Use of standardised patients to assess quality of tuberculosis care: a pilot, cross-sectional study

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Summary

Background Existing studies of the quality of tuberculosis care have relied on recall-based patient surveys, questionnaire surveys of knowledge, and prescription or medical record analysis, and the results mostly show the health-care provider's knowledge rather than actual practice. No study has used standardised patients to assess clinical practice. Therefore we aimed to assess quality of care for tuberculosis using such patients.

Methods We did a pilot, cross-sectional validation study of a convenience sample of consenting private health-care providers in low-income and middle-income areas of Delhi, India. We recruited standardised patients in apparently good health from the local community to present four cases (two of presumed tuberculosis and one each of confirmed tuberculosis and suspected multidrug-resistant tuberculosis) to a randomly allocated health-care provider. The key objective was to validate the standardised-patient method using three criteria: negligible risk and ability to avoid adverse events for providers and standardised patients, low detection rates of standardised patients by providers, and data accuracy across standardised patients and audio verification of standardised-patient recall. We also used medical vignettes to assess providers' knowledge of presumed tuberculosis. Correct case management was benchmarked using Standards for Tuberculosis Care in India (STCI).

Findings Between Feb 2, and March 28, 2014, we recruited and trained 17 standardised patients who had 250 interactions with 100 health-care providers, 29 of whom were qualified in allopathic medicine (ie, they had a Bachelor of Medicine & Surgery [MBBS] degree), 40 of whom practised alternative medicine, and 31 of whom were informal health-care providers with few or no qualifications. The interactions took place between April 1, and April 23, 2014. The proportion of detected standardised patients was low (11 [5%] detected out of 232 interactions among providers who completed the follow-up survey), and standardised patients' recall correlated highly with audio recordings (r=0·63 [95% CI 0·53–0·79]), with no safety concerns reported. The mean consultation length was 6 min (95% CI 5·5–6·6) with a mean of 6·18 (5·72–6·64) questions or examinations completed, representing 35% (33–38) of essential checklist items. Across all cases, only 52 (21% [16–26]) of 250 were correctly managed. Correct management was higher among MBBS-qualified doctors than other types of health-care provider (adjusted odds ratio 2·41 [95% CI 1·17–4·93]; p=0·0166). Of the 69 providers who completed the vignette, knowledge in the vignettes was more consistent with STCI than their actual clinical practice—eg, 50 (73%) ordered a chest radiograph or sputum test during the vignette compared with seven (10%) during the standardised-patient interaction; OR 0·04 (95% CI 0·02–0·11); p<0·0001.

Interpretation Standardised patients can be successfully implemented to assess tuberculosis care. Our data suggest a big gap between private provider knowledge and practice. Additional work is needed to substantiate our pilot data, understand the know-do gap in provider behaviour, and to identify the best approach to measure and improve the quality of tuberculosis care in India.

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Introduction

India accounts for a quarter of the 9 million estimated cases of tuberculosis that occur worldwide, and for 1 million of the 3 million missing cases (ie, undiagnosed or not reported to tuberculosis control programmes).[1] India's tuberculosis burden is exacerbated by fragmented provision of health care through diverse providers, and an unregulated private sector that accounts for half of the provision of tuberculosis treatment.[2,3] The private sector includes qualified allopathic doctors (eg, Bachelor of Medicine and Surgery [MBBS] degree), practitioners of alternative health systems (eg, ayurveda), and informal providers with few or no formal qualifications.

Data from India have raised concerns about the poor quality of medical care in general.[4–7] Results of a systematic review[8] showed that in most Indian studies, less than half of providers knew to order sputum microscopy tests for patients with symptoms of tuberculosis, and less than a third knew the correct treatment regimen. Adherence to International Standards for Tuberculosis Care (ISTC) was significantly lower in the private sector than in the public sector.[8] Results of studies about patient pathways for tuberculosis have shown convoluted paths,[9] with patients

Research in context

Evidence before this study

We did a systematic review of PubMed, Embase, and the Web of Science with the search terms "tuberculosis", "knowledge", "practice", "health-care providers", and "India", with no language restrictions, for studies published between January, 2000, and September, 2014. We found that in most studies in India, less than half of health-care providers knew to order sputum microscopy tests for patients with symptoms of tuberculosis, and less than a third knew the correct treatment regimen for this disease. Additionally, the quality of care for patients with suspected or confirmed tuberculosis was worse in the private sector than in the public sector. Existing studies of quality of tuberculosis care in India and elsewhere have relied on recall-based patient surveys, questionnaire surveys of knowledge, and analysis of prescription or medical records. No study has used standardised (simulated) patients to assess actual clinical practice.

Added value of this study

Our study is the first assessment of quality of care for tuberculosis using the standardised-patient method. The results suggest that this method can be successfully implemented for tuberculosis. Our pilot data suggest low adherence of providers to established standards of tuberculosis care in clinical practice despite markedly high levels of knowledge.

Implications of all the available evidence

Previously published data and our results show a big gap between what health-care providers know about tuberculosis, and what they actually do in their clinical practice. Future iterations of the standardised-patient method might help with the design of programmes to control tuberculosis, and monitoring and assessment of indicators for quality of tuberculosis care.

seeing a median of three health-care providers (range 2–12) over a median of 55 days (IQR 47–62) from onset of symptoms to diagnosis and treatment.[10]

Studies of quality of tuberculosis care in India and elsewhere have relied on recall-based patient surveys, questionnaire surveys of knowledge, and analysis of prescription and chart records,[8] but these methods might not be an accurate representation of actual practice.[4,6,11–14] Consequently, standardised patients—ie, people who have been trained to portray, in a standardised way, patients in a medical situation—are increasingly used in low-income countries to assess quality of medical care, as shown by studies from India and China.[5,6,13] By comparison with other methods, data from standardised patients yield an assessment of provider practice that is free from observation bias, are less susceptible to recall bias than patient exit interviews, and are more complete than medical records.[14,15] Furthermore, standardised patients enable estimation of case-detection rates because illnesses are fixed by design. Finally, because case presentations are standardised, the standardised-patient method enables valid quality comparisons to be made across different types of health-care providers. We therefore did a pilot validation study of the standardised-patient method to assess the quality of tuberculosis care in the private sector in New Delhi.

Methods

Study design and participants

See Online for appendix

This pilot, cross-sectional study was done in Delhi. In an urban setting, the risk of detecting standardised patients is small because many patients are unknown to health-care providers. Apparently healthy individuals were recruited to be standardised patients, and intensively screened and trained for 3 weeks. These standardised patients included both individuals who had participated in previous studies and new recruits. A convenience sample of 106 private health-care providers practising in outpatient settings was recruited in low-income and middle-income areas of Delhi. High-income areas were excluded. All recruited providers were informed that over the subsequent 6 months they might receive someone who is not a real patient, and if they suspected any of their patients to not be genuine, they should record the name of the patient and date of the visit. We randomly allocated standardised patients to providers stratified by case and sex, using Stata analysis software (version 13 [StataCorp, TX, USA]). Within 1 h of each interaction between the standardised patient and health-care provider, we used a structured questionnaire to extract information from the standardised patient about what each provider had done.

We obtained ethical approvals from McGill University in Montreal, and the Institute of Socio-Economic Research on Development and Democracy (ISERDD) in Delhi. Written informed consent was obtained from all recruited providers (including the use of audio recorders), and confidentiality was assured. No consent was required for standardised patients because they were employees. The questionnaires, case scripts, checklists, and vignettes are available from the authors on request.

Procedures

We developed four tuberculosis tracer scenarios (cases; table 1; appendix) with a group of international and Indian experts on tuberculosis, using the Standards for Tuberculosis Care in India (STCI) as the benchmark.[16] The STCI itself is based on the ISTC.[17] Although many standards exist, the expert group focused on the most important aspects of detection and treatment of tuberculosis, and helped to put together case-specific checklists of essential and recommended treatments (ie, the expected

	Case description	Presentation of patient	Expected correct case management
Standardised patient 1	Classic case of presumed tuberculosis with 2–3 weeks of cough and fever	Presents with presumptive tuberculosis, for the first time, to a private health-care provider	Recommendation for sputum testing, chest radiograph, or referral to a public DOTS centre or qualified provider
Standardised patient 2	Classic case of presumed tuberculosis in a patient who has had 2–3 weeks of cough and fever and a history of taking a broad-spectrum antibiotic (amoxicillin) for 1 week, given by another health-care provider, with no improvement	Presents after an initial, failed (empirical) treatment for symptoms with broad-spectrum antibiotics	Recommendation for sputum testing, chest radiograph, or referral to a public DOTS centre or qualified provider
Standardised patient 3	Chronic cough with a positive sputum smear report for tuberculosis from a public health facility	Presents with evidence of microbiologically confirmed tuberculosis	Either referral to a public DOTS centre, a qualified private provider or specialist, or (in the case of a qualified private provider) initiation of treatment with standard, four-drug, first-line antituberculosis therapy (isoniazid, rifampicin, pyrazinamide, and ethambutol [the HRZE regimen])
Standardised patient 4	Chronic cough, a positive sputum smear report for tuberculosis from a public health facility, and, if asked, a history of previous, incomplete treatment for tuberculosis, which would raise the suspicion of multidrug-resistant tuberculosis.	Presents as a previously treated patient with tuberculosis with recurrence of the disease (ie, suspicion of drug resistance)	Recommendation for any drug-susceptibility test (culture, line probe assay, or Xpert MTB/RIF) or referral to a public DOTS centre or a specialist

DOTS=directly observed treatment, short-course.

Table 1: **Standardised-patient cases and expected correct case management**

correct case management; table 1). The scenarios roughly outlined the pathways for tuberculosis care in the country. The medical representations of the tracer scenarios were further enhanced with the psychosocial aspects of tuberculosis presentation in the community. These so-called tuberculosis scripts were developed by social scientists with the help of the recruited standardised patients to make the diagnosis as obvious and uncomplicated as possible. For instance, in the case of standardised patient 1, appropriate questioning would reveal that the patient has had a cough for 2–3 weeks, produces sputum, has fever with night sweats, and has lost appetite and weight. According to STCI, this should lead the provider to suspect tuberculosis and order appropriate microbiological tests or refer the patient for tuberculosis testing. All scripts were translated into Hindi, the vernacular language. Script development and standardised-patient training methods are described in the appendix. All standardised patients paid the providers their usual fee.

We assessed quality of care through health-care providers' adherence to case-specific checklists of recommended care, the appropriateness of treatment, and the use of unnecessary or contraindicated treatments (eg, steroids). The checklists for recommended care include only items that can be completed in low-resource settings and are in accord with the STCI.[16] The list of recommended questions, and the subset that was regarded as essential, are in the appendix. Additionally, we obtained data about the duration and cost of the consultation, and medicines for each interaction. Costs were calculated in 2014 Indian rupees and 2014 US dollars (rate, 1 US dollar=62·27 Indian rupees). Purchasing-power-parity adjustment would result in an exchange rate of 16·76 rupees per dollar. Costs were the fee paid at the time of the interaction to the provider plus prices for medicines and did not include laboratory tests or other fees for procedures that standardised patients did not complete. Finally, the interactions recorded with digital recorders by randomly selected (with Stata version 13) standardised patients were used to assess accuracy of patient recall, measured using a structured recall questionnaire.[18]

3–4 weeks after the completion of standardised-patient visits, we visited the participating providers and asked whether they suspected any fake patients at their clinics, and if so, to describe the presenting symptoms, age, and sex of the suspected standardised patient. These data were used to assess detection rates. Additionally, providers were tested using a medical vignette that described exactly the same case scenario as standardised patient 1 (2–3 weeks of cough). The vignette started with the opening statement from standardised patient 1, and the provider was asked to proceed exactly as they might with a real patient. This vignette was used to assess knowledge of diagnosis and treatment for standardised patient 1 and to compare the providers' knowledge in the vignette with what they did in practice with the standardised patient.

Outcomes

The key objective was to validate the standardised-patient method for assessing the quality of tuberculosis care in the private sector using three criteria: negligible risk and ability to avoid adverse events for providers and standardised patients, low detection rates of standardised patients by providers, and data accuracy across standardised patients and audio verification of standardised patient recall.

Statistical analysis

After the data were compiled, the list of labelled medicines and prescriptions given by the health-care providers to the standardised patients were coded by two doctors with expertise in tuberculosis (SS) and infectious diseases (RS) working independently of one another, who then identified drugs as antituberculosis drugs, antibiotics

(other than tuberculosis drugs), or steroids. Among the antibiotics, we specifically coded fluoroquinolones as a distinct category, in view of their ability to mask underlying tuberculosis. We did not code other drug classes (eg, bronchodilators or cough suppressants) that had been prescribed or dispensed because they had no direct bearing on tuberculosis care. We employed two independent pharmacists to identify any loose, unlabelled pills that had been given to the standardised patients, and on the basis of their assessments we identified whether the medicines included at least one antibiotic. Because chemical analysis is expensive and could not be done, we report the proportion of interactions in which an antibiotic was used in labelled and unlabelled pills separately.

We used logistic regression to assess associations between provider qualifications and various components of case management for all four standardised patient cases combined. These components included the following: an overall index of correct case management aggregated across all cases; individual components of case management (referrals for all cases, recommendations for chest radiographs, or sputum tests for standardised patients 1 and 2, and initiation of tuberculosis treatment for standardised patients 3 and 4); and the use of antibiotics and fluoroquinolones for all cases. We report results as adjusted odds ratios (ORs) for MBBS-qualified versus non-MBBS-qualified providers (rationale in the appendix). All regression models included the age and sex of the provider, the number of real patients waiting at the time when the standardised patient entered the clinic (as an index of patient caseload), and standardised patient and case fixed-effects. Additional specifications with standardised patients' age, sex, height, and weight as independent variables instead of the case fixed-effects are in the appendix. We used both *t* tests and logistic regression to assess the gap between provider knowledge elicited through medical vignettes for standardised patient 1 and provider practice measured with all standardised patients. The differences are the result of *t* tests comparing the vignette performance with the standardised-patient performance for each item as a percentage or total difference. Some differences are

	Standardised patient 1	Standardised patient 2	Standardised patient 3	Standardised patient 4	All standardised patients
Patient–provider interactions	75	75	50	50	250
Time with provider (min)	5·96 (5·19–6·73)	4·27 (3·62–4·91)	8·04 (6·10–9·99)	6·64 (5·49–7·79)	6·00 (5·45–6·56)
Number of questions and examinations	6·31 (5·56–7·05)	5·93 (5·13–6·73)	5·60 (4·57–6·63)	6·94 (5·68–8·21)	6·18 (5·72–6·64)
% of essential history checklist asked by provider	36% (32–40)	32% (27–37)	46% (40–51)	30% (25–36)	35% (33–38)
Cost of consultation and medicines combined (Indian rupees)*	133·68 (107·01–160·35)	130·96 (107·52–154·39)	150·29 (101·24–199·35)	156·32 (115·99–196·64)	140·71 (124·46–156·96)
Cost of consultation and medicines combined (US dollars)*	2·14 (1·71–2·57)	2·10 (1·72–2·47)	2·40 (1·62–3·19)	2·50 (1·86–3·15)	2·25 (1·99–2·51)
Case management					
Correctly managed the case†	9 (12%, 6–21)	13 (17%, 10–27)	19 (38%, 26–52)	11 (22%, 13–35)	52 (21%, 16–26)
Ordered a chest radiograph	7 (9%, 5–18)	9 (12%, 6–21)	18 (36%, 24–50)	22 (44%, 31–58)	56 (22%, 18–28)
Ordered a sputum test	3 (4%, 1–11)	5 (7%, 3–15)	3 (6%, 2–16)	3 (6%, 2–16)	14 (6%, 3–9)
Ordered drug-susceptibility test or Xpert MTB/RIF (GeneXpert)	0 (0%, 0–5)	0 (0%, 0–5)	1 (2%, 0·4–11·0)	1 (2%, 0·4–11·0)	2 (1%, 0·2–2·9)
Started patient on treatment for tuberculosis	0 (0%, 0–5)	0 (0%, 0–5)	7 (14%, 7–26)	4 (8%, 3–19)	11 (4%, 2–8)
Referred the case	2 (3%, 0·7– 9·2)	1 (1%, 0·2– 7·2)	13 (26%, 16–40)	10 (20%, 11–33)	26 (10%, 7–15)
Asked patient to return	56 (75%, 64–83)	59 (79%, 68–86)	34 (68%, 54–79)	41 (82%, 69– 90)	190 (76%, 70–81)
Tests and medicines given					
Number of laboratory tests done	0·25 (0·08–0·43)	0·35 (0·16–0·53)	0·82 (0·51–1·13)	0·98 (0·63–1·33)	0·54 (0·42–0·66)
Number of medicines given or prescribed	4·85 (4·52–5·19)	5·05 (4·75–5·36)	3·86 (3·15–4·57)	3·64 (2·95–4·33)	4·47 (4·23–4·72)
Gave any labelled antibiotic	48 (64%, 53–74)	41 (55%, 43–65)	18 (36%, 24–50)	19 (38%, 26–52)	126 (50%, 44–57)
Gave any antibiotic‡	66 (88%, 79–94)	58 (77%, 67–85)	26 (52%, 39–65)	24 (48%, 35–61)	174 (70%, 64–75)
Gave any fluoroquinolone	12 (16%, 9–26)	9 (12%, 6–21)	5 (10%, 4–21)	8 (16%, 8–29)	34 (14%, 10–18)
Gave any steroid	6 (8%, 4–16)	10 (13%, 7–23)	3 (6%, 2–16)	4 (8%, 3–19)	23 (9%, 6–13)

Data are mean (95% CI) or n (%, 95% CI). *2014 costs. †Defined as a chest radiograph, sputum test, or referral (for standardised patients 1 and 2), isoniazid, rifampicin, pyrazinamide, and ethambutol (the HRZE regimen), or referral (for standardised patient 3), and a drug-susceptibility test, GeneXpert, or referral (for standardised patient 4). ‡Labelled antibiotic use is a lower bound estimate because only identified drugs were included. Any antibiotic use also includes cases for which an unlabelled medicine was identified as an antibiotic by chemists who were specifically recruited to identify unlabelled medicines.

Table 2: **Main outcomes of interactions with standardised patients**

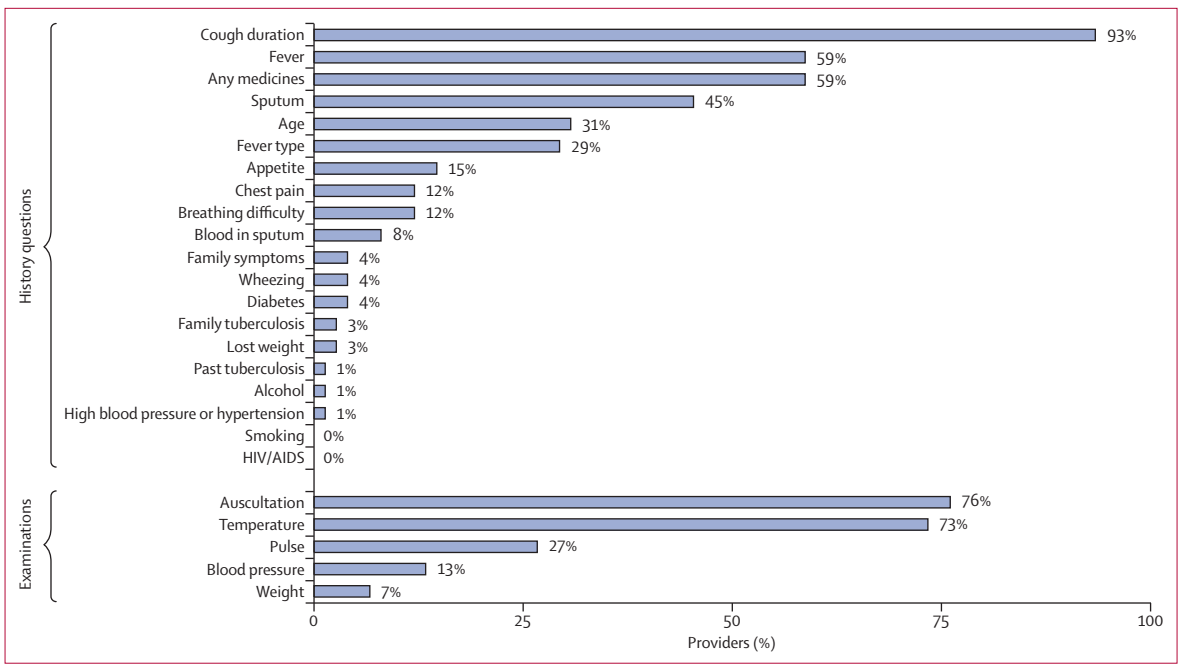

Figure 1: **Proportion of providers who completed history and physical examinations for standardised patient 1 cases (n=75 interactions)**
Standardised patient 1 presented as a classic case of presumed tuberculosis with 2–3 weeks of cough and fever. Each bar shows the proportion of providers who asked the corresponding question or completed the corresponding examination. For instance, 93% of all providers asked about cough duration and 76% of all providers auscultated the patient.

inexact because of rounding. We report ORs as estimated by logistic regression where computable. We used the Wilson interval without continuity correction for binary variables. We analysed all data with Stata version 13.

Role of the funding source

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

Results

Between Feb 2, and March 28, 2014, we screened 22 individuals and randomly assigned 17 as standardised patients across 100 health-care providers for a total of 250 interactions (appendix). Six providers were kept as reserves. The interactions took place between April 1 and April 23, 2014. 97 (97%) of 100 providers were male with a mean age of 47 years (SD 10·37, range 22–75). 29 (29%) had an MBBS degree (qualified allopathic doctors), 40 (40%) held degrees in alternative systems of medicine, and the remaining 31 (31%) were informal health-care providers with few or no qualifications. A mean of 1·27 patients (SD 2·25) were waiting in the clinic at the time of the standardised-patient visit.

93 providers completed the detection survey and participated in 232 of the 250 interactions (we obtained survey data between May 22 and June 13, 2014).

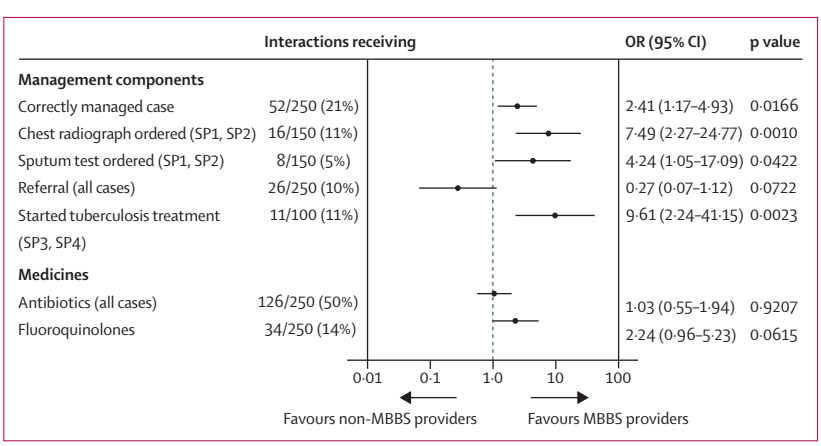

Figure 2: **Effect of provider qualifications on main standardised-patient outcomes**
Adjusted ORs of providing correct case management (defined in table 1) for 71 interactions with MBBS-qualified providers versus 179 interactions with providers without an MBBS. The antibiotics measure is a lower bound estimate because only identified drugs are included. Drug-susceptibility testing and Xpert MTB/RIF (GeneXpert) are excluded from regression because their incidences were too low for statistical inference. Regressions are controlled for provider age, provider sex, and provider's caseload on arrival of the standardised patient, and case and individual fixed-effects. MBBS=Bachelor of Medicine and Surgery. OR=odds ratio.

Eight providers reported 11 (5%) detections. Of the 11 detections, seven were reported to have occurred during the visit, although in none of the cases did the provider voice suspicion during the interaction with the standardised patient, and four were reported after the completion of the interaction, mainly because the standardised patient did not return for follow-up. In 14 (6%) of 232 cases, providers mistook real patients to be standardised patients.

	Interactions with MBBS providers	Interactions with non-MBBS providers	Odds ratio (95% CI)	p value
Management components				
Correctly managed the case	21/71 (30%)	31/179 (17%)	2·41 (1·17–4·93)	0·0166
Chest radiograph ordered (SP1, SP2)	12/43 (28%)	4/107 (4%)	7·49 (2·27–24·77)	0·0010
Sputum test ordered (SP1, SP2)	5/43 (12%)	3/107 (3%)	4·24 (1·05–17·09)	0·0422
Referral (all cases)	2/71 (3%)	24/179 (13%)	0·27 (0·07–1·12)	0·0722
Started tuberculosis treatment (SP3, SP4)	8/28 (29%)	3/72 (4%)	9·61 (2·24–41·15)	0·0023
Medicines				
Antibiotics (all cases)	36/71 (51%)	90/179 (50%)	1·03 (0·55–1·94)	0·9207
Fluoroquinolones	13/71 (18%)	21/179 (12%)	2·24 (0·96–5·23)	0·0615

Data are interactions receiving outcome/total possible interactions (%). SP=standardised patient.

Table 3: **Main standardised-patient outcomes stratified by provider qualifications**

None of the 93 providers who completed the detection survey voiced concern that participation in the study adversely affected them. Additionally, no financial losses were incurred by providers because the standardised patients paid normal fees to receive services, and there were no added inconveniences to the provider because standardised patients were trained to immediately step aside if an emergency occurred in the clinic that demanded the provider's attention. None of the 17 standardised patients had any threats to their safety.

129 interactions were recorded by six randomly selected standardised patients. Data from the audio recordings were highly correlated with data from the structured recall questionnaires (r=0·63, 95% CI 0·53–0·79).

The mean standardised-patient interaction lasted 6 min, with a mean payment of 140·71 rupees (95% CI

	Desired or unnecessary procedure/interaction	Performance in vignettes (n=69)	Performance with standardised-patient 1 (n=69)	Percentage or total difference (% or n [95% CI])	Odds ratio	
					OR (95% CI)	p value
Mentioned tuberculosis	Desired	39 (60%)	5 (7%)	–52·8% (–66·1 to –39·4)	0·05 (0·02–0·15)	<0·0001
Medicines given or prescribed for patients	..	3·01 (2·03)	4·86 (1·46)	1·84 (1·25–2·43)	..	..
Gave any antibiotic	Unnecessary	48 (70%)	44 (64%)	–5·8% (–21·8 to 10·2)	0·77 (0·38–1·57)	0·4705
Referred the case	Desired	20 (29%)	2 (3%)	–26·1% (–37·7 to –14·5)	0·07 (0·02–0·33)	0·0006
Completed examinations and laboratory assessments						
Chest radiograph	Desired	47 (68%)	7 (10%)	–58·0% (–71·3 to –44·7)	0·05 (0·02–0·13)	<0·0001
Sputum acid-fast bacillus test	Desired	31 (45%)	3 (4%)	–40·6% (–53·5 to –27·7)	0·06 (0·02–0·19)	<0·0001
Chest radiograph and sputum test	Desired	28 (41%)	3 (4%)	–36·2% (–49·0 to –23·5)	0·07 (0·02–0·23)	<0·0001
Chest radiograph or sputum test	Desired	50 (73%)	7 (10%)	–62·3% (–75·3 to –49·5)	0·04 (0·02–0·11)	<0·0001
Auscultation	Desired	21 (30%)	51 (74%)	43·5% (28·2–58·7)	6·48 (3·08–13·61)	<0·0001
Temperature	Desired	35 (51%)	51 (74%)	23·2% (7·2–39·2)	2·75 (1·35–5·63)	0·0055
Weight	Desired	10 (14%)	5 (7%)	–7·3% (–17·7 to 3·2)	0·46 (0·15–1·43)	0·1793
Xpert MTB/RIF (GeneXpert)	Desired	0	0	..	..	..
HIV test	Desired	0	0	..	..	..
Diabetes test	Desired	1 (1%)	2 (3%)	1·5% (–3·5 to 6·4)	2·03 (0·18–22·92)	0·5670
Tuberculosis QuantiFERON-TB Gold test	Unnecessary	2 (3%)	0	–2·9% (–6·9 to 1·1)	..	..
Tuberculosis ELISA test	Unnecessary	0	0	..	..	..
Mantoux test	Unnecessary	24 (35%)	1 (1%)	–33·3% (–45·1 to –21·6)	0·03 (0·00–0·21)	0·0005
Completed history questions						
Duration of cough	Desired	63 (91%)	65 (94%)	2·9% (–5·9 to 11·7)	1·55 (0·42–5·75)	0·5141
Produced sputum	Desired	46 (67%)	32 (46%)	–20·3% (–36·8 to –3·8)	0·43 (0·22–0·86)	0·0171
Past tuberculosis	Desired	4 (6%)	1 (1%)	–4·4% (–10·6 to 2·0)	0·24 (0·03–2·19)	0·2058
Family tuberculosis	Desired	4 (6%)	2 (3%)	–2·9% (–9·8 to 4·0)	0·49 (0·09–2·74)	0·4128
Blood in sputum	Desired	16 (23%)	6 (9%)	–14·5% (–26·7 to –2·3)	0·32 (0·12–0·86)	0·0247
Fever duration	Desired	51 (74%)	42 (61%)	–13·0% (–28·8 to 2·7)	0·55 (0·27–1·13)	0·1040
Loss of appetite	Desired	21 (30%)	11 (16%)	–14·5% (–28·6 to –0·4)	0·43 (0·19–0·99)	0·0467
Weight loss	Desired	17 (25%)	2 (3%)	–21·7% (–32·8 to –10·7)	0·09 (0·02–0·41)	0·0019
Taken any medicine	Desired	35 (51%)	42 (61%)	10·1% (–6·6 to 26·9)	1·51 (0·77–2·97)	0·2311

Data are n (%) or mean (SD), unless otherwise specified. Percentages represent the proportion of providers who did that item during a standardised-patient visit or vignette.

Table 4: **Know-do gap: vignettes versus interactions with standardised patient 1 among the same providers**

124–157; roughly US$2·25 [1·99–2·51]; table 2). Providers completed a mean of 6·18 (95% CI 5·72–6·64) questions or examinations per interaction, representing 35% (33–38) of the essential checklist (table 2). Standardised patients 1 and 2 were the classic presumptive patients with tuberculosis, and the use of chest radiographs, sputum tests, and referral rates were lower than the existing standards recommend. Correct case management was given by only nine (12%, 95% CI 6–21) of 75 providers for standardised patient 1 and only slightly more providers (13 [17%, 10–27] of 75) gave correct case management for standardised patient 2. Antibiotic use was high: at least 48 (64%; 95% CI 53–74) of 75 standardised-patient-1 cases and 41 (55%; 43–65) of 75 standardised-patient-2 cases received labelled antibiotics and 66 (88%; 79–94) and 58 (77%; 67–85) of standardised patients 1 and 2, respectively, received any antibiotic once unlabelled medicines were taken into account.

Although standardised patients 3 and 4 both had laboratory reports that microbiologically confirmed a diagnosis of tuberculosis, a large proportion of these patients were recommended chest radiographs (table 2). The proportion of cases that were correctly managed was highest for standardised patient 3, with seven (14%, 7–26) of 50 started on tuberculosis treatment and 13 (26%, 16–40) referred to the directly observed treatment short-course (DOTS) centre or qualified providers, but the proportion referred to a DOTS centre or a qualified provider fell to ten (20%, 11–33) of 50 for standardised patient 4, showing both the low use of drug-susceptibility tests that are necessary for investigations of a patient with recurrent tuberculosis, and low referrals to the public sector. The low proportions of correct case management are also partly a result of the low use of essential and recommended actions (figure 1; appendix). In the case of standardised patient 1, for instance, although most providers asked about cough duration, auscultated the chest, and measured temperature, few checked weight or blood pressure and few asked about blood in their sputum.

Individual pathways to diagnosis and treatment were complex. The different actions that the four standardised-patient cases encountered are in the appendix. Broad-spectrum antibiotics were widely given for standardised patients 1 and 2; fluoroquinolones were used in at least 10–16% of all cases, and steroids in at least 13% of all interactions for standardised patient 2. The proportions of referrals were higher for standardised patients 3 and 4, but the use of antibiotics for both cases and initiation of tuberculosis treatment for standardised patient 4 were lower than for standardised patients 1 and 2 (table 2). Of the seven tuberculosis drug prescriptions that were given for standardised-patient-3 interactions, six were correct regimens. Of all medicines that were dispensed in the clinic, 607 (54%) of 1118 were loose, unlabelled pills and therefore could not be coded.

Figure 2 and table 3 shows that MBBS-qualified providers were more likely to correctly manage standardised-patient cases than were non-MBBS providers, although they were less likely to refer but not significantly so. For standardised patients 1 and 2, MBBS doctors were more likely to order chest radiographs and sputum tests. They were, however, equally likely to prescribe broad-spectrum antibiotics and were more likely to prescribe fluoroquinolones than were non-MBBS providers (figure 2, table 3).

Disaggregating by standardised-patient cases suggests that any advantage conferred by an MBBS qualification was most marked for standardised patient 1, for whom recommendation of chest radiographs and sputum tests were negligible from non-MBBS-qualified doctors, but the correct treatment advantage was also present for standardised patients 2 and 3 (data not shown). For standardised patient 4, MBBS providers were less likely to correctly treat the patient because they were more prone to starting tuberculosis treatment rather than referring the standardised patient or recommending drug-susceptibility testing (figure 2). Finally, provider age, sex, and the number of patients waiting at the time of the arrival of the standardised patient were not significantly associated with correct case management or the use of antibiotics (data not shown).

69 providers both received a standardised-patient-1 case and completed the vignettes. Provider performance in the vignettes was markedly more consistent with STCI than with the standardised-patient test, with a significantly higher proportion ordering chest radiographs and sputum tests during the vignette (table 4). The proportion of providers questioning the production of sputum or blood in sputum were also higher in vignettes; however, both in vignettes and in practice providers were equally unlikely to ask about any past occurrence of tuberculosis or family history of the disease. Notably, referrals were significantly lower for standardised patients than for vignettes (table 4).

Discussion

Our study, the first assessment of quality of care for tuberculosis using the standardised-patient method, builds on similar research by our team members for other health conditions.[5,6] Our results suggest that the standardised-patient method can be successfully implemented for tuberculosis—the detection rate in our study compares well with detection rates of 0–25% (mean of 15%) in other standardised-patient studies, including those from India, and could be further reduced by increasing the study duration.[5,6,19]

India has the world's highest tuberculosis burden, and multidrug-resistant tuberculosis is a growing threat.[20,21] In recognition of this problem, the Revised National Tuberculosis Control Program has formulated an ambitious national strategic plan (2012–17), with the goal of universal access to quality tuberculosis diagnosis and treatment for all patients with tuberculosis in the

community.[22] This goal is consistent with the End Tuberculosis Strategy by WHO, which emphasises patient-centred care and engagement of all providers.[23] Because the private sector is a major provider of health care,[2,3,24] to know how private providers manage tuberculosis in their practice, and factors associated with suboptimal care, is important.[25] Such information is essential for designing public–private mix interventions.

In our study, no risks to either providers or standardised patients were apparent, and recall by standardised patients compared well with audio recordings. Thus, future iterations of this method might help tuberculosis-control programmes to design monitoring and assessment indicators for quality of tuberculosis care.

However, our study had limitations. It was a pilot study, designed to validate the use of standardised patients in a sample of consenting private providers; therefore, a random or comprehensive sample of providers was not the goal. The ideal population of providers would be a random sample of providers from both private and public sectors, and would cover diverse areas, in view of the geographical variation in quality of care in India.[4–6,11]

A second disadvantage, inherent in the standardised-patient approach, is that data should be analysed in the same manner that it is obtained. This limitation is noticeable in our analysis of drugs dispensed: because 54% of all pills were unlabelled (loose) drugs, we were unable to conclusively assess the amount of antibiotic and steroid use in such cases. Standardised patients were instructed to not ask about the nature of the pills, because this is not consistent with typical patient behaviour, and increases detection risk. We attempted to identify these unlabelled drugs through local pharmacists, but in the absence of chemical analysis, their identification cannot be substantiated. Chemical analysis of pills is possible, but expensive. This is a limitation in any context in which unidentified pills are given to patients, and prescription of unidentified pills, by itself, suggests poor quality of medical care. Although the unlabelled medicines were highly unlikely to be antituberculosis drugs, our estimates of antibiotic and steroid use represent the lower bounds of their actual use in the population.

Our standardised patients did not have physical signs (eg, crackles) that could be identified by chest auscultation, and providers might have been misled by the absence of physical findings. We analysed data separately for providers who undertook auscultation and those who did not for standardised patients 1 and 2 and were unable to detect systematic differences in their behaviour (data not shown).

The standardised-patient method works well with one-time and new patient interactions, as opposed to many visits to the same provider or the use of patients who are already known to the doctor. In 190 (76%) of all 250 interactions with standardised patients, the provider asked the patients to come back if they did not get better or to come back with the recommended test results. However, our standardised patients did not return because this would have increased the risk of detection, and case scenarios would have become more complex and less standardised.

The interviews with providers for the detection survey showed a potential pathway whereby providers try out a cocktail of drugs for 1 week to 10 days and, if the patient does not improve, move on to a different set of drugs and ultimately chest radiographs and sputum tests. The standardised-patient-2 case was specifically designed to assess this pathway because patients might visit new providers rather than return to the original doctor.[9] However, the proportions of sputum tests and chest radiographs for standardised patient 2 were low and indistinguishable from the proportion for standardised patient 1. A design with repeated standardised-patient visits might therefore produce new insights; such a study, although challenging, could be worth pursuing in the future.

Despite these limitations, our results support those from several Indian studies,[8] using tests of knowledge or prescription practices that show low adherence among private providers to recommended standards, and highly variable practices among providers.

Our study also raises policy-relevant issues. First, informal providers are widely believed to contribute to poor diagnosis and treatment.[9,26] We did note important differences in diagnoses between MBBS-qualified providers and non-MBBS providers, with the non-MBBS providers less likely to order either sputum tests or chest radiographs for standardised patients 1 and 2. However, overall rates of laboratory investigations were low for both groups: even among MBBS-qualified providers, sputum tests were ordered in only eight (11%, 95% CI 6–21) of 71 interactions (appendix), and a drug-susceptibility test was never ordered for the suspected multidrug-resistant case. Contrary to concerns about the use of unnecessary laboratory tests in the private sector, our data suggest that people with symptoms of tuberculosis in India might be severely undertested, although repeat visits by standardised patients will be necessary to better understand this occurrence. Furthermore, our data suggest that non-MBBS-qualified providers do not seem to prescribe tuberculosis drugs, even for standardised-patient-3 and standardised-patient-4 cases (appendix). Also, no providers used the serological tests to diagnose tuberculosis that were banned in 2012 because they have little accuracy.

Our data also cast doubt about the hypothesis that insufficient knowledge and capacity constraints are the limiting factors in the accurate diagnosis and treatment of tuberculosis, and suggest a big gap between knowledge and action—the so-called know-do gap. Doctors seemed to be unaware of key requirements (on vignettes), such as asking about past history of tuberculosis or about Xpert MTB/RIF testing, but many did know about sputum

testing and chest radiographs, yet did not order them in practice. We are doing additional work to substantiate our pilot data, understand the know-do gap in provider behaviour, and identify the best approach to measure and improve quality of tuberculosis care in India.

Contributors

JD and MP obtained funding and designed the study. JD, AK, SS, VD, and MP developed the standardised-patient cases and scripts. AK, RKD, and VD did the data collection or supervised data collection. BD, SS, and RS coded the data. VD, MP, and AK trained the standardised patients. JD and BD analysed the data, and JD, BD, and MP interpreted the data. The report was written by JD, BD, MP, AK, and SB, and all authors provided critical review and comments on the revision of the report.

Declaration of interests

MP serves as a consultant for the Bill & Melinda Gates Foundation. He has no financial conflicts to disclose. RS is funded by the National Institutes of Health. All other authors declare no competing interests.

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References

1 WHO. Global Tuberculosis Report 2014. Geneva: World Health Organization, 2014.

2 Satyanarayana S, Nair SA, Chadha SS, et al. From where are tuberculosis patients accessing treatment in India? Results from a cross-sectional community based survey of 30 districts. *PLoS One* 2011; **6:** e24160.

3 Hazarika I. Role of private sector in providing tuberculosis care: evidence from a population-based survey in India. *J Glob Infect Dis* 2011; **3:** 19–24.

4 Das J, Hammer J. Money for nothing: the dire straits of medical practice in Delhi, India. *J Dev Econ* 2007; **83:** 1–36.

5 Das J, Holla A, Das V, Mohanan M, Tabak D, Chan B. In urban and rural India, a standardized patient study showed low levels of provider training and huge quality gaps. *Health Aff (Millwood)* 2012; **31:** 2774–84.

6 Mohanan M, Vera-Hernandez M, Das V, et al. The know-do gap in quality of health care for childhood diarrhea and pneumonia in rural India. *JAMA Pediatr* 2015; **169:** 349–57.

7 Bhargava A, Pinto LM, Pai M. Mismanagement of tuberculosis in India: causes, consequences, and the way forward. *Hypothesis* 2011; **9:** 1–13.

8 Satyanarayana S, Subbaraman R, Shete P, et al. Quality of tuberculosis care in India: a systematic review. *Int J Tuberc Lung Dis* 2015; **19:** 751–63.

9 Kapoor SK, Raman AV, Sachdeva KS, Satyanarayana S. How did the TB patients reach DOTS services in Delhi? A study of patient treatment seeking behavior. *PLoS One* 2012; **7:** e42458.

10 Sreeramareddy CT, Qin ZZ, Satyanarayana S, Subbaraman R, Pai M. Delays in diagnosis and treatment of pulmonary tuberculosis in India: a systematic review. *Int J Tuberc Lung Dis* 2014; **18:** 255–66.

11 Das J, Hammer J. Which doctor? Combining vignettes and item response to measure clinical competence. *J Dev Econ* 2005; **78:** 348–83.

12 Das J, Hammer J, Leonard K. The quality of medical advice in low-income countries. *J Econ Perspect* 2008; **22:** 93–114.

13 Sylvia S, Shi Y, Xue H, et al. Survey using incognito standardized patients shows poor quality care in China's rural clinics. *Health Policy Plan* 2015; **30:** 322–33.

14 Rethans JJ, Gorter S, Bokken L, Morrison L. Unannounced standardised patients in real practice: a systematic literature review. *Med Educ* 2007; **41:** 537–49.

15 Glassman PA, Luck J, O'Gara EM, Peabody JW. Using standardized patients to measure quality: evidence from the literature and a prospective study. *Jt Comm J Qual Improv* 2000; **26:** 644–53.

16 WHO Country Office for India. Standards for TB care in India. 2014. http://www.tbcindia.nic.in/pdfs/STCI%20Book_Final%20%20060514.pdf (accessed April 7, 2015).

17 TB CARE I. International Standards for Tuberculosis Care, 3rd edn. 2014. http://www.istcweb.org (accessed April 7, 2015).

18 Luck J, Peabody JW. Using standardised patients to measure physicians' practice: validation study using audio recordings. *BMJ* 2002; **325:** 679.

19 Rosen GM, Phillips WR. A cautionary lesson from simulated patients. *J Am Acad Psychiatry Law* 2004; **32:** 132–33.

20 Udwadia ZF, Amale RA, Ajbani KK, Rodrigues C. Totally drug-resistant tuberculosis in India. *Clin Infect Dis* 2012; **54:** 579–81.

21 Dalal A, Pawaskar A, Das M, et al. Resistance patterns among multidrug-resistant tuberculosis patients in greater metropolitan Mumbai: trends over time. *PLoS One* 2015; **10:** e0116798.

22 Sachdeva KS, Kumar A, Dewan P, Kumar A, Satyanarayana S. New vision for Revised National Tuberculosis Control Programme (RNTCP): universal access—"reaching the un-reached". *Indian J Med Res* 2012; **135:** 690–94.

23 Uplekar M, Weil D, Lonnroth K, et al. WHO's new End TB Strategy. *Lancet* 2015; **385:** 1799–801.

24 MAQARI team. Mapping medical providers in rural India: four key trends. Feb 1, 2011. http://cprindia.org/sites/default/files/policy-briefs/policy%20brief_1%20%281%29.pdf (accessed July 24, 2015).

25 Pai M, Das J. Management of tuberculosis in India: time for a deeper drive into quality. *Natl Med J India* 2013; **26:** e1–4.

26 Udwadia ZF, Pinto LM, Uplekar MW. Tuberculosis management by private practitioners in Mumbai, India: has anything changed in two decades? *PLoS One* 2010; **5:** e12023.

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Supplementary webappendix

This webappendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

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SUPPLEMENTARY APPENDIX

Supplement to:

Use of standardized patients to assess quality of tuberculosis care: a pilot, cross-sectional study

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Supplementary Methods

1. Description of tracer conditions:

Four tracer conditions were developed to document the level and variation in quality of care for TB among recruited providers. These were:

- SP1 – classic case of presumed TB with 2-3 weeks of cough and fever. The SP presents to the providers and begins the interaction with the opening statement (in Hindi): "*Doctor, I have a cough that is not getting better and some fever too*."
- SP2 – classic case of presumed TB who has had 2-3 weeks of cough and fever, and a history of 1 week of broad-spectrum antibiotic treatment by another provider, with no improvement. The SP carries the blister pack of amoxicillin with him/her and begins the interaction by saying: "*Doctor, I have had cough and fever. It is not getting better, even though I went to a doctor and took medicines also.*"
- SP3 – chronic cough with positive sputum smear report for TB from a public health facility. The SP carries the sputum microscopy test report and displays it prominently on his/her lap, mentioning that he/she has had her sputum tested. The SP begins the interaction by saying: "*I am having a cough for almost a month now and also have a fever. I visited the Government hospital, and they gave me some medicines and did sputum tests.*"
- SP4 – chronic cough and a positive sputum smear report from a public health facility, and, if asked, history of previous, incomplete TB treatment, which would raise the suspicion of MDR-TB. The SP carries the sputum test report and displays it prominently on his/her lap. The SP begins the interaction by saying: "*Doctor, I am suffering from a bad cough. One year ago I got treatment in the Government hospital, and it had got better, but now have a cough again. I went back to the same hospital and they did a sputum test.*"

2. SP recruitment, script development and SP training:

A total of 17 SPs were recruited from an initial group of 22 who were extensively screened and trained for 3 weeks. These SPs included both those who had participated in previous studies and new recruits. The 17 SPs differed by age, sex, height and weight. The mean age of recruited SPs was 35; the youngest was 24 and the oldest was 51; 10 (59%) were male with weights ranging from 50 to 74 kilograms and heights from 160 to 173 centimeters. Female weights ranged from 40 to 72 kilograms and heights from 150 to 160 centimeters.

Scripts were developed under the guidance of an anthropologist (VD) with active SP participation that described the social and family contexts of the patient. The two most important considerations for script development and SP training were: First, the clinical symptoms and case history had to reflect the social and cultural milieu of which the SP was assumed to be a member, and second, the presentation of symptoms and answers to history had to be consistent with biomedical facts about the disease. SPs brought a lot of socially appropriate understanding of the local vocabularies through which symptoms were to be presented and also about typical life histories that would correspond to the age, sex, caste, religion and class of the character that the SP was portraying. As a simple but crucial example, people among the strata the SPs were drawn from do not often use thermometers to measure temperature but report fever on the basis of the sensation of heat and rapid pulse. The inputs by SPs in script development were crucial from this perspective.

The second issue was to train SPs to present symptoms and answer questions pertaining to case history that were medically correct. For example all opening statements and questions pertaining to the type of cough and its duration were standardized. A critical part of the training was to help SPs distinguish between questions to which answers could be improvised but had to be appropriate to the social role of the SP and answers that had to be given using local idioms but in a standardized format without any alterations. The dual aim of presenting the disease in a manner that was not misleading and avoiding detection were largely successful because the reasoning behind both objectives was carefully and repeatedly explained to the SPs and because of their active involvement in the script development and hands-on training. SP case scripts, checklists, and vignettes are available from the authors upon request.

All SPs underwent rigorous training for 150 hours that started with a focus on the cases and the development of scripts and proceeded to memorization and appropriate role-playing, as well as techniques to perfect recall of the

questions asked and examinations completed during the interaction. Following the training, SPs visited doctors who were working with our team to provide feedback on their presentation and realistic depiction of the cases. Finally, dry runs were completed with unannounced visits to consented providers to help build the confidence of the SPs and take them through a number of "real-life" situations. Once protocols were in place for the variety of these experiences, the fieldwork was initiated.

3. Essential and recommended history questions for each SP case:

SP1 CLASSIC CASE OF SUSPECTED TB WITH NO ANTIBIOTICS OR X-RAY		
	Item	*Proportion of providers who completed the item (n=75)*
Essential History	Did the provider ask about duration of cough?	93%
	Did the provider ask whether sputum is produced?	45%
	Did the provider ask if you had TB in the past?	1%
	Did the provider ask about history of TB in the family?	3%
Recommended History	Did the provider ask about Blood in the sputum?	8%
	Did the provider ask that do you have cough throughout the day?	24%
	Did the provider ask about Fever?	59%
	Did the provider ask about type of fever (low grade vs. high grade)?	29%
	Did the provider ask about family members and similar symptoms in the family?	4%
	Did the provider ask about chest pain?	12%
	Did the provider ask about any loss of appetite?	15%
	Did the provider asked have you lost weight?	3%
	Did the provider ask about any wheezing?	4%
	Did the provider ask about any difficulty in breathing?	12%
	Did the provider ask about anything about smoking?	0%
	Did the provider ask anything about alcohol history?	1%
	Have you taken any medicines for your illness?	59%
	Did the provider ask anything about Diabetes?	4%
	Did the provider ask anything about HIV-AIDS?	0%
	Did the provider ask anything about high blood pressure or hypertension?	1%
	Did the provider ask your age?	31%
	The provider recorded the information he took from you.	60%

SP2 CLASSIC CASE OF SUSPECTED TB, ALREADY TREATED WITH ANTIBIOTICS		
	Item	*Proportion of providers who completed the item (n=75)*
Essential History	Did the provider ask about duration of cough?	83%
	Did the provider ask whether sputum is produced?	41%
	Did the provider ask which kind of doctor did you see?	31%
	Did the provider ask what medicine you took?	2%
	Did the provider ask for how long did you take these medicines?	16%
	Did the provider ask about history of TB in the family?	1%
Recommended History	Did the provider ask about Blood in the sputum?	5%
	Did the provider ask that do you have cough throughout the day?	11%
	Did the provider ask about Fever?	53%
	Did the provider ask about type of fever (low grade vs high grade)?	36%
	Did the provider ask if you had been diagnosed with typhoid earlier?	0%
	Did the provider ask if you had TB in the past?	1%
	Did the provider ask about family members and similar symptoms in the family?	1%
	Did the provider ask about chest pain?	16%
	Did the provider ask about any loss of appetite?	2%
	Did the provider asked have you lost weight?	4%
	Did the provider ask about any wheezing?	0%
	Did the provider ask about any difficulty in breathing?	8%
	Did the provider ask about anything about smoking?	3%
	Did the provider ask anything about alcohol history?	0%
	Have you taken any medicines for your illness?	17%
	Did the provider ask anything about Diabetes?	0%
	Did the provider ask anything about HIV-AIDS?	0%

	Did the provider ask anything about high blood pressure or hypertension?	0%
	Did you have any other illness recently?	0%
	Did the provider ask your age?	19%
	The provider recorded the information he took from you.	61%

SP3 PATIENT WITH TB SYMPTOMS AND A POSITIVE SPUTUM SMEAR RESULT ("TB CASE")		
	Item	*Proportion of providers who completed the item (n=50)*
Essential History	Did the provider ask about duration of cough?	7%
	Did the provider ask whether sputum is produced?	22%
	Did the Provider ask to see sputum test results?	86%
	Did the provider ask if you have been treated for TB in the past?	4%
Recommended History	Did the provider ask about Blood in the sputum?	14%
	Did the provider ask that do you have cough throughout the day?	6%
	Did the provider ask about Fever?	48%
	Did the provider ask about type of fever (low grade vs high grade)?	22%
	Did the provider ask about TB in the family?	8%
	Did the provider ask about family members and similar symptoms in the family?	2%
	Did the provider ask about chest pain?	16%
	Did the provider ask about any loss of appetite?	14%
	Did the provider asked have you lost weight?	4%
	Did the provider ask about any wheezing?	2%
	Did the provider ask about any difficulty in breathing?	12%
	Did the provider ask about anything about smoking?	4%
	Did the provider ask anything about alcohol history?	0%
	Have you taken any medicines for your illness?	32%
	Did the provider ask anything about Diabetes?	0%
	Did the provider ask anything about HIV-AIDS?	0%
	Did the provider ask anything about high blood pressure or hypertension?	0%
	Did the provider specifically ask about presence of children in the family?	4%
	Did the provider ask your age?	42%
	The provider recorded the information he took from you.	30%

SP4 A CASE OF SUSPECTED MDR-TB WITH PREVIOUS HISTORY OF TB TREATMENT		
	Item	*Proportion of providers who completed the item (n=50)*
Essential History	Did the provider ask about duration of cough?	74%
	Did the provider ask whether sputum is produced?	3%
	Did the Provider ask to see current sputum test result?	84%
	Did the provider ask if any medication were taken in last month for the present illness?	28%
	Did the provider ask if the patient had visited government hospital for the previous illness?	16%
	Did the provider ask what treatment did he get for the previous illness?	8%
	Did the provider ask if sputum or the x-ray tests were done for the previous illness?	18%
	Did the provider ask if the diagnosis was given by the government hospital for the previous illness?	16%
	Did the provider ask if you have been treated for TB in the past?	36%
	Did the provider ask how long you took the medication?	26%
	Did the provider ask why you stopped taking the medications?	16%
	Did the provider ask for any previous treatment's medical records?	1%
Recommended History	Did the provider ask about Blood in the sputum?	24%
	Did the provider ask that do you have cough throughout the day?	16%
	Did the provider ask about Fever?	36%
	Did the provider ask about type of fever (low grade vs high grade)?	12%
	Did the provider ask that have you had similar symptoms before?	8%
	Did the provider ask if anyone in the family have had TB?	8%
	Did the provider ask about chest pain?	1%
	Did the provider ask about any loss of appetite?	22%
	Did the provider asked have you lost weight?	12%
	Did the provider ask about any wheezing?	2%
	Did the provider ask about any difficulty in breathing?	12%
	Did the provider ask about anything about smoking?	0%
	Did the provider ask anything about alcohol history?	2%
	Did the provider ask anything about Diabetes?	0%

Did the provider ask anything about HIV-AIDS?	0%
Did the provider ask anything about high blood pressure/hypertension?	0%
Did the provider specifically ask about presence of children in the family?	6%
Did the provider ask your age?	4%
The provider recorded the information he took from you.	44%

4. The assignment process of SP cases to providers:

Across 100 providers, SP1 and SP2 cases were randomly assigned to 75 providers each (50 providers received both SP1 and SP2 cases), and then 50 were randomly assigned SP3, and the remaining 50 who were not assigned SP3 received SP4. Random assignment of SPs to providers ensures that any SP-specific effect is uncorrelated to provider type. Interactions occurred during April 1-23, 2014, and all providers in the sample were visited by either two or three SPs, none of which were the same case. Providers were visited first by individuals trained as SP1 and/or SP2 and then visited by individuals trained as SP3 or SP4, in order to prevent priming that may occur if providers saw a patient with a more advanced stage of TB first. All providers could not receive all 4 SPs as this would have significantly increased the likelihood of detection. None of the providers received both SP3 and SP4 to decrease detection rates, since SPs trained in both these cases were carrying reproduced sputum test results that looked similar. Finally, in order to lower detection given the short time span, we ensured that no provider received more than 3 cases.

5. Logistic regression model

A logistic regression model was used to assess the association between provider qualifications and various components of case management for all four SP cases combined. For this analysis, all providers were grouped into two categories: MBBS and non-MBBS providers. MBBS refers to the degree which qualified, allopathic doctors in India receive at the end of their 5.5 years of medical education. The non-MBBS category included all other practitioners, i.e. practitioners of alternative systems (i.e. those who get degrees in Ayurveda, Yoga, Unani, Siddha, or Homeopathy, usually grouped as AYUSH in India, and formally recognized by the government of India which has a separate Ministry of AYUSH http://indianmedicine.nic.in/) and informal providers. The informal provider group was heterogeneous and included practitioners with minimum or no qualifications.

Our rationale for creating two groups (MBBS vs. non-MBBS) for the analysis was as follows:

a) Previous SP studies in India have shown minimal differences between AYUSH and informal providers (1).

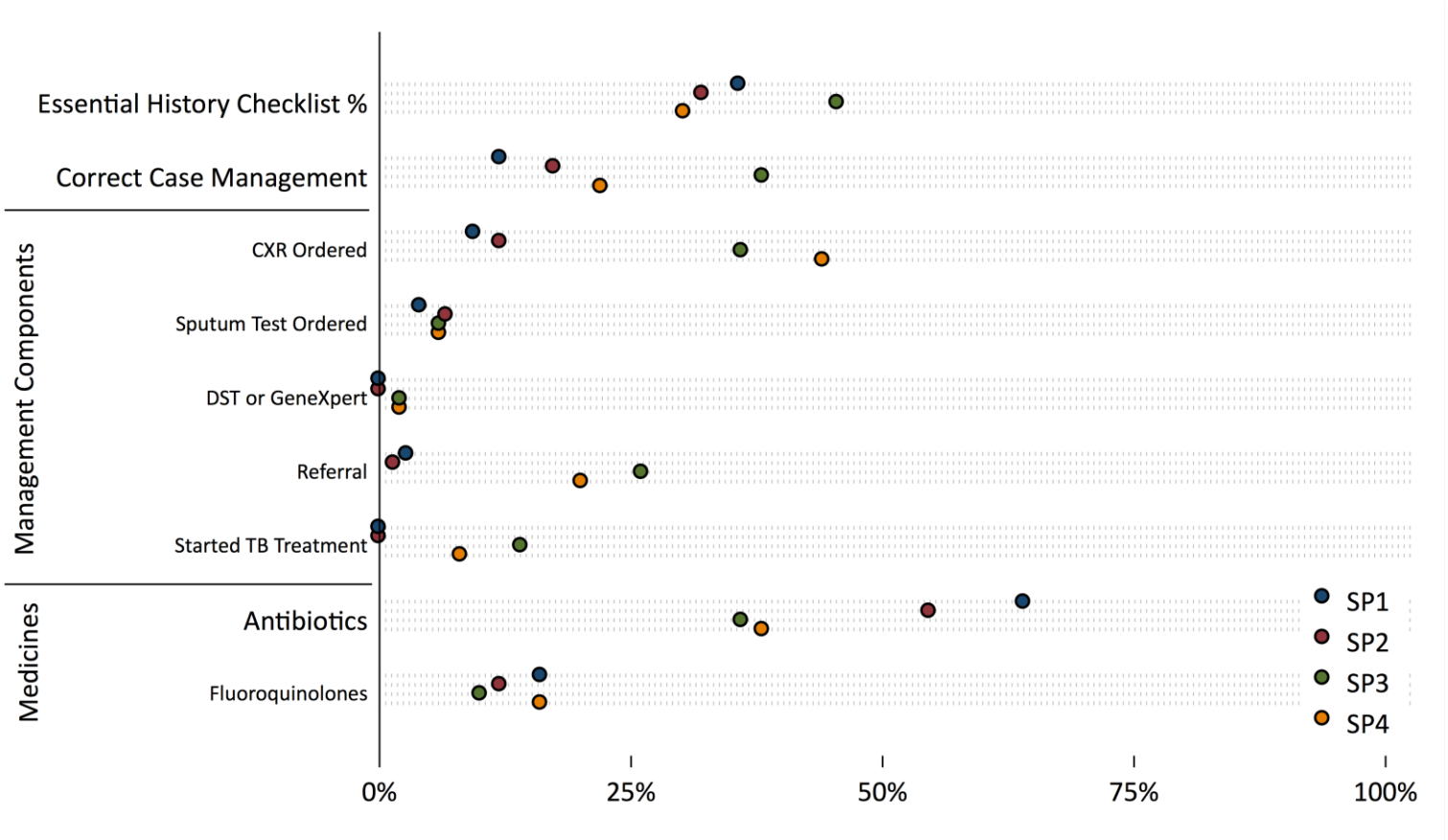
b) In our data (Table below), we found the AYUSH group to resemble the informal group, except that because they are less likely to refer, they are actually worse in overall correct case management than the informal group.

	Percentages		
	Others (informal)	AYUSH	MBBS
Correct Treatment	24%	14%	30%
CXR Ordered (SP1,2)	0%	5%	29%
Sputum Test Ordered (SP1,2)	0%	4%	12%
Referral	24%	8%	3%
TB Treatment (SP3,4)	0%	6%	29%
Antibiotics	57%	48%	50%
Fluoroquinolones	14%	11%	19%

c) Lastly, since our pilot study had only 100 providers, a dichotomous exposure variable was a more reasonable choice than dummy variables.

In the logistic regression model, we use a full set of SP dummies to eliminate any SP-specific effect from the estimates. We can include a full set of such dummies because each SP was sent to multiple providers, and each provider received multiple SPs. In addition, the design also allows us to assess whether SPs who differed in age, sex, height and weight were treated differentially by providers. These coefficients are of interest in their own right, since they provide potential evidence of differential treatment that may be included in future SP study designs and they allow us to assess whether 'healthier looking' SPs were treated differently. Table S1 reproduces the estimation from Figure 2, with SP age, sex, height and weight included as explanatory variables, replacing SP dummies. There is some evidence that female SPs were more likely to be correctly managed, with higher likelihood of referrals and chest X-rays, but these results are not statistically significant. There is no association between SP age, height or weight and the main outcome variables presented in Figure S1. The results suggest some differential treatment by sex, but the study is insufficiently powered to detect this difference statistically. There appears to be no evidence of differential treatment by age, height or weight.

Figure S1. Major outcomes, stratified by standardized patient case



Notes: For each outcome, SP1 value is on the top; moving downwards, SP4 at bottom. Correct case management for these four cases were defined as:

- SP1 & SP2: Recommendation for sputum testing or chest radiograph, or referral to a public DOTS center or qualified provider
- SP3: Either referral to a public DOTS center, a qualified private 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)
- SP4: Recommendation for any drug-susceptibility test (culture/DST, line probe assay or GeneXpert MTB/RIF), or referral to a public DOTS center

CXR: chest x-ray
DST: drug-susceptibility testing
GeneXpert: Xpert MTB/RIF test (Cepheid Inc., CA)

Table S1. Impact of provider qualifications, provider characteristics, and SP characteristics on main standardized patient outcomes

	Correct Case Management	Chest X-Ray (SP1,2)	Sputum Test (SP1,2)	Referral (All Cases)	Started TB Treatment (SP3,4)	Antibiotics (All Cases)	Fluoroquinolones
MBBS	2.63***	8.97***	4.12**	0.27*	9.73***	1.18	2.18*
	(0.01)	(0.00)	(0.05)	(0.07)	(0.00)	(0.59)	(0.06)
Provider Age	0.99	1.01	1.01	1.00	1.03	0.97***	0.98
	(0.72)	(0.64)	(0.86)	(0.99)	(0.47)	(0.01)	(0.27)
Provider Male	2.38	1.36	0.61	0.85	0.84	0.44	0.52
	(0.38)	(0.85)	(0.77)	(0.89)	(0.92)	(0.30)	(0.44)
Patients Waiting	0.86*	0.89	1.25*	0.80	0.92	1.02	0.85
	(0.08)	(0.41)	(0.09)	(0.30)	(0.48)	(0.79)	(0.18)
Male SP	0.32*	0.22	0.48	0.29	5.45	0.78	1.35
	(0.05)	(0.32)	(0.70)	(0.13)	(0.21)	(0.63)	(0.68)
SP Height (cm)	1.08	1.12	1.11	1.05	0.72	1.00	1.02
	(0.12)	(0.21)	(0.31)	(0.62)	(0.11)	(0.96)	(0.75)
SP Weight (kg)	1.02	1.00	0.94	1.09	1.02	1.01	1.03
	(0.64)	(0.92)	(0.30)	(0.20)	(0.93)	(0.58)	(0.37)
SP Age	1.04	1.07	0.93	1.04	0.75	1.01	1.01
	(0.43)	(0.39)	(0.54)	(0.64)	(0.27)	(0.79)	(0.82)
Number of observations	250	150	150	250	100	250	250
Mean	0.21	0.11	0.05	0.10	0.11	0.50	0.14

Notes: Results are reported as adjusted odds ratios. The MBBS qualification variable indicates outcomes for MBBS providers (n=29) relative to non-MBBS (n=71), which includes practitioners of alternative systems of medicine and informal providers with minimum or no qualifications. Correct case management is defined as a chest x-ray [CXR] or sputum test or referral for SP1 and SP2; as an HRZE regimen or referral for SP3; and as a drug-susceptibility test [DST] or Xpert MTB/RIF (GeneXpert) or referral for SP4. The antibiotics measure is a lower bound as only identified drugs are included. DST and GeneXpert are excluded from regression because the incidence rate is too low for statistical inference. Regressions are controlled for SP case fixed effects. *** $p<0.01$, ** $p<0.05$, * $p<0.1$

Figure S2. Case Management for SP1 (Classic case of presumed TB with 2-3 weeks of cough and fever)

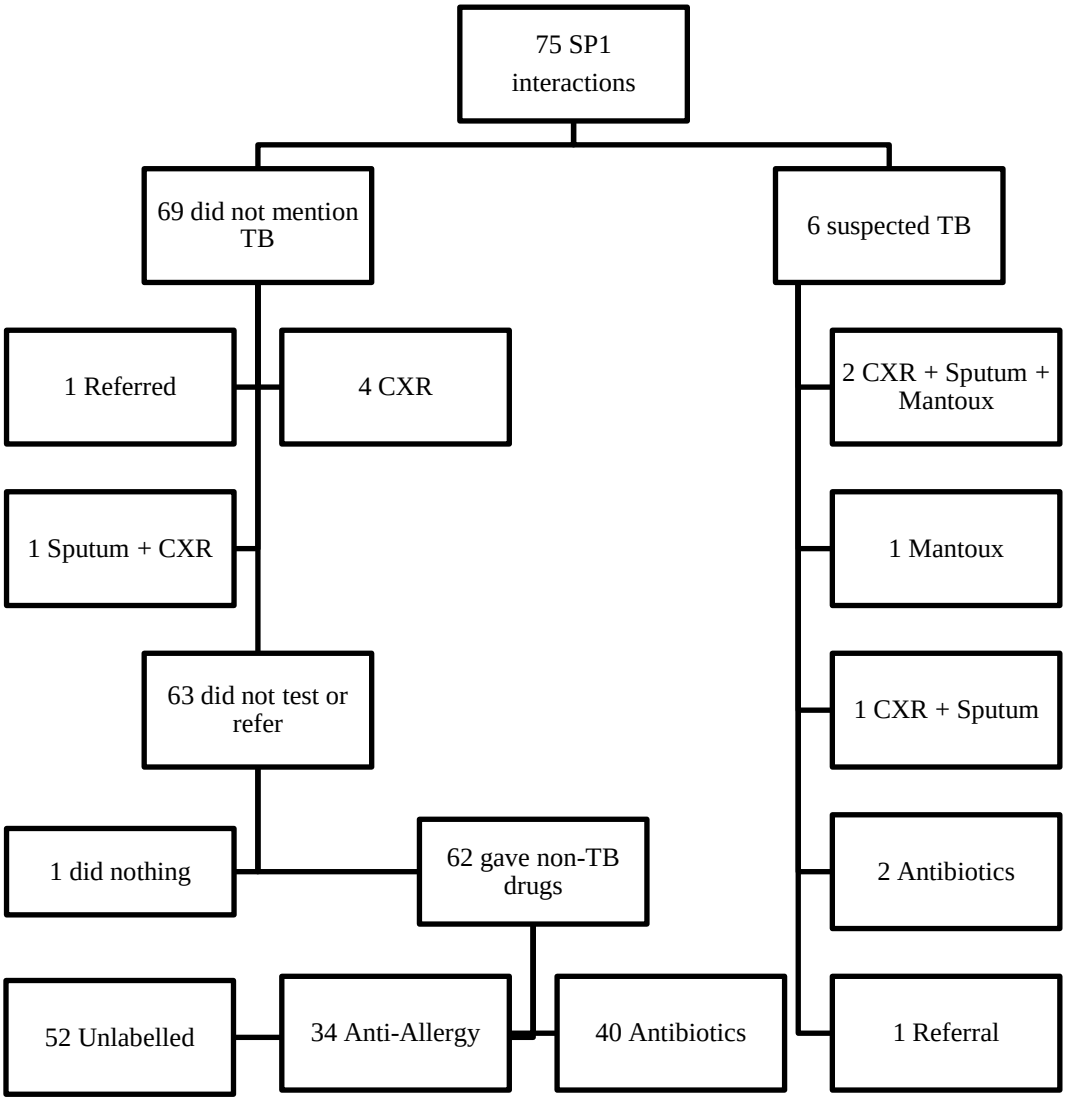


Figure S3. Case Management for SP2 (Classic case of presumed TB who has had 2-3 weeks of cough and fever and a history of 1 week of broad-spectrum antibiotic)

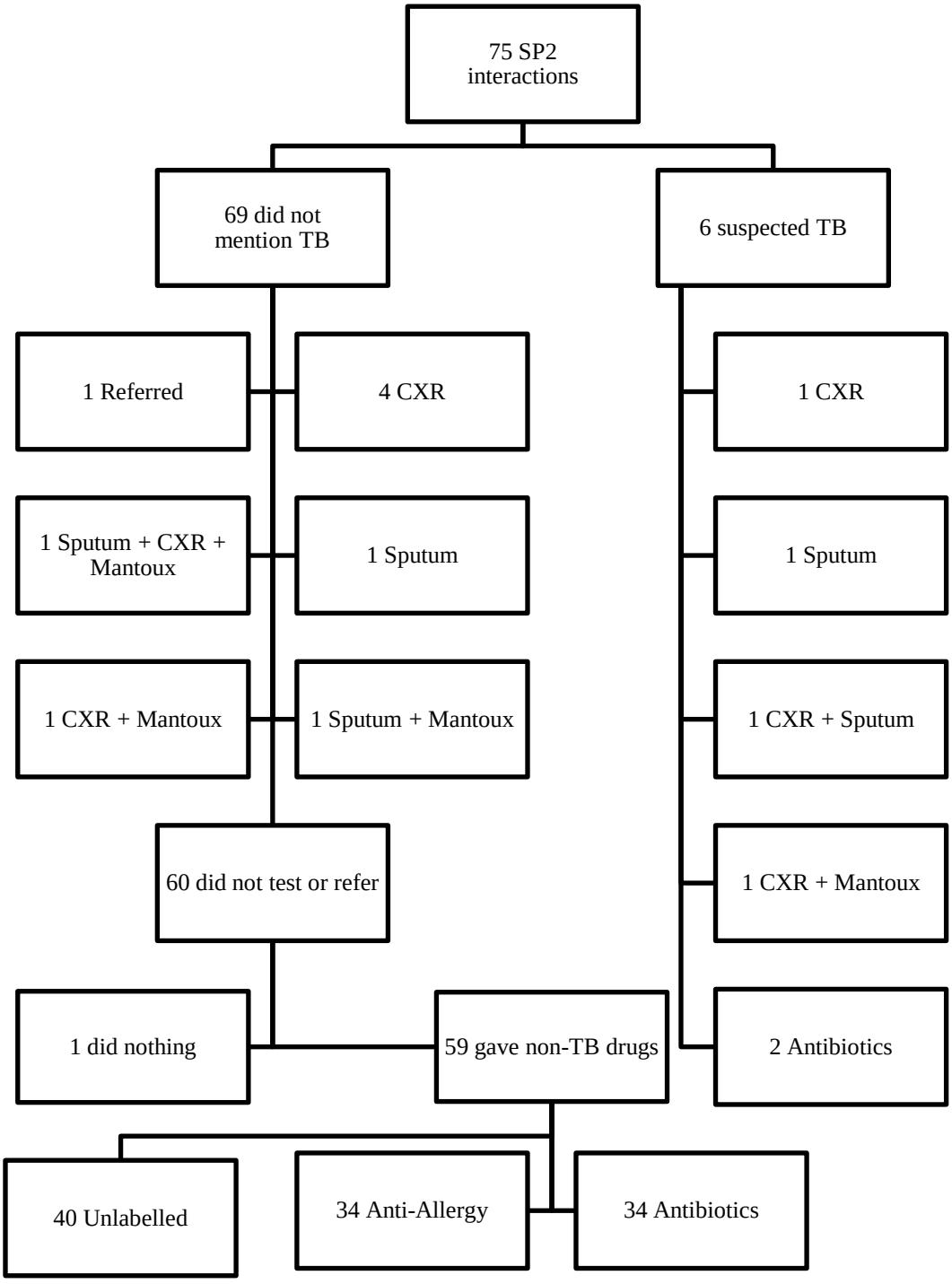


Figure S4. Case Management for SP3 (Chronic cough with positive sputum smear report for TB from a public health facility)

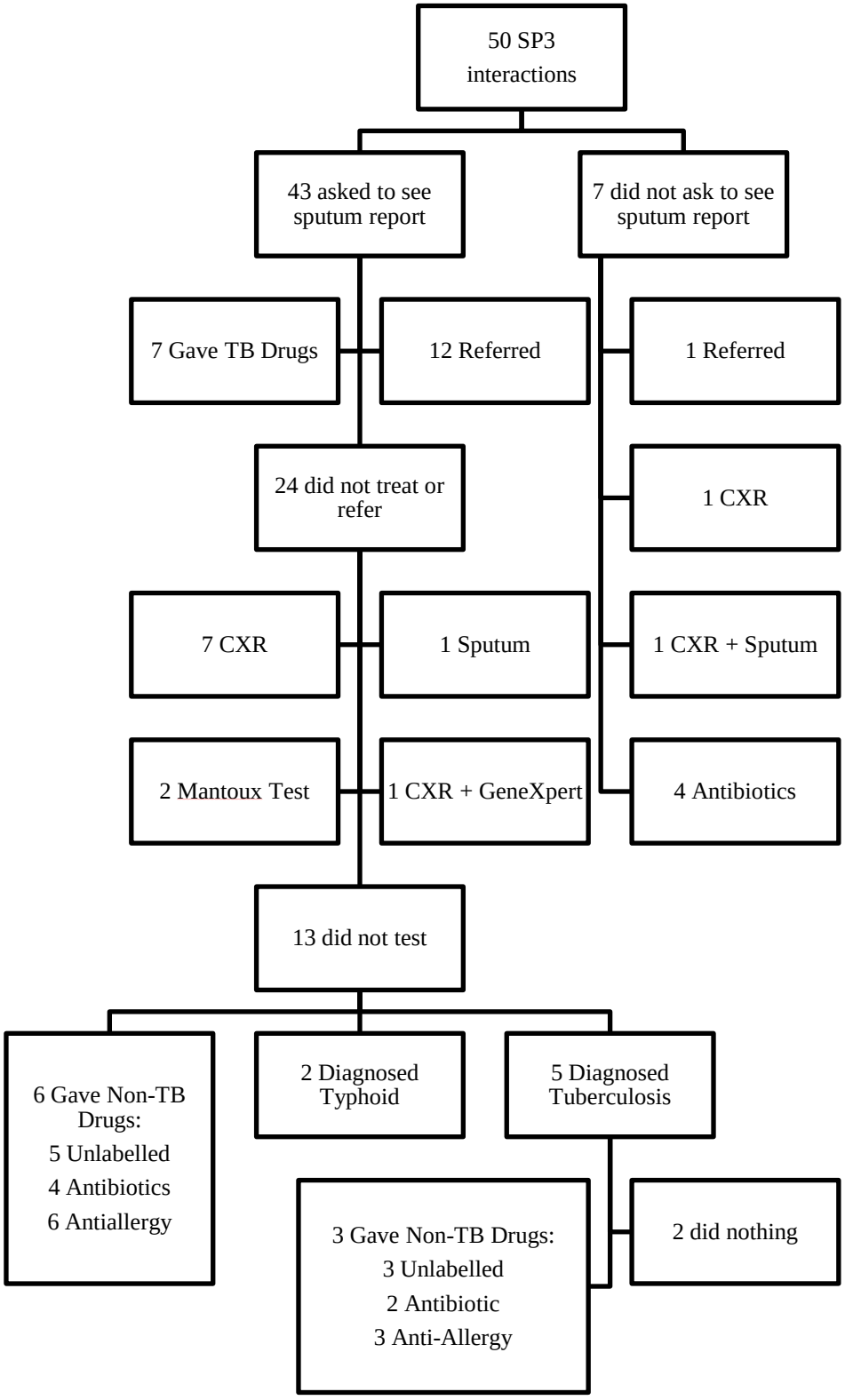
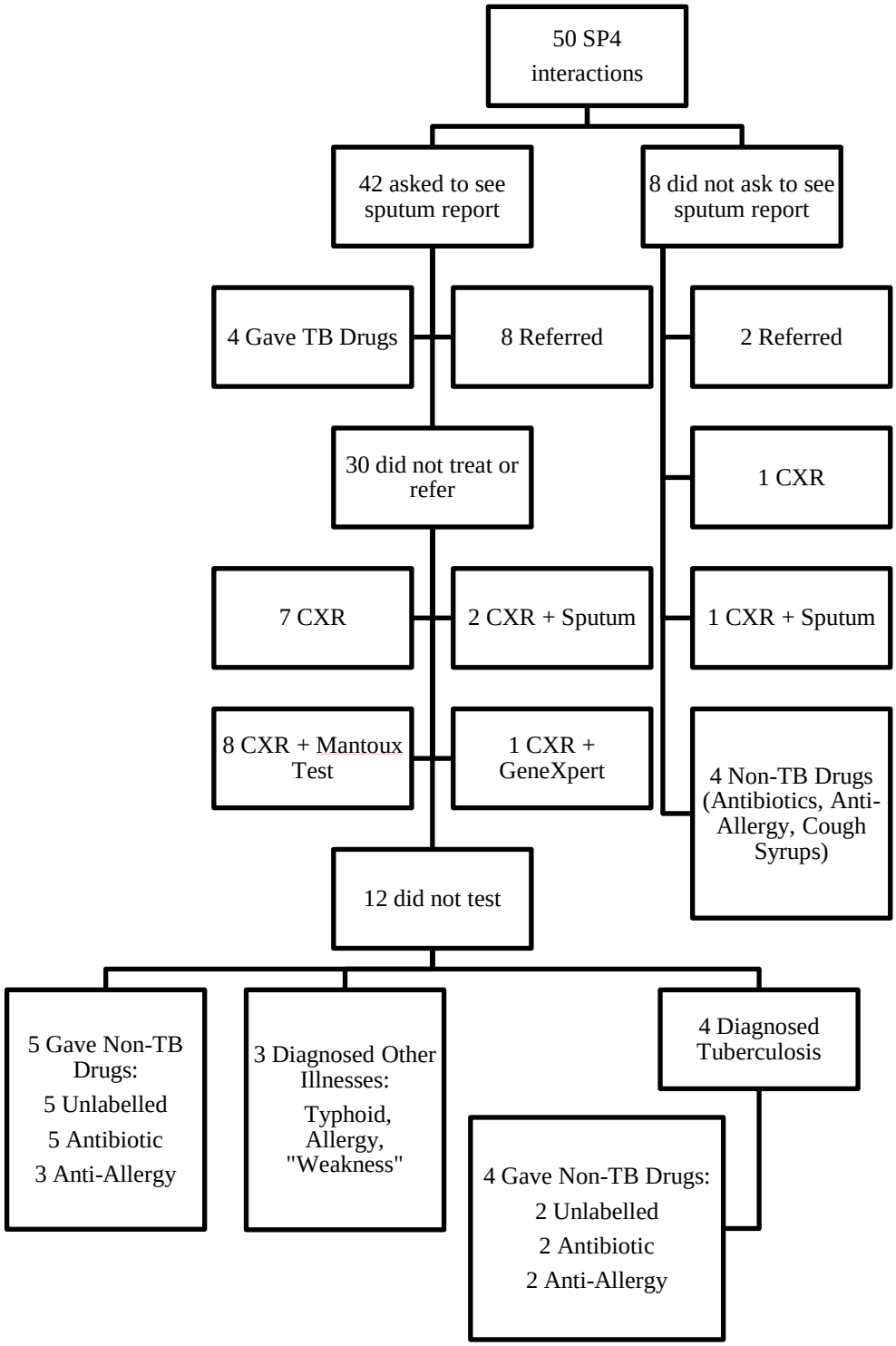


Figure S5. Case Management for SP4 (Chronic cough and a positive sputum smear report from a public health facility, and history of previous, incomplete TB treatment)



References

1. Das J, Holla A, Das V, Mohanan M, Tabak D, Chan B. In Urban And Rural India, A Standardized Patient Study Showed Low Levels Of Provider Training And Huge Quality Gaps. *Health Affairs* 2012; **31**(12):2774-84.