previously treated patient with TB with recurrence of the disease (i.e., suspicion of drug resistance), saying "Doctor, I am suffering from a bad cough. One year ago I had got treatment in [the local public hospital], and it had got better. But now I am having cough again"	Recommendation for any DST (culture, line probe assay, or Xpert MTB/RIF) or referral to a public DOTS center or a private provider or specialist.
	CXR: chest X-ray DOTS: directly observed treatment, short-course. DST: drug susceptibility test HRZE: isoniazid, rifampicin, pyrazinamide, and ethambutol MDR: multidrug-resistant SP: standardized patient TB: tuberculosis Xpert MTB/RIF: Xpert Mycobacterium tuberculosis/Rifampicin **Table content was taken with permission from Kwan et al. (2018), PLOS Medicine.**		

TABLE 2. Distributions of standardized patient-provider interactions stratified by location, provider qualification, and tuberculosis case presented.

		Case 1		Case 2		Case 3		Case 4		Total
	Characteristics	Interactions	SPs	Interactions	SPs	Interactions	SPs	Interactions	SPs	
Patna (non-MBBS)	Informal providers	207	13	48	2	57	2	43	2	355
Patna (MBBS)	MBBS Higher degree holders	366	13	90	2	93	3	115	2	664
Mumbai (non-MBBS)	AYUSH providers	558	8	142	2	135	3	258	4	1093
Mumbai (MBBS)	MBBS Higher degree holders	246	8	105	2	69	3	70	4	490
Total	…	1377	…	385	…	354	…	486	…	2602

SP: Standardized patient

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 रैंक दे जिसमें 10 सबसे अधिक और 1 सबसे कम है।		☐☐

FIGURE 1. Eight-item global assessment scale found in section six of the exit questionnaire completed by standardized patients.

TABLE 3. Distributions of elements capturing objective quality.

	Tuberculosis case	**Number of SP-provider interactions**	**Value**	**Count (%)**	**Bootstrapped 95% CI**
Clinical management	Case 1	1377	Correct	543 (39%)	[37% - 42%]
			Not correct	834 (61%)	[58% - 63%]
	Case 2	385	Correct	254 (66%)	[61% - 71%]
			Not correct	131 (34%)	[29% - 39%]
	Case 3	354	Correct	106 (30%)	[25% - 35%]
			No	248 (70%)	[65% - 75%]
	Case 4	486	Yes	56 (12%)	[9% - 15%]
			No	429 (88%)	[85% - 91%]
	Overall*	2602	Yes	959 (37%)	[35% - 39%]
			No	1643 (63%)	[61% - 65%]
	History-taking – proportion completion of the essential questionnaire (%)	2602	0% - 100%	50%	[21% -78%]
	Provider suspected tuberculosis	2602	Tuberculosis was suspected	987 (38%)	[36% - 40%]
			Was not suspected	1615 (62%)	[60% - 64%]

*: Kwan et al. (2018) reported weighted city-representative estimates. To draw comparisons between measures and tables in this thesis work, we consistently used crude estimates for descriptive statistics.

TABLE 4. Distributions of elements for standardized patients' (SP) subjective assessment of providers and subjective quality or SPs' client experience.

Item	Question	Number of SP-provider interactions	Responses	Count (%) or Mean	Bootstrapped 95% CI
G1*	Do you like this doctor?	2602	Yes	2146 (82%)	[81% - 84%]
			No	449 (17%)	[16% - 18%]
G2*	Would you go to the doctor again?	2602	Yes	2053 (79%)	[78% - 81%]
			No	543 (21%)	[19% - 23%]
G3	Did the provider create an environment in which you could convey your symptoms easily?	2602	Definitely	1887 (73%)	[71% - 74%]
			Somewhat/Not at all	708 (27%)	[26% - 29%]
G4	Did the provider appear knowledgeable about your illness?	2600	Very	1224 (47%)	[45% - 49%]
			Somewhat/Not at all	1376 (53%)	[51% - 55%]
G5	Did the provider address your worries seriously?	2600	Very	1223 (47%)	[45% - 49%]
			Somewhat/Not at all	1377 (53%)	[51% - 55%]
G6	Did the provider explain your illness?	2600	Very well	209 (8%)	[7% - 9%]
			Cursorily/Not at all	2391 (92%)	[91% - 93%]
G7	Did the provider explain your treatment plan?	2600	Very well	601 (23%)	[22% - 25%]
			Cursorily/Not at all	1999 (77%)	[75% - 79%]
G8*	Provide a 1-10 ranking of the provider	2601	1-10 units	6.27	6.18 – 6.36
-	Presence of environmental disruptions**	2600	Yes	663 (26%)	[24% - 27%]
			No	1937 (74%)	[73% - 76%]

*Items used in the composite index for standardized patients' subjective assessment of providers (to follow).
**Disruptions are defined as a TV being on, provider using their cellphone, or others being present in the consultation room.

TABLE 5. Distributions of other elements of quality.

Question	Number of interactions	Responses	Count (%) or Mean	Bootstrapped 95% CI
Provider physically recorded information	2599	Yes	276 (11%)	[9% - 12%]
		No	2323 (89%)	[88% - 91%]
Presence of clinical assistant	2598	Yes	1646 (63%)	[61% -65%]
		No	956 (37%)	[35% - 39%]
Duration of the consultation (minutes)	2592	0 – 50.7 minutes	6.29	[6.11 – 6.47]
Other patients waiting	2602	0 – 45 patients	2.10	[1.95 – 2.25]

TABLE 6. Associations between correct clinical management and various quality markers. Difference testing presented as odds of correct clinical management using generalized estimating equations with a logit link that accounts for provider-level clustering for predictors capturing objective quality, subjective assessment, subjective quality or client experience, and other interactional elements.

			Clinical management Correct (n=954)		Not correct (n=1642)		Odds of correct clinical management adjusted for tuberculosis case and city	
	Predictor	**Responses**	**Mean or count (%)**	**Bootstrapped 95% CI**	**Mean or count (%)**	**Bootstrapped 95% CI**	**Odds Ratio**	**95% CI**
Objective quality	History-taking – proportion completion of the essential questionnaire (%)	0% - 100%	56%	[24% - 88%]	46%	[19% - 72%]	5.03	[3.54 - 7.14]
	Provider suspected the likelihood of tuberculosis	Yes	492 (52%)	[48% - 55%]	495 (30%)	[28% - 32%]	4.58	[3.72 - 5.64]
		No	467 (49%)	[46% - 52%]	1148 (70%)	[68% - 72%]		
Subjective assessment	Did you like the doctor?	Yes	880 (92%)	[90% - 94%]	1266 (77%)	[75% - 79%]	3.84	[2.88 - 5.14]
		No	74 (8%)	[6% - 9%]	376 (23%)	[21% - 25%]		
	Would you go to the doctor again?	Yes	852 (89%)	[87% - 91%]	1201 (73%)	[71% - 75%]	3.46	[2.67 - 4.48]
		No	102 (11%)	[19% - 3%]	441 (27%)	[25% - 29%]		
	Provide a 1-10 ranking of the provider	1 - 10 units	7.21 units	[7.09 - 7.32]	5.72 units	[5.62 - 5.83]	1.50	[1.42 - 1.57]
Subjective quality or Client experience	Did the provider create an environment in which you could convey your symptoms easily?	Definitely	768 (81%)	[80% - 83%]	1119 (68%)	[66% - 70%]	2.12	[1.73 - 2.59]
		Somewhat/Not at all	186 (20%)	[17% - 22%]	523 (32%)	[30% - 34%]		
	Did the provider appear knowledgeable about your illness?	Very knowledgeable	655 (69%)	[66% - 72%]	566 (34%)	[32% - 37%]	4.87	[4.01 - 5.91]
		Somewhat/Not at all	299 (31%)	[28% - 34%]	1076 (65%)	[63% - 68%]		
	Did the provider address your worries seriously?	Very seriously	616 (65%)	[62% - 68%]	605 (37%)	[34% - 39%]	3.17	[2.65 - 3.80]
		Somewhat/Not at all	338 (35%)	[32% - 39%]	1037 (63%)	[61% - 60%]		
	Did the provider explain your illness?	Very well	105 (11%)	[9% - 13%]	104 (6%)	[5% - 8%]	2.40	[1.80 - 3.20]
		Cursorily/Not at all	849 (89%)	[87% - 91%]	1538 (94%)	[93% - 95%]		
	Did the provider explain your treatment plan?	Very	294 (31%)	[28% - 34%]	306 (19%)	[17% - 21%]	2.07	[1.70 - 2.48]
		Cursorily/Not at all	660 (69%)	[66% - 72%]	1336 (81%)	[79% - 83%]		
	Presence of environmental disruptors (TV was one, provider used cellphone, or others were in the consultation room)	Yes	218 (23%)	[20% - 26%]	445 (27%)	[25% - 29%]	0.81	[0.67 - 0.99]
		No	736 (77%)	[75% - 80%]	1197 (73%)	[71% - 75%]		

Others	Provider physically recorded information	Yes	119 (12%)	[10% - 15%]	157 (10%)	[8% - 11%]	1.29	[1.01 - 1.65]
		No	833 (87%)	[85% - 90%]	1484 (90%)	[89% - 92%]		
	Presence of clinical assistant	Yes	704 (74%)	[71% - 76%]	942 (57%)	[55% - 60%]	1.94	[1.61 - 2.34]
		No	255 (27%)	[24% - 29%]	697 (42%)	[40% - 45%]		
	Duration of the consultation (minutes)	0 – 50.7 minutes	6.82	[6.52 - 7.11]	5.98	[5.76 - 6.21]	1.05	[1.03 - 1.08]
	Other patients waiting	0 – 45 patients	2.57 patients	[2.30 - 2.85]	1.83 patients	[1.66 - 2.00]	1.05	[1.03 - 1.08]

TABLE 7. Characteristics of the index for standardized patients' subjective assessment of providers, derived from principal component analysis.

Total variance accounted by PC1 (%)	PC1 range [Min – Max]	PC1 Mean ± SD	PC1 loadings	
82.4%	[-3.75 – 1.49]	0.00 ± 1.57	G1	0.59
			G2	0.60
			G8	0.54

Item from the global assessment scale
G1: Did you like this doctor?
G2: Would you go to this doctor again?
G8: 1-10 ranking of the provider as determined by the standardized patient.
PC1: principal component 1

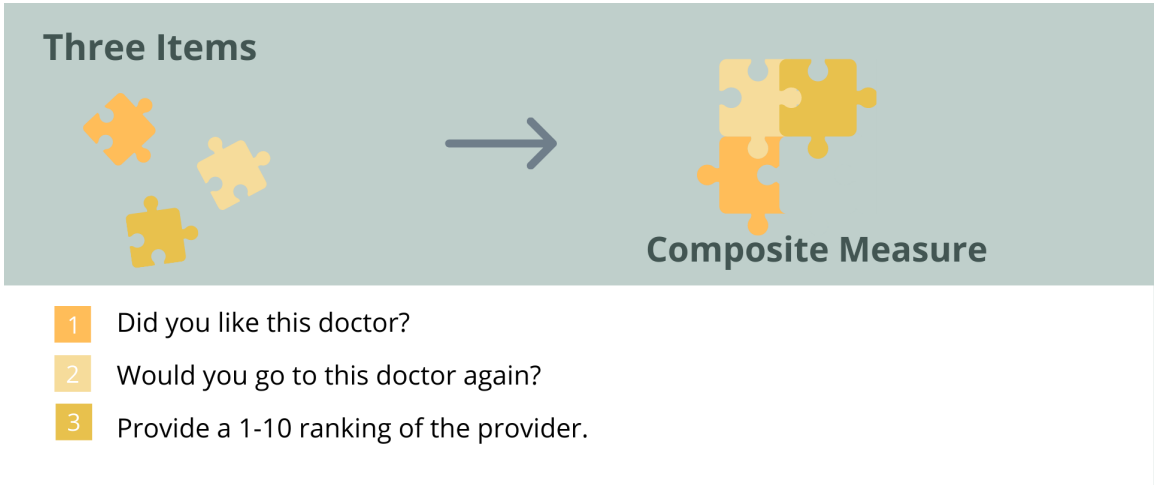


FIGURE 2. Questions from the global assessment scale that constitute the three-item composite measure to capture standardized patients' subjective assessment of providers.

TABLE 8. Characteristics of the index for subjective quality generated using principal component analysis.

Total variance accounted by PC1 (%)	**PC1 range [Min – Max]**	**PC1 Mean ± SD**	**PC1 loadings**	
43.2%	[-4.52 – 2.88]	0.00 ± 1.61	Created private environment	0.39
			Appeared knowledgeable	0.47
			Addressed worries	0.50
			Explained illness	0.41
			Explained treatment	0.38
			Disruptions arose	-0.23

PC1: Principal component 1

NB: This index was only used for descriptive statistics purposes, Figure 3 (next page).

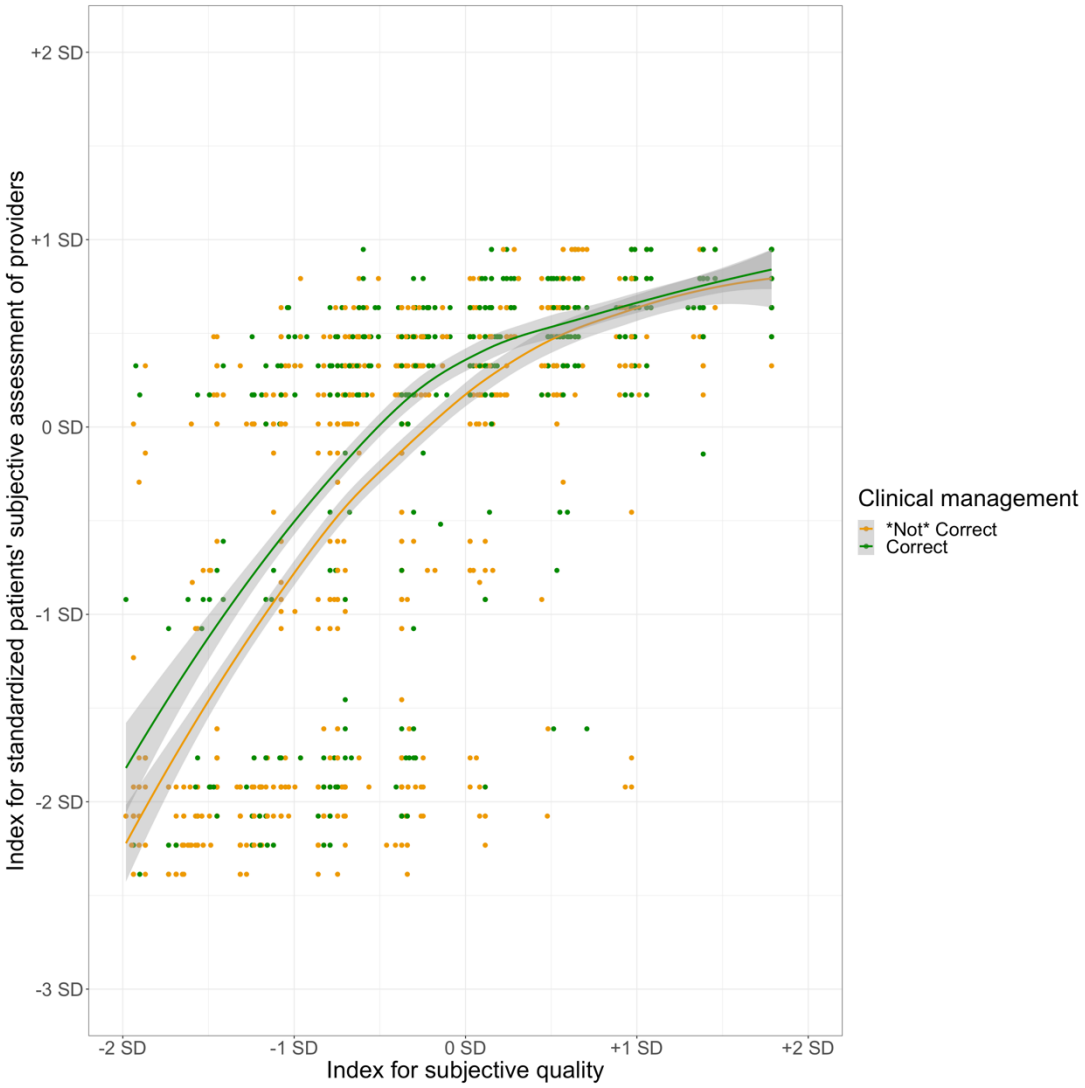


FIGURE 3. Standardized patients' subjective assessment of providers as a function of the index for subjective quality stratified by clinical management.

This figure plots a three-item composite index representing provider assessment scores (continuous) against a six-item index for subjective quality (continuous). The measure for subjective assessment was operationalized by grouping the following variables involving standardized patients' (SPs) response to: How much they liked their provider; willing to return to their provider for another consult; and their overall impression as determined by a 1-10 ranking. The aggregate measure for subjective quality was achieved by grouping the following variables involving the degree to which providers: Created a private environment; appeared knowledgeable; appropriately addressed SPs' concerns; delivered clear explanations on illness; delivered clear explanations on a treatment plan; posed essential history-taking questions; and limited the occurrence of disruptions. The solid nonparametric lines for correct (green) and non-correct (orange) clinical management were produced using a LOWESS fit (span = 0.75) and are flanked by 95% confidence intervals (grey). After accounting for a limited number of missing values, this graph captures a total of 2,595 standardized patient-provider interactions of which 954 were correctly handled and 1,641 were not by private Patna or Mumbai-based providers.

TABLE 9. Expected change in standardized patients' (SP) subjective assessment using mixed-effects linear regression analyses with a random intercept for SP identity and accounting for potential clustering at the provider level using robust standard errors for predictors capturing objective quality, subjective quality or client experience, other features of quality, and interactional demographics.

	Predictor	Change in subjective assessment [95% CI] adjusted for TB case and city.	Full model – Adjusted* change in subjective assessment [95% CI]	Absolute Difference
Objective quality	**Clinical management**			
	Defined as correct	0.65 [0.56 – 0.73]	0.06 [-0.03 – 0.15]	0.59
	History-taking			
	100% completion in the essential checklist	2.56 [2.38 – 2.74]	1.21 [1.01 – 1.40]	1.35
	Provider suspected the likelihood of tuberculosis			
	Yes	0.85 [0.75 – 0.94]	0.23 [0.13 – 0.33]	0.62
Subjective quality or Client experience	**Did the provider create an environment in which you could convey your symptoms easily?**			
	Definitely	1.17 [1.08 – 1.26]	0.51 [0.41 – 0.61]	0.66
	Did the provider appear knowledgeable?			
	Very knowledgeable	1.24 [1.16 – 1.32]	0.46 [0.35 – 0.57]	0.78
	Did the provider address your worries seriously?			
	Very seriously	1.36 [1.27 – 1.44]	0.60 [0.49 – 0.70]	0.76
	Did the provider explain your illness?			
	Very well	1.02 [0.86 – 1.17]	-0.01 [-0.18 – 0.16]	1.03
	Did the provider explain your treatment plan?			
	Very well	0.95 [0.85 – 1.04]	0.26 [0.15 – 0.37]	0.69
	Presence of environmental disruptors**	-0.43 [-0.52 - -0.33]	-0.15 [-0.24 - -0.05]	-0.28
Other	**Provider physically recorded information**	0.46 [0.33 – 0.59]	0.06 [-0.06 – 0.19]	0.40
	Presence of clinical assistant	0.43 [0.35 – 0.51]	0.13 [0.05 – 0.22]	0.30
	Duration of interaction			
	Time in minutes (centered at 6.29 minutes)	0.06 [0.05 – 0.07]	0.01 [0.00 – 0.02]	0.05
	Proxy for wait time			
	Other patients waiting	0.02 [0.01 – 0.03]	0.02 [0.00 – 0.03]	0.00
Demographics	**Provider qualification**			
	MBBS	0.64 [0.56 – 0.73]	0.04 [-0.06 – 0.14]	0.60
	Provider presenting sex			
	Male	-0.10 [-0.21 – 0.02]	-0.09 [-0.21 – 0.03]	-0.01
	Provider age			
	Between 30-50 years	0.16 [-0.03 – 0.35]	0.05 [-0.13 – 0.23]	0.11
	Older than 50 years	0.28 [0.08 – 0.48]	0.06 [-0.14 – 0.25]	0.22
	Standardized patient gender			
	Man	0.10 [-0.51 – 0.71]	0.18 [-0.26 – 0.62]	-0.08

CI: Confidence interval
TB: tuberculosis
MBBS: Bachelor of Medicine, Bachelor of Surgery (Formal medical accreditation in India).
*Adjusted for objectively quality, subjectively quality, other elements, patient-provider demographics.
**Disruptors are defined as a TV being on, provider using their cellphone, or others being present in the consultation room.

4.7 Appendix to analyses

4.7.1 Study design recapitulation

TABLE A1.1. Key study characteristics of Kwan et al.'s (2018) primary study titled *Variations in the quality of tuberculosis care in urban India: A cross-sectional, standardized patient study in two cities.*

Urban site(s)	Study timelines (Start – End)	SP-provider interactions	Health facilities frequented	Provider Sampling	Provider consent	Number of providers
Patna	21 Nov. 2014 – 28 Feb. 2015	1019	473	Random Sample The "universe list" of private providers was derived from street-by-street mapping of health localities both engaged and non-engaged with Private Provider Interface Agencies (PPIAs).	Waived by research ethics boards	331 (MBBS)* 500 (non-MBBS)
Mumbai	02 Apr. 2015 – 21 Aug. 2015	1583	730			471 (MBBS) 120 (non-MBBS)
Total	…	2602	1203	…	…	1422

MBBS: Bachelor or Medicine, Bachelor of Surgery (Formal medical training accreditation in India comparable to the MD degree in the United States).
*In Mumbai, MBBS providers may work communally; therefore, this number does not capture stand-alone providers.

4.7.2. Statistical analysis

i. Principal component analyses

We provide an example on how principal component analyses were conducted using the measures for SPs' subjective assessment of providers. First, the respective mean and standard deviations of each variable were investigated (**Table A1.2**).

TABLE A1.2. Pooled and city-specific mean and standard deviation of variables constituting the composite variable for standardized patients' subjective assessment of providers.

		Patna (n=1019)		Mumbai (n=1583)		Pooled (n=2602)	
Question	**Values**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Did you like the doctor?	1 = Yes 0 = No	0.86	± 0.35	0.81	± 0.40	0.83	± 0.38
Would you go to the doctor again?	1 = Yes 0 = No	0.82	± 0.38	0.77	± 0.42	0.79	± 0.41
Provide a 1-10 ranking of the provider.	Max = 10 Min = 1	6.50	± 2.08	6.12	± 2.28	6.27	± 2.21

We then systematically aggregated three measures from the global assessment scale using principal component analysis (PCA) on a correlation matrix. Specifically, we included the variables outlined in **Figure 2** of the manuscript. According to Song et al. (2013), weighted averaging is commonly applied to create composite scores for variables that are conceptually-tied.[1] This can be achieved by generating linear combinations, or principal components (PCs), of the original variables.[1] Our PCA resulted in three unique PCs, whereby PC1 accounted for the majority of the variance: 82.4%. The scree plot found in **Figure. A1.1** offers crude comparisons between the amount of variance described by each PC. Lastly, the biplot in **Figure A1.2** shows how all variables contributed towards PC1.

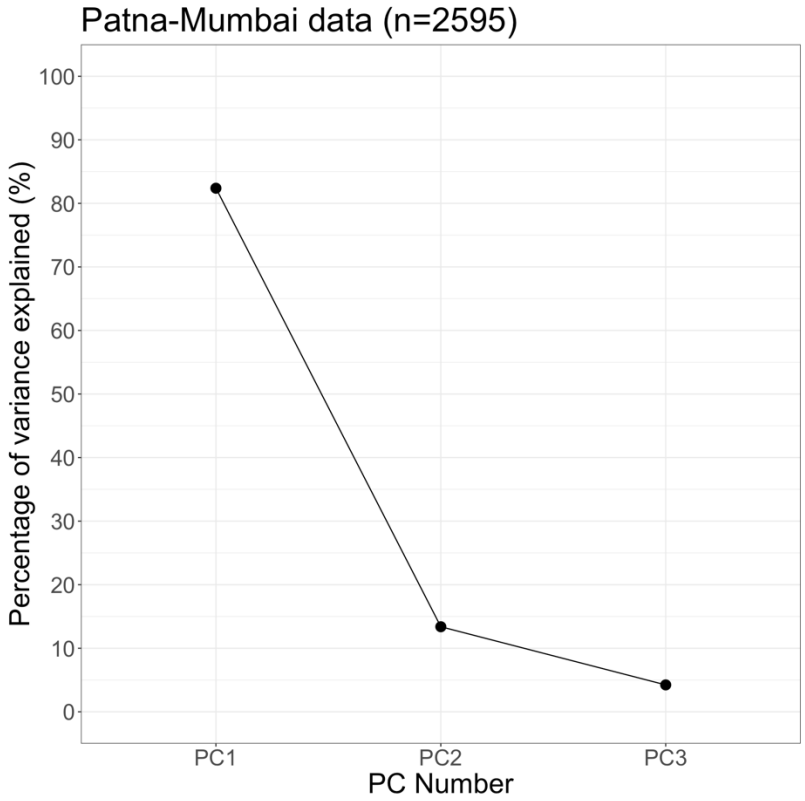


FIGURE A1.1. Scree plot and resulting variance for each principal component (PC) derived using principal component analysis for data related to standardized patients' subjective assessment of providers.
Specifically, there is a steep decline from PC1, which accounts for the majority of the variance of the original variables: 82.4%.

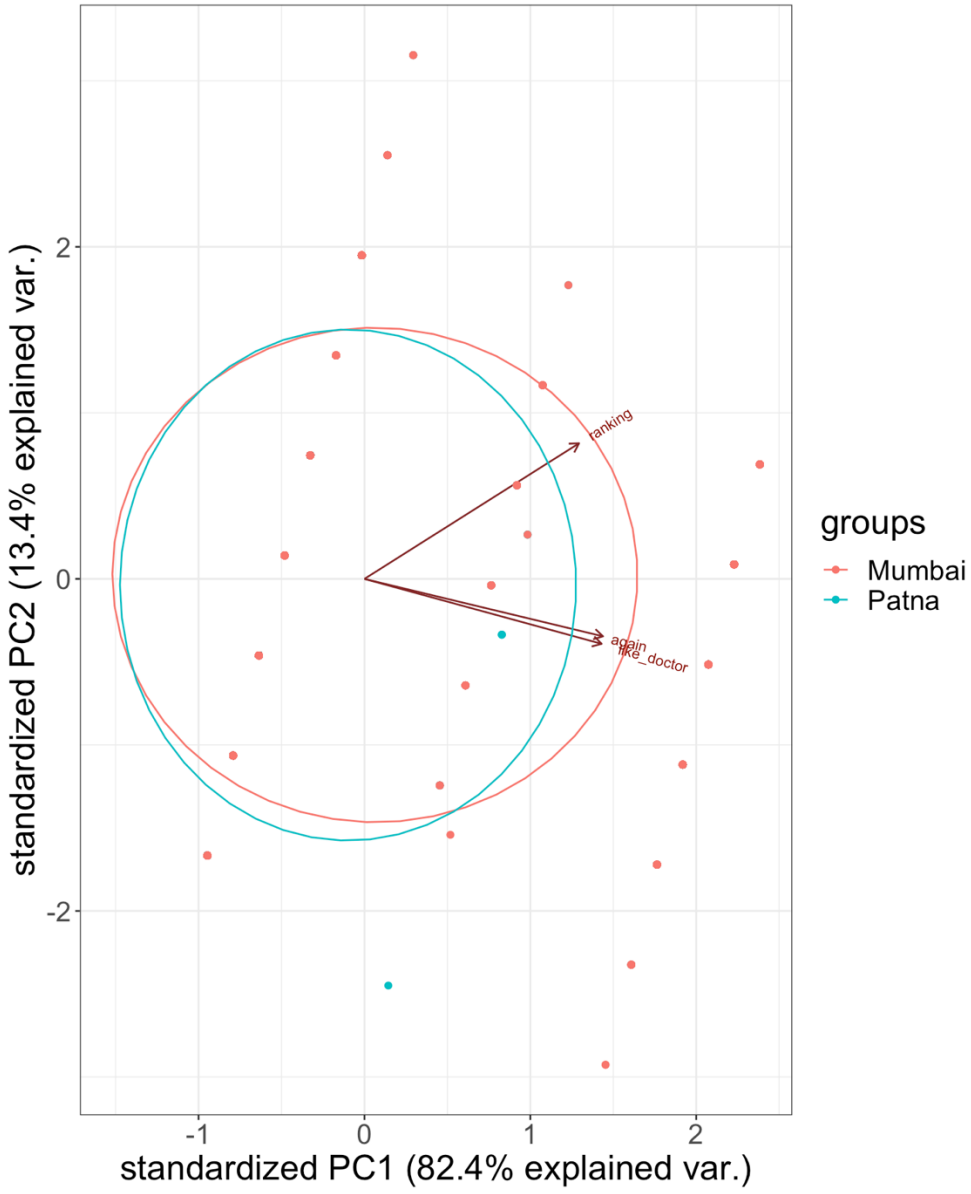


FIGURE A1.2. City-specific biplot graphically illustrating the contribution of each subjective variable on principal component 1 and 2.
The red ellipse represents the city of Mumbai, while the blue ellipse represents Patna; they are nearly superimposed and share similarities. The origin of the vectors begins at the tail end (PC1 = 0, PC2 = 0). Two of the subjective variables share a small angle which indicates there is a positively correlation between them. The vector titled “ranking” deviates most from the other vectors and contributes less towards the principal component i.e., it has a smaller relative loading.

ii. Regression predictor selection

From the predictors originally collected during the primary study, we included clinically-meaningful variables in our models. **Table A1.4** presents the repertoire of measures for objective quality, subjective quality, and pertinent interactional elements, including demographics. This table also showcases how these variables were collected and identified.

→ *Variable manipulation*

To facilitate model interpretations, we re-categorized the distribution of tri-categorical variables (**Figure 1**; G3:G7) to be binary. By grouping the middle-ground response with the lower-level option and identifying them as '0', we can code the highest-level response as '1', and then subsequently interpret the corresponding regression slope when providers executed the highest degree of care versus not.

We also generated a new variable titled 'disruptions' that captures whether at least one of the following occurred: presence of individuals other than the provider in the room, use of a cellular device by the provider, television being on. Lastly, we created a proxy measure for wait time, which is the average the number of other patients waiting.

TABLE A1.3. Primary study variable method of collection and determination pertinent to quality care.

	Predictor/Variable	Coded as	Type of predictor/variable	Determined by
Objective quality	**Correct clinical management**	Not correct = 0 Correct = 1	Dichotomous/binary	Analysis team
	Essential checklist	Proportion completed (fraction)	Continuous	Analysis team
	Tuberculosis suspicion	Tuberculosis not suspected = 0 Tuberculosis suspected = 1	Dichotomous/binary	Standardized patient
	Referred case*	Standardized patient did not receive referral = 0 Standardized patient received referral = 1	Dichotomous/binary	Standardized patient
	Chest X-ray*	Chest X-ray not prescribed = 0 Chest X-ray prescribed = 1	Dichotomous/binary	Standardized patient/ Analysis team
	Sputum AFB*	Sputum AFB not prescribed = 0 Sputum AFB prescribed = 1	Dichotomous/binary	Standardized patient/ Analysis team
	Xpert MTB/RIF*	Xpert MTB/RIF not prescribed = 0 Xpert MTB/RIF prescribed = 1	Dichotomous/binary	Standardized patient/ Analysis team
	Any medicine*	Prescribed no medicine = 0 At least one medicine = 1	Dichotomous/binary	Analysis team
	Polypharmacy*	Number of medicines prescribed	Continuous	Analysis team
Subjective quality	**Did the provider create a private environment?**	Not at all/Somewhat = 0 Definitely = 1	Dichotomous/binary	Standardized patient
	Did the provider appear knowledgeable?	Not at all/Somewhat = 0 Very knowledgeable = 1	Dichotomous/binary	Standardized patient
	Did the provider address [standardized patients'] worries seriously?	Not at all/Somewhat = 0 Very seriously	Dichotomous/binary	Standardized patient
	Did the provider explain your illness?	Not at all/Cursorily = 0 Very well = 1	Dichotomous/binary	Standardized patient
	Did the provider explain your treatment plan?	Not at all/Cursorily = 0 Very well = 1	Dichotomous/binary	Standardized patient
	Other individuals in the room**	Others not in the room = 0 Others in the room = 1	Dichotomous/binary	Standardized patient
	Provider used cellphone**	Did not use cellphone = 0 Used cellphone = 1	Dichotomous/binary	Standardized patient
	TV on during interaction**	TV was off or not present = 0 TV was on during interaction = 1	Dichotomous/binary	Standardized patient
Other	**Provider recorded information**	No = 0 Yes = 1	Dichotomous/binary	Standardized patient
	Provider has clinical assistant	Clinical assistant not present = 0 Presence of clinical assistant = 1	Dichotomous/binary	Standardized patient
	Duration of consultation	Number of minutes	Continuous	Standardized patient
	Number of other patients waiting upon arrival***	Number of patients	Continuous	Standardized patient
	Number of other patients waiting on departure***	Number of patients	Continuous	Standardized patient
Interactional demographics	**Provider qualification**	Non-MBBS = 0 MBBS = 1	Dichotomous/binary	Predetermined by research team
	Provider's presenting sex	Presenting as female = 0 Presenting as male = 1	Dichotomous/binary	Standardized patient
	Provider's age	Younger than 30 years = 1 Between 30-50 years = 2 Older than 50 years = 3	Categorical	Standardized patient
	Standardized patient gender (self-identified)	Woman = 0 Man = 1	Dichotomous/binary	Standardized patient
Study	**Tuberculosis case Presented**	Case 1 = 1 Case 2 = 2	Categorical	Predetermined by research team

		Case 3 = 3 Case 4 = 4		
	City	Patna = 2 Mumbai = 3	Categorical	Predetermined by research team
Table A2.4. Continued.				
	MBBS: Bachelor or Medicine, Bachelor of Surgery (Formal medical training accreditation in India) Xpert MTB/RIF: GeneXpert, Cepheid Inc., CA *Items used to create the variable for medical correct care. **Items used to create the variable for disruptions ***Items used to create the variable for other patients waiting			

iv. Regressions

→ *Intra-class correlation investigations*

We computed Intra-class correlation (ICC) coefficients to assess any clustering using the following formula:

$$ICC = \frac{Variance_{between}}{Variance_{between} + Variance_{within}}$$

To draw meaning from ICC values:

- An ICC of 1 implies that the variability is attributable to the cluster
- An ICC of 0 implies that the variability is within each cluster i.e., the clustering effect can be ignored

The following relevant clusters or levels were considered:

- Standardized patients
  - The ICC for **SPs was 0.23 [95% CI 0.15-0.38]**
- Providers
  - The ICC for **providers was 0.25 [95% CI 0.20-0.30]**
- Clinical TB cases
  - The case-specific ICCs were low and not necessary to report

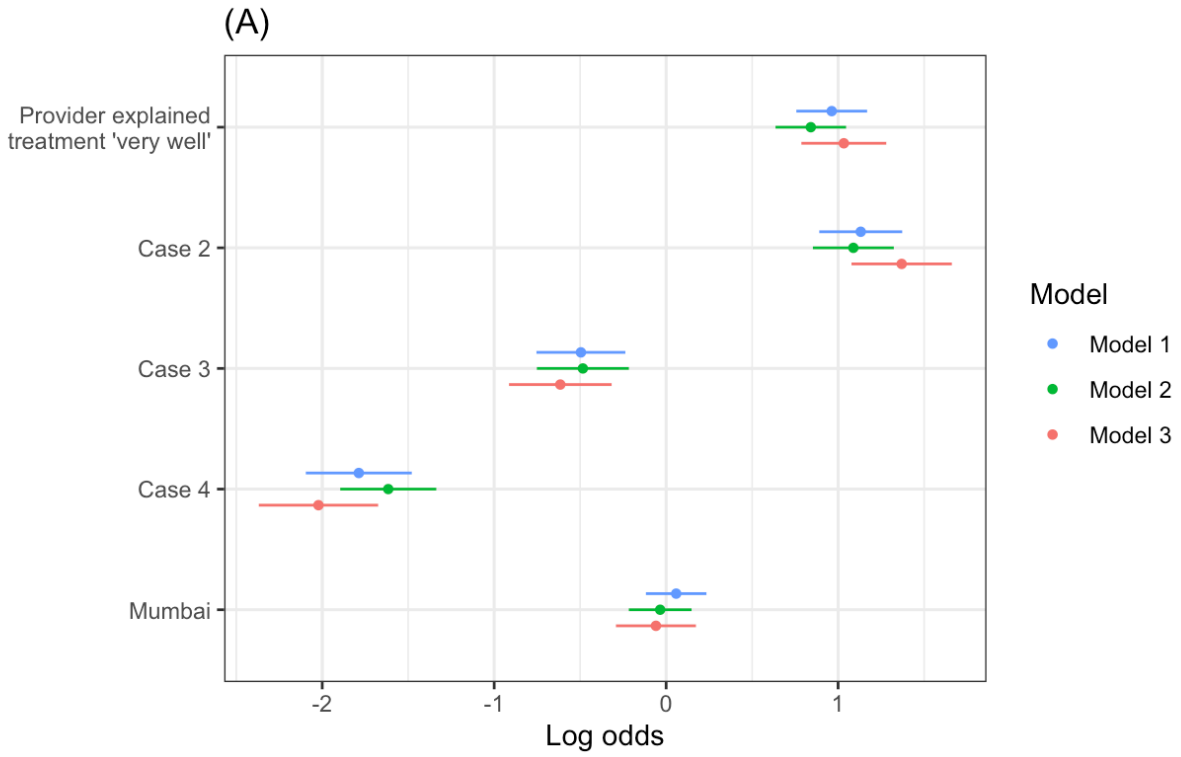
We note the upper 95% CI for SPs to be 0.38, i.e., considerably high, and that for providers to be of 0.30. Thus, it would be advisable to build regression models that will account for SP-level and/or provider-level clusters based on the chosen dependent variable.

1. Odds of correct clinical management as seen in Table 6.

→ ***Model selection***

Our model selection for the odds of correct clinical management (dependent variable) should account for provider-level clustering, as observations are not independent. We fit three logistic regression models with logic link for all SP-provider interactions: The first using the standard logistic regression model; the second using generalized estimating equations (GEEs); and the third, using generalized linear mixed models (GLMM) with a random intercept for provider identity. We conducted regression analyses individually for a series of predictors shown in **Table 6** of the manuscript, while controlling for TB case presented and city where the interaction took place. We are presenting two predictors as examples to compare estimates across models: 'explanation of treatment plan' (binary) and 'full completion of the essential history checklist' (continuous). **Figure A1.3** presents the coefficients on the log odds scale.

Generally, we see the point estimates and confidence intervals to be similar across models:



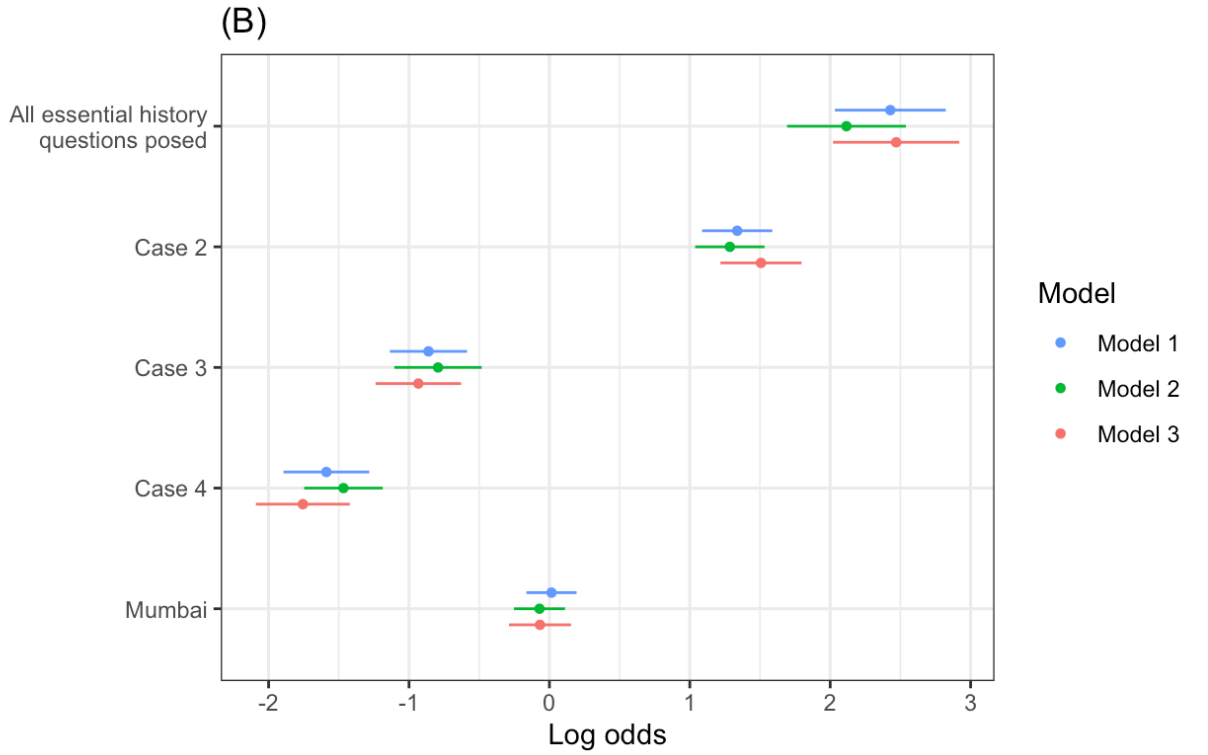


FIGURE A1.3. Coefficient plot for model comparison showing the log odds in correct clinical management adjusted for tuberculosis case and city site.
The following predictors were separately considered: (A) Clear explanations on treatment were received; and (B) Proportion completion of the essential history question checklist. Model 1 uses the standard logistic regression model, Model 2 uses generalized estimating equations, and Model 3 uses generalized linear mixed models.

We ultimately selected the parametric estimates from the GEEs which uses robust standard errors i.e., Model 2. The coefficient generated represents the average population-level change across all clusters for a-unit change in an independent variable, while holding others constant. We justified this selection primarily because the observations between clusters of providers are likely to be independent and the number of provider identities is large (n=1,203). GEEs are also typically used when one level of clustering is being considered and is also robust to violations of the correlation structure specified.[2]

→ ***GEE Logistic regression for the population average model***

$$logit[P(Y_{ij} = 1|X_{ij})] = \beta_0 + \beta_1 X_{ij} + \beta_2 TB\ Case_{ij} + \beta_3 City_{ij}$$

Y	Log odds of correct management
X	Singular predictor, continuous or categorical in nature
β_0	The intercept
β_1	The expected change in Y when X is increased by one unit
i	Represents each cluster (i.e., for each provider identity)
j	Denotes observations within each cluster

2. Change in standardized patients' client satisfaction as seen in Table 9.

→ ***Model Selection***

As the change in SPs' subjective assessment of providers is inherently subjective, we must consider another level of clustering other than provider level. The rationale being that each SP (n=24) is likely to have a different subjective point of reference that will randomly vary around the mean. Since our fully adjusted model will be most important here, we provide a more elaborate discussion for this model. We fit two multiple linear models for all SP-provider interactions: The first using generalized linear mixed models (GLMM) with a random intercept for both SP identity and provider identity; and a second, using generalized linear mixed models (GLMM) with a random intercept for SP identity and accounting for provider-level clustering using robust standard errors. In this case, we did not investigate standard linear regressions as the presence of between-SP heterogeneity is clear from our ICC analyses. Also, as observations are not independent across interactions, the main assumptions of the linear standard regressions are not met.

Overall, the coefficients obtained from each model have similar point estimates and overlapping confidence intervals.

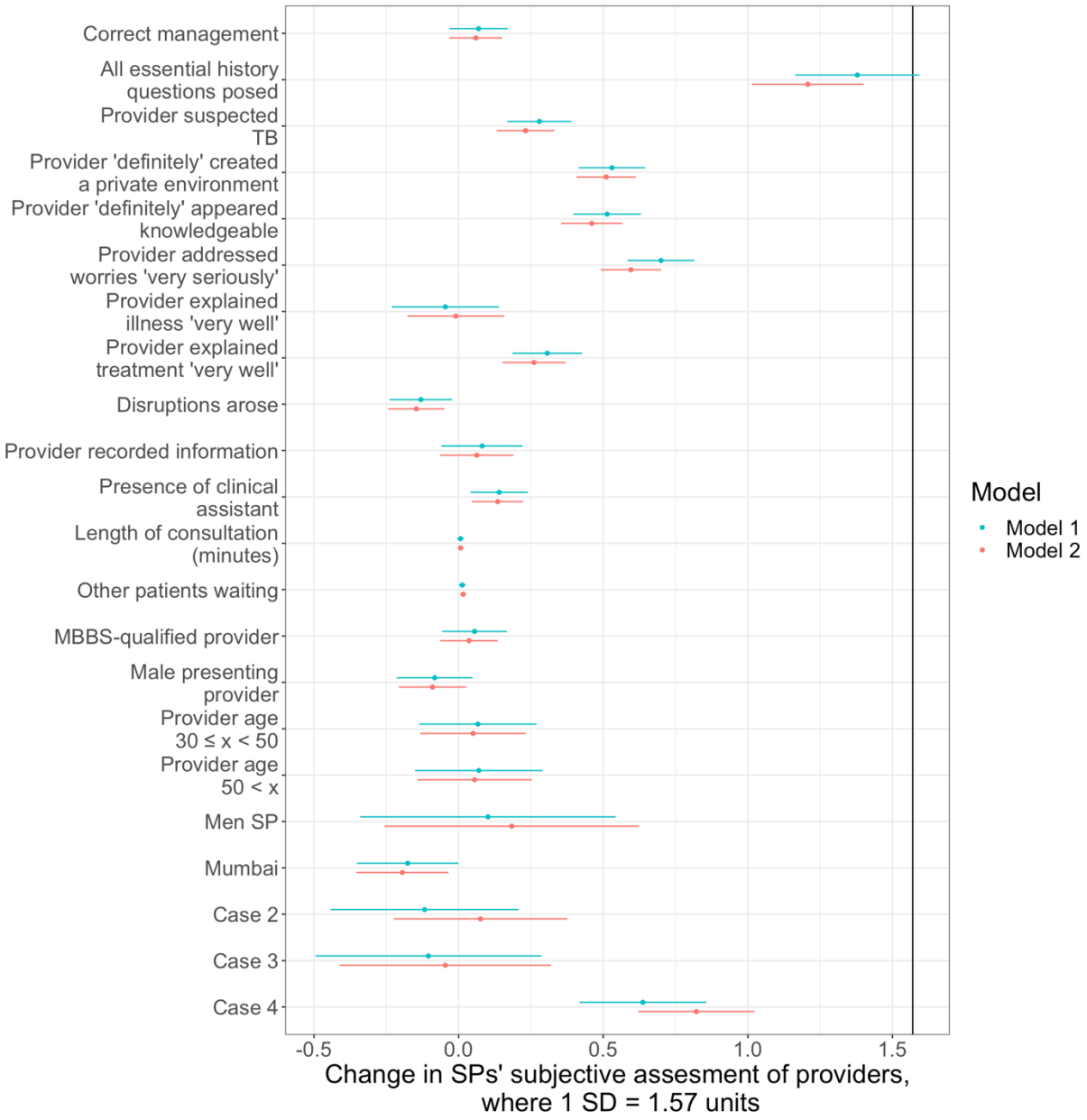


FIGURE A1.4. Coefficient plot for model comparison for the expected change in standardized patients' subjective assessment of providers adjusted for objective quality, subjective quality, other quality elements, interactional demographics, tuberculosis case, and city.
The dark vertical lines marks x = 1.57 units, which is 1 standard deviation. Model 1 uses a random intercept for both SP identity and provider identity. Model 2 uses a random intercept for SP identity and accounts for potential provider-level clustering using robust standard errors.
SD = Standard deviation.

We chose Model 2 which is the mixed-effects regression model with a random intercept for just SP identity and robust standard errors for potential provider-level clustering. We used the robustlmm::rlmer() function in R which computationally accounts for clustering. Given that our

composite variable for subjective assessment is on a continuous scale, we will proceed forward with *linear* regressions.

→ *Mixed-effects - linear regression*

Our first step included running what was denoted as 'simple' linear analyses in the manuscript to observe how select predictors explained SPs' subjective assessment. By definition, simple models contain only the dependent variable and *a singular* independent variable. In our analyses however, we consistently adjusted for TB case and city as well as had a random intercept for SP identity. Therefore, our use of the term 'simple' is mainly relative to the fully adjusted model.

The generalized, mixed-effects regression goes as follows:

$$E[Y_{ij}] = (\beta_0 + SP(effect)_i) + \beta_1 X_{ij} + \beta_2 TB\ Case_{ij} + \beta_3 City_{ij}$$

Y	Client experience presented as a continuous measure
X	Singular predictor, continuous, binary, or categorical in nature
β_0	The fixed intercept i.e., reference point for client experience
β_1	The expected change in Y when X is increased by one unit
$SP(effect)$	The random intercept
i	Represents each cluster (i.e., for each SP identity)
j	Denotes observations within each cluster

The SP-effect is the random intercept which is commonly denoted as $u_{i,}$ and added to the fixed intercept β_0.

$$\beta_{0i} = \beta_0 + SP(effect)$$
$$\beta_{0i} = \beta_0 + u_i$$

→ ***Mixed-effects - Multiple linear regressions***

The same rationale can be applied for mixed-effects *multiple* linear regression models, which enables the inclusion of multiple predictors. Our fully adjusted model comprised the following:

$$
\begin{aligned}
E[Y_{ij}] = \ & (\beta_0 + SP(effect)_i) + \ \beta_1 Correct_{ij} + \beta_2 Essential\ history\ checklist_{ij} \\
& + \beta_3 TB\ suspicion_{ij} + \beta_4 Private\ environment_{ij} + \ \beta_5 Knowledgeable_{ij} \\
& + \ \beta_6 Addressed\ worries_{ij} + \ \beta_7 Explanation\ of\ illness_{ij} \\
& + \beta_8 Explanation\ of\ treatment_{ij} + \ \beta_9 Disruptions_{ij} \\
& + \ \beta_{10} Record\ of\ information_{ij} + \beta_{11} Presence\ of\ clinical\ assistant_{ij} \\
& + \beta_{12} Length\ of\ consultation_{ij} + \beta_{13} Other\ patients\ waiting_{ij} \\
& + \ \beta_{14} Qualification_{ij} + \beta_{15} Provider's\ presenting\ sex_{ij} \\
& + \beta_{16} Provider\ age_{ij} + \beta_{17} SP\ gender_{ij} + \ \beta_{18} TB\ Case_{ij} + \beta_{19} City_{ij}
\end{aligned}
$$

Y	Client experience presented as a continuous measure
X	String of predictors, continuous or categorical in nature
β_0	The fixed intercept i.e., reference point for client experience
β_n	The expected change in Y when X is increased by one unit
$SP(effect)$	The random intercept
i	Represents each cluster (i.e., for each SP identity)
j	Denotes observations within each cluster

This fully adjusted model had a variance of $\sigma_u^2 = 0.25$ for the random intercept, and a variance of $\sigma_\varepsilon^2 = 0.87$ for the errors. Using ICC, the correlation within SPs was 0.22, which is considerably low. This supports the notion that SPs are so well trained that their subjective baselines are similar; nevertheless, our decision to opt for mixed models is still justified.

→ ***Addressing potential concerns for collinearity***

As the subjective quality measures are related, it is worth investigating correlations between these markers to avoid collinearity issues in linear models. **Figure A1.5** demonstrates that the highest correlation is 0.61, which is still acceptable. Therefore, all predictors can be included in the full model.

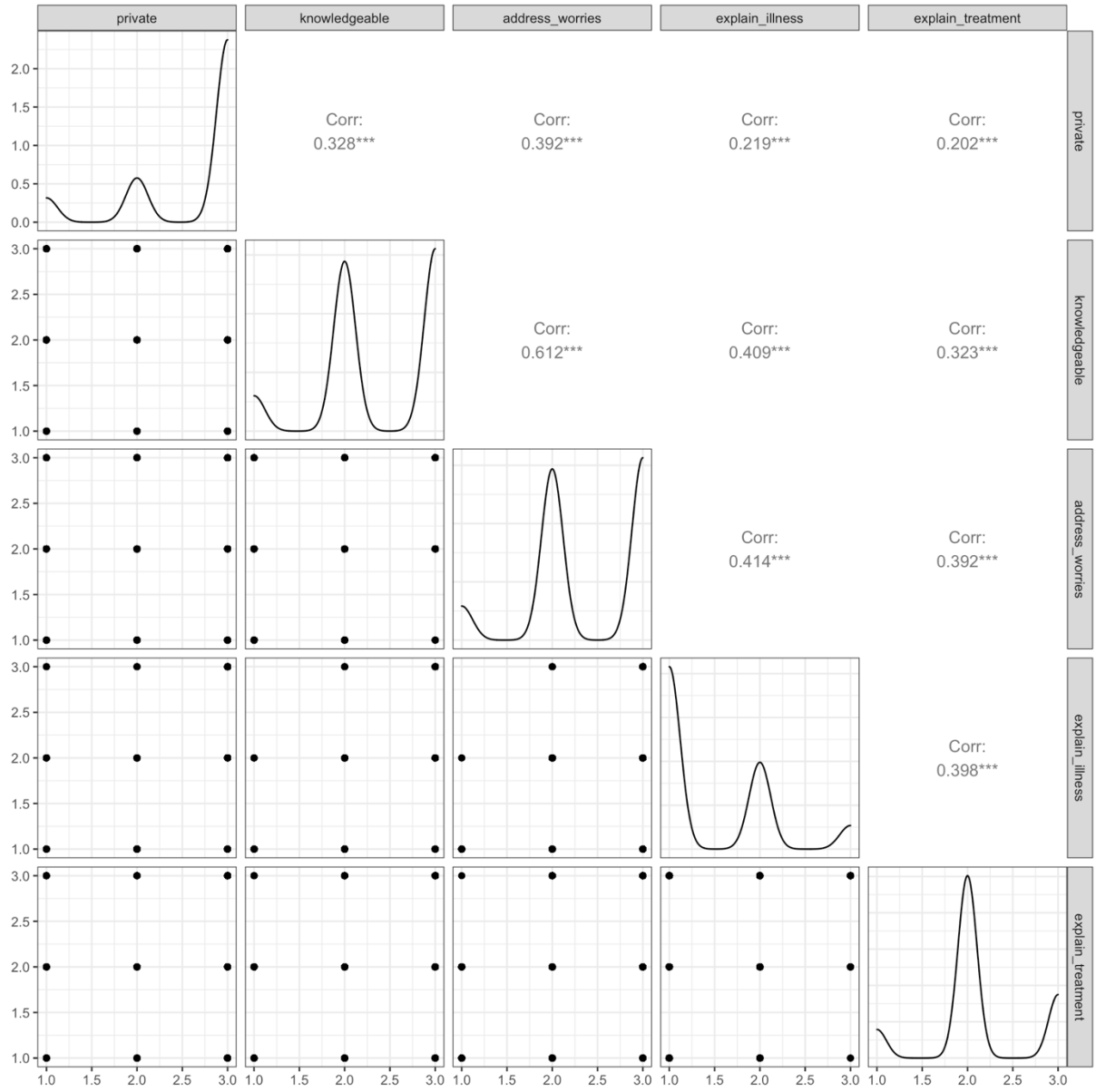


FIGURE A1.5. Correlation plot for subjective quality markers.

→ ***Linearity assumption for continuous predictors***

Overall, viewing where the majority of the data lies, each predictor shows an acceptable linear relationship with the SPs' subjective assessment index.

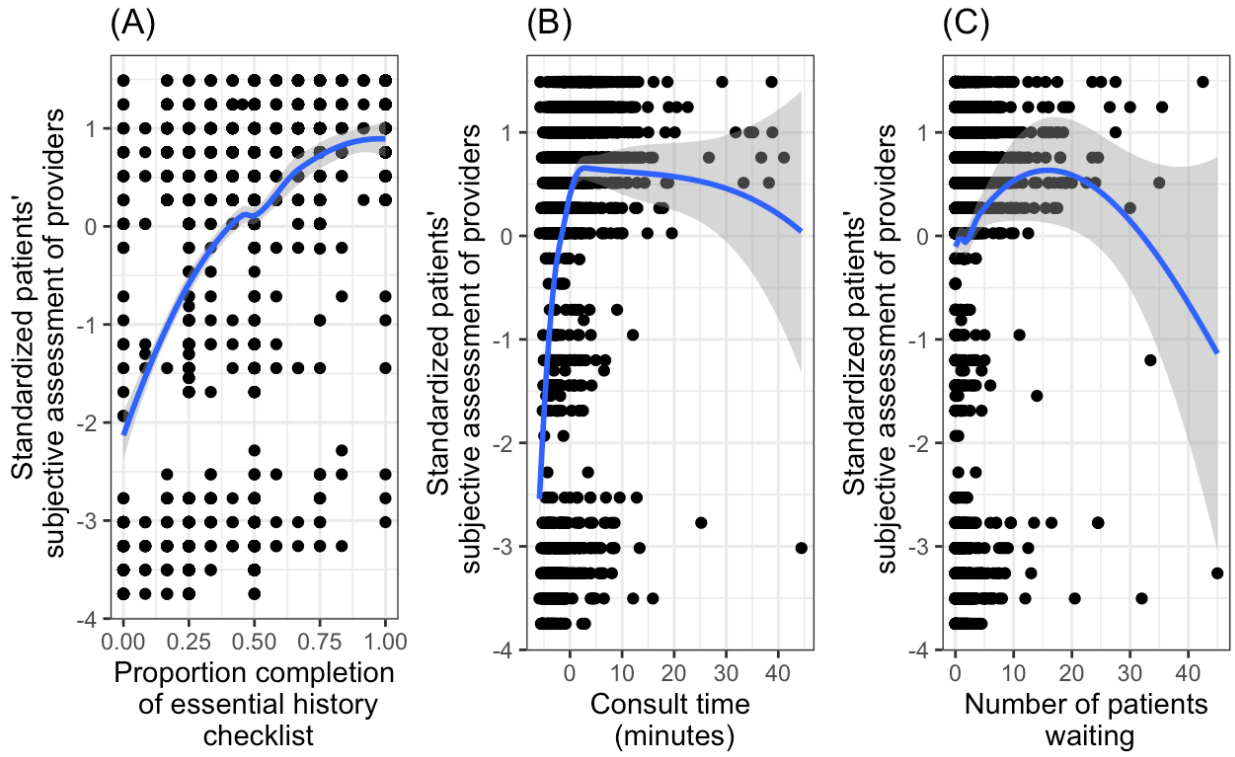


FIGURE A1.6. Investigation of linearity assumption for continuous predictors.
A LOWESS fit was applied with span = 0.75. Grey areas mark 95% confidence intervals.

→ ***Tests for model assumptions***

The assumptions for the fully adjusted mixed-effects model are each graphically represented:

1) **<u>Normality assumption</u>** for the residuals is required for both u_i and ε_i:

According to the histograms below, the residuals are nearly normally distributed, with panel A being slightly right skewed.

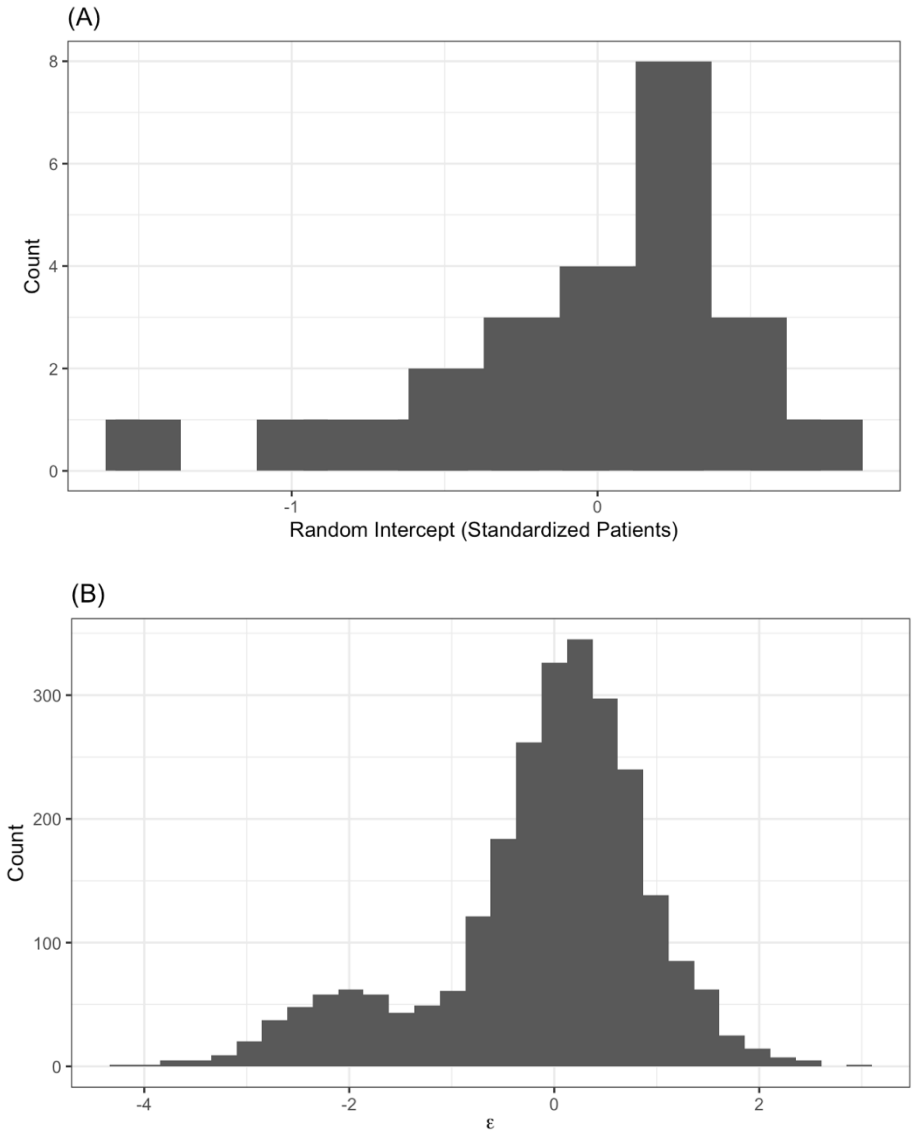
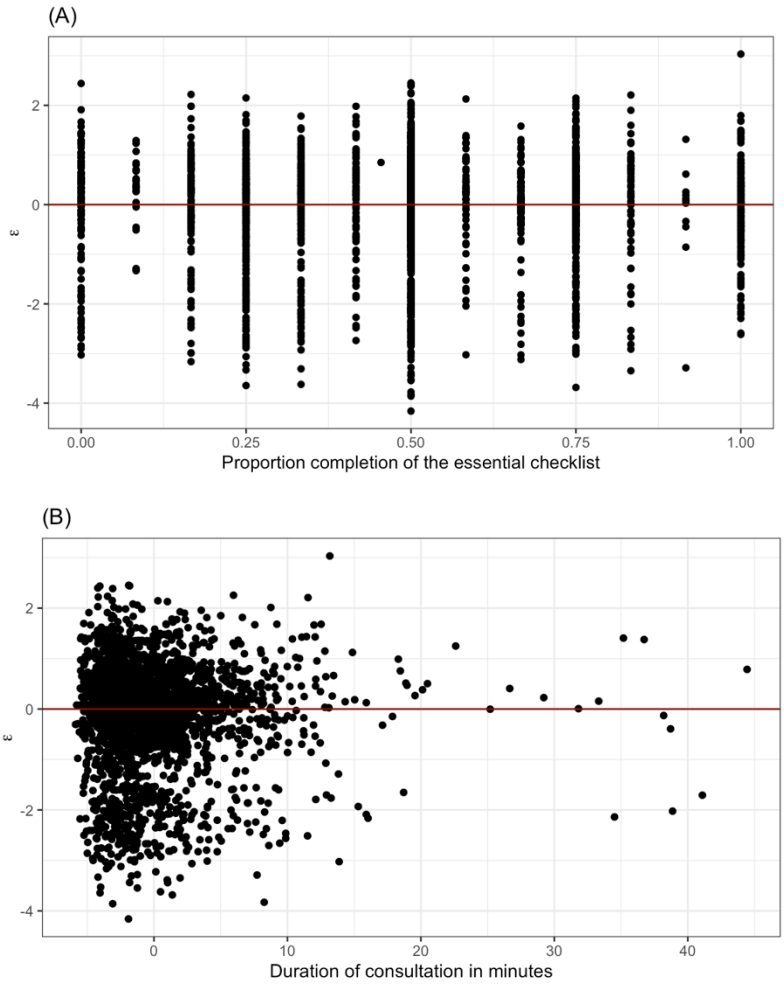


FIGURE A1.7. Verification of normality assumption of the mixed-effects model's residuals. (A) Distribution for the random intercept representing standardized patients. (B) Distribution for model errors.

2) **Constant variance assumption** for continuous measures

Overall, constant variance seems to hold true for the majority of the data. We notice that with increases in duration of consultation and number of patients, the variance decreases with larger values of x. This can be acceptable since the range for both measures were large, and observations can be expected to behave differently when falling far from the average.



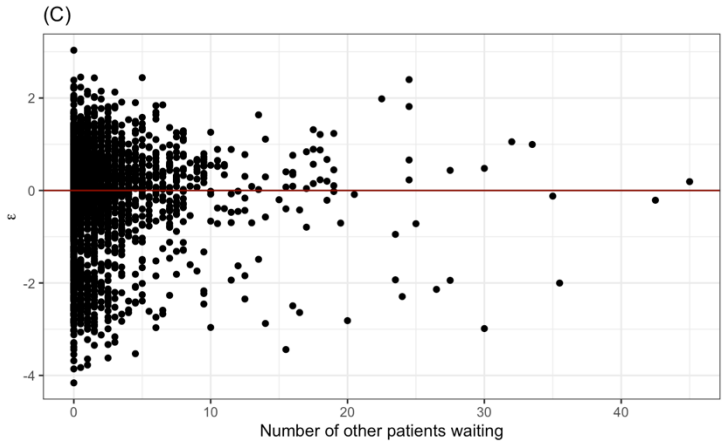


FIGURE A1.8. Verification of constant variance assumption for continuous predictors from the mixed-effects model's residuals. (A) Completion of the essential history checklist presented as a fraction; (B) Consultation time in minutes; and (C), Average number of other patients entering and exiting the facility when the standardized patient visited.

Generally, we see that the variance across SP-specific random intercepts to be constant. Even though not completely random, the pattern in acceptable.

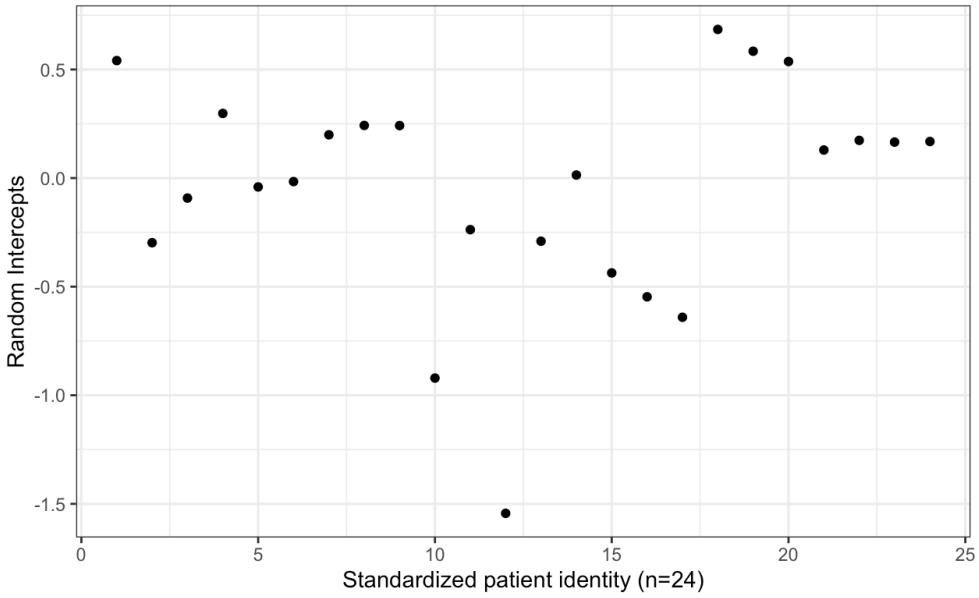


FIGURE A1.9 Verification of constant variance assumption for random intercepts for standardized patient identity.

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Chapter 5 – Discussion

5.1 Summary of findings

We used standardized patient data from Patna and Mumbai, India, to quantify the associations between objective and subjective forms of quality and identify elements of patient-centered care that serve as signals for technical quality. We sourced publicly-available data from a primary study that curated the SP method for four TB tracer conditions[25] and analyzed a total of 2,602 SP-provider medical consults that occurred in the private health sector between 2014 and 2015. We evaluated associations between objective quality and subjective quality (or client experience) primarily using an index for SPs' subjective assessment of providers which aggregated three measures. We present findings from a perspective that conforms to the SP study design, which is recognized as the gold standard method for health quality research in LMIC contexts:[25]

We conclude the following:

1. Aspects of care reflecting client experience are strong predictors of medical correctness; therefore, there exists a tangible association between subjective quality and objective quality.
    - In particular, dimensions of quality falling under therapeutic communication served as moderate signals for technical quality. This is seen with providers' commitment to provide clear explanations pertaining to illnesses. In the simple model, this marker led to a positive expected change in SPs' subjective assessment index; however, when adjusting for medical correctness, its effect is substantially decreased. Complimentarily, when adjusting for subjective quality, the expected change in the index for objective quality markers, such as when the providers posed all essential history questions, also noticeably weakened.
2. Elements of subjective quality or affecting client experience also have persisting effects, which SPs found important.
    - Positive changes in SPs' subjective assessment were relatively high in the fully adjusted model for when providers created a safe environment, appeared knowledgeable, addressed SPs' worries seriously, or provided clear explanations pertaining to treatment plans

- We also note that environmental disruptors resulted in decreases in provider scores, which remained true between simple and multiple analyses;

3. Importantly, as SPs possess knowledge on correct care, their subjective assessment of providers were still attuned to interpersonal aspects of care, which at times were higher than when providers delivered correct care or even suspected TB;
4. SPs can be used as participants in healthcare to collect patient-centred data which can be leveraged to inform policy recommendations and formulate standards for user experience measures, which are lacking for TB;
5. As witnessed in many research endeavours that aim to quantify patient input, SPs' appraisals of provider practice were generally high despite SPs' greater medical knowledge.

Our findings contribute to the TB literature and are comparable with those found in other research areas. Regarding signals of technical quality, many studies report on provider actions that lead to positive health outcomes for patients, which, in part, are a result of providers' medical competence. This was seen in a randomized control trial where the intervention physician group received training to improve their communication skills. Results showed that hypertension patients randomized to intervention doctors had greater health outcomes, which suggests patients were managed more appropriately.[42] This result resonates with other RCT studies where pooled results showed that patient-clinician relationship determined favourable health outcomes.[43]

To further highlight the value of effective communication, patient counselling or education is received positively by TB patients as reflected in their motivation to complete prescribed courses of treatment.[12,44] This association is also seen in other disease areas.[33]

Lastly, the high subjective ratings of SPs for TB care that was generally divergent from standards of care coincide with ratings seen in TB[12] and across other health conditions from 56 LMICs. This study showed that 81.3% of persons were satisfied with services from health centers that provided care that adhered less to standards than hospitals, which received a comparably lower satisfaction rating of 74.7%.[36]

5.2 Study strengths and limitations

We inferred associations using SP data for diagnostic care wherein adult SPs visited a city-representative random selection of private providers. Due to our use of SP data, our conclusions are especially compelling. First, SPs are experts in reliably conveying TB case presentations and can recall interaction information with minimal error, thereby allowing the collection of valid measures. Second, echoing previous work, SP recruits' physical appearances and scripts closely reflected the general population's age and education distributions, ultimately lending credence to the generalizability of our findings. [23,40] Furthermore, although official records of TB notifications in the public health sector continue to surpass those in the private sector,[45] evidence from TB drug sales supports that the private sector manages a larger volume of TB patients than is documented.[14] Because we used data from the private sector, our conclusions have implications for informing private-sector policy. Previous work using this dataset justified that the allocation of SP gender is comparable to being randomized across providers.[23] This finding implies that our results on SPs' subjective assessment of providers originate just as equally from each gender group (measured as binary). Lastly, maintaining patient engagement is critical for TB. For this reason, first consults with providers are particularly important, which SP data mirrors.

Nonetheless, we must also consider some limiting factors in our conclusions. The primary study was not specifically designed to address our objectives here; the SP training modules may therefore not have been foolproof, e.g., SPs may have been unsure whether they should be reporting subjective impressions on behalf of themselves or as the TB patient they were portraying.[46] SPs are also systematically different from patients, which has implications for our overall interpretations. For instance, wait time and duration of consult did not substantially impact SPs' assessment of providers. A reason behind this may be because SPs were employees; therefore, they did not feel their day was disrupted by coming to the clinic. Furthermore, SPs visited multiple providers over the course of the data collection period. Typically, the time spent with providers is recorded to be five minutes in India, [38] which is also supported by our SP data. SPs, having repeatedly undergone interactions lasting around that amount of time, were likely to be desensitized to it. Furthermore, SPs' narratives were designed to depict the average health user; thus, we do not know how marginalized members of society would fare and/or critique provider practice. Moreover, the cross-sectional, one-interaction fabric of the SP methodology

precludes its ability to assess measures throughout the continuum of care. As mentioned, initial impressions regarding the first point-of-contact provider are important, but some dimensions of care, such as the subjective experience with disclosure of sensitive test results are still not possible to measure with the current form of the SP design. Another limitation is how our global assessment scale tool comprised solely positively-worded questions. Using random assignment, Dunsch et al. (2018) have statistically shown that the wording of questions can influence patients' responses such that a 19-percentage point difference can be observed between positively and negatively-framed questions.[18]

5.3 Future directions

In future SP studies aimed at studying the association between technical care and subjective care, subjective questions should include a mix of positively- and negatively-framed questions that contain factual information to avoid inflations or deflations in responses, respectively. Furthermore, the SP method offers a modality for teaching that can be leveraged to define context-specific user expectations that could then translate to their subjective assessment of providers. Reinforcing the baseline level of expectations is also important, as over the course of the study, SPs' expectation levels are likely to shift throughout. Therefore, it would also be advisable to organize refresher training sessions to maintain baseline expectation levels.

SPs were functionally a part of the research team and, consequently, they were exposed to standards of TB medical practice. It would be important to quantify this knowledge threshold to properly identify the importance SPs are placing on correct care. Collection of qualitative data to support SPs' quantitative perceptions is also an advisable avenue to explore in forthcoming SP studies. For example, a number of interactions (n=677) indicated that SPs deemed providers to be very knowledgeable even if they did not suspect the onset of TB. Moreover, although subjective provider scores generally shared a positive association with subjective quality (or client experience), there were still exceptional cases in which medical providers delivered appropriate care but to whom SPs attributed a negative assessment, and vice versa. Thus, the global assessment scale could benefit from the inclusion of open-ended questions to address such uncertainties. Furthermore, as our work was limited to the urban-private health sector, there is

the possibility to expand the scope of this analysis to encompass rural settings and the public sector.

5.4 Conclusions

Our results recognize an association between objective and subjective forms of quality. Most notably, measures for subjective quality have shown to serve as indicators of medical competence and to be valued by clients. Our findings also highlight the importance of communication between patients and providers, which SPs deemed valuable even though they were not naïve to definitions for correct care.

As our data source was from a primary study, there is room to broaden the scope and expand the collection of subjective measures to better understand associations between different forms of quality. To this end, future SP studies would be required to define these specific areas.

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