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Supplementary webappendix

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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).

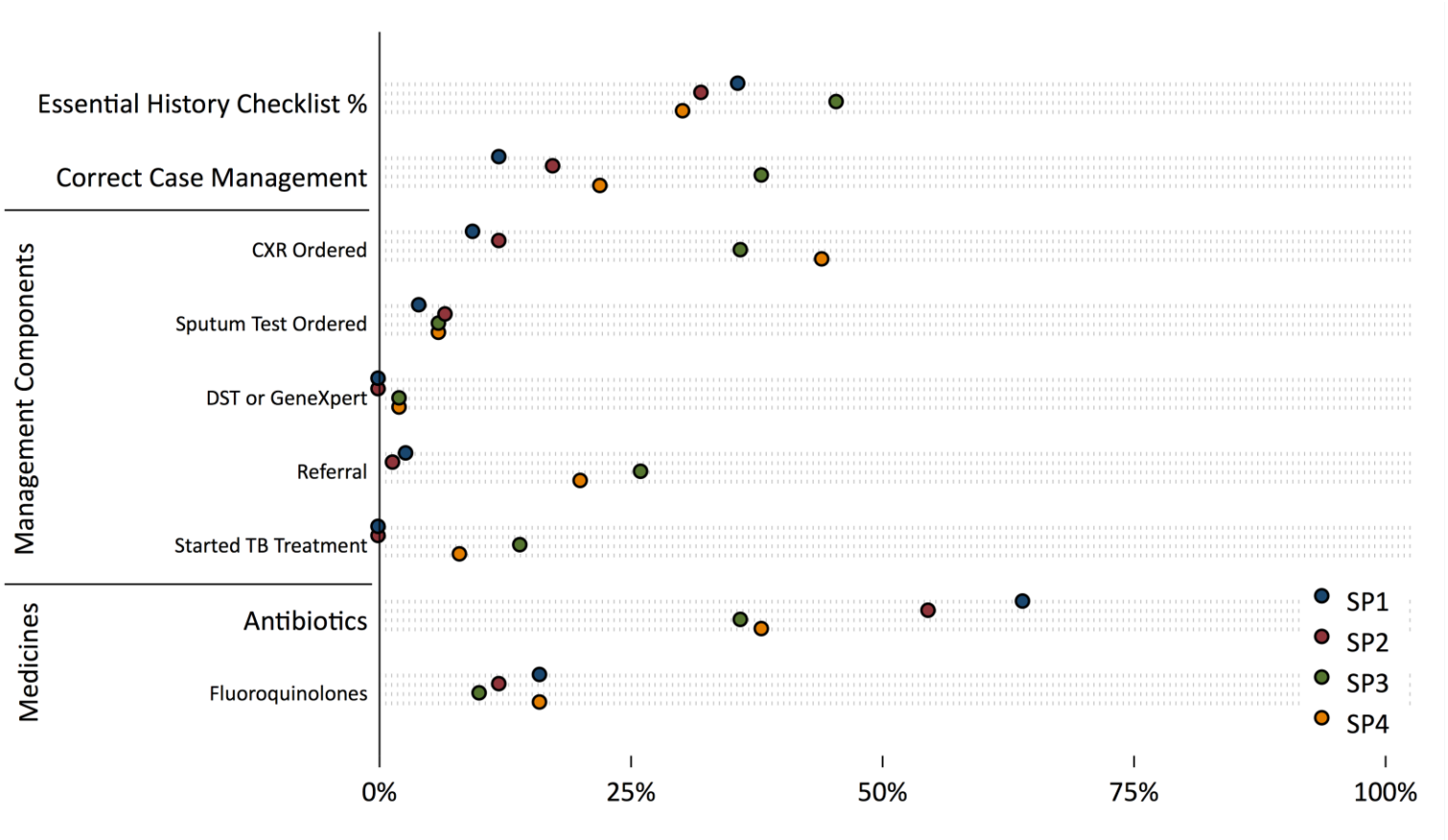
b) In our data (Table below), we found the AYUSH group to resemble the informal group, except that because they are less likely to refer, they are actually worse in overall correct case management than the informal group.

	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)

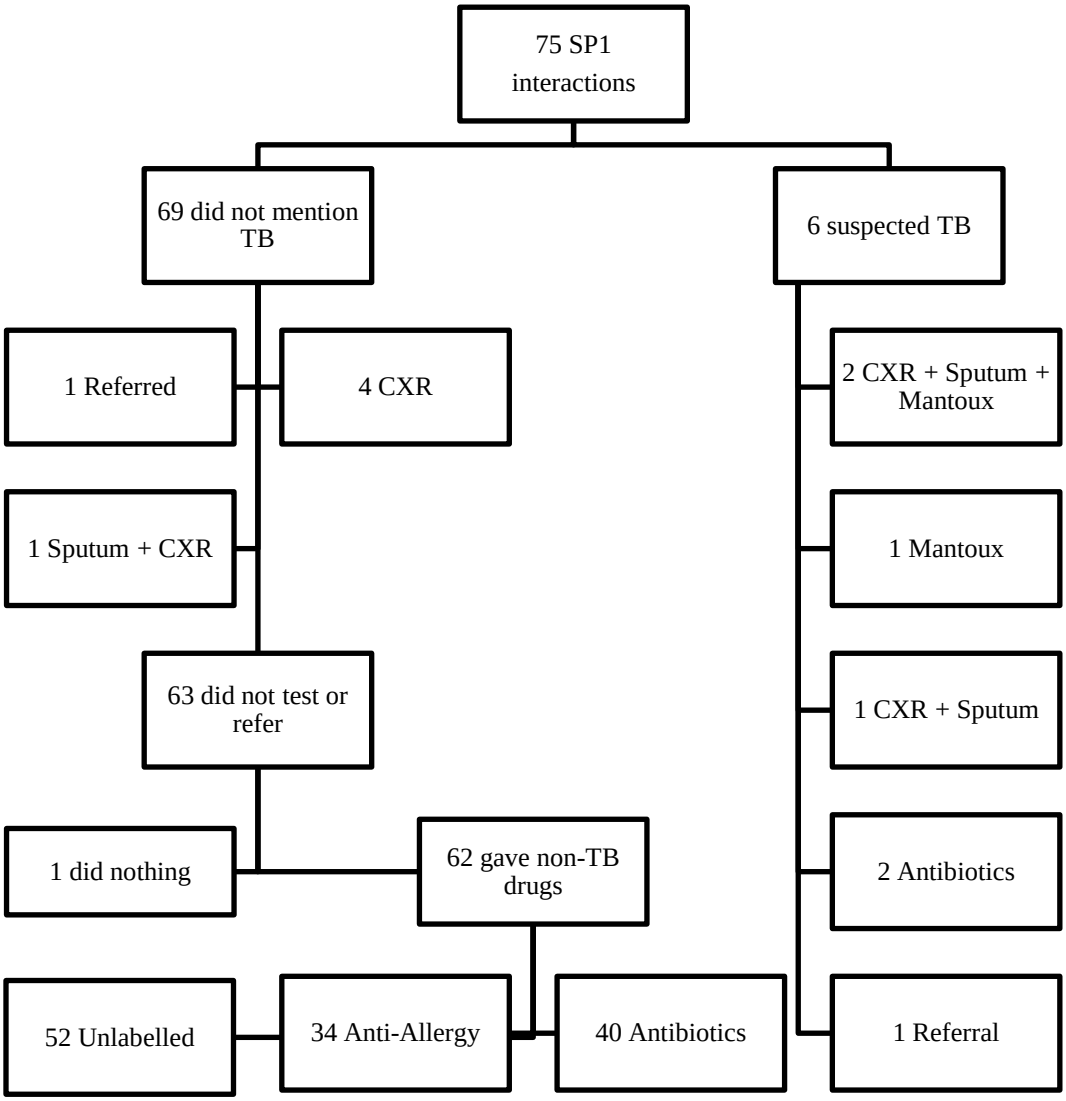


Figure S3. Case Management for SP2 (Classic case of presumed TB who has had 2-3 weeks of cough and fever and a history of 1 week of broad-spectrum antibiotic)

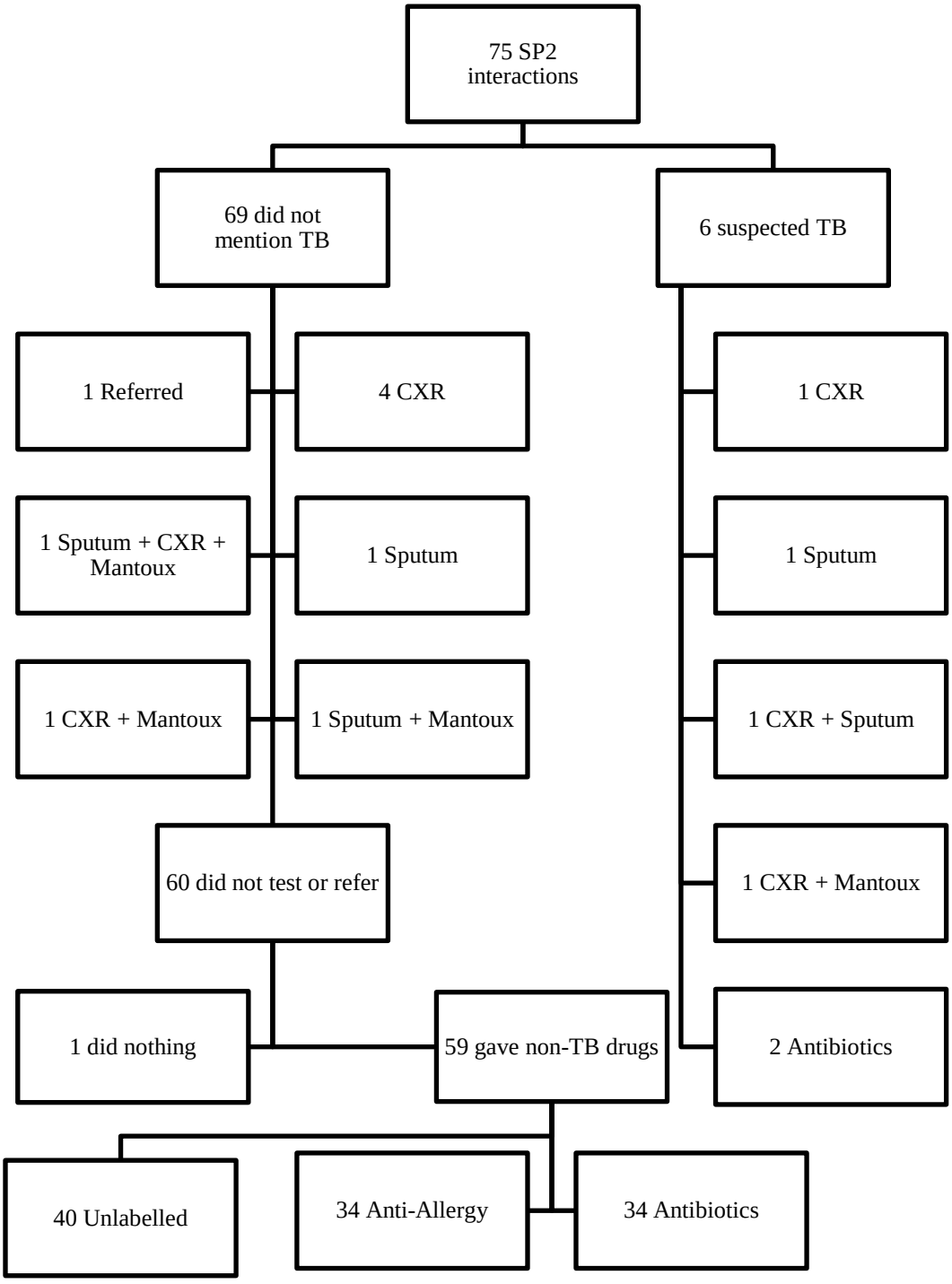


Figure S4. Case Management for SP3 (Chronic cough with positive sputum smear report for TB from a public health facility)

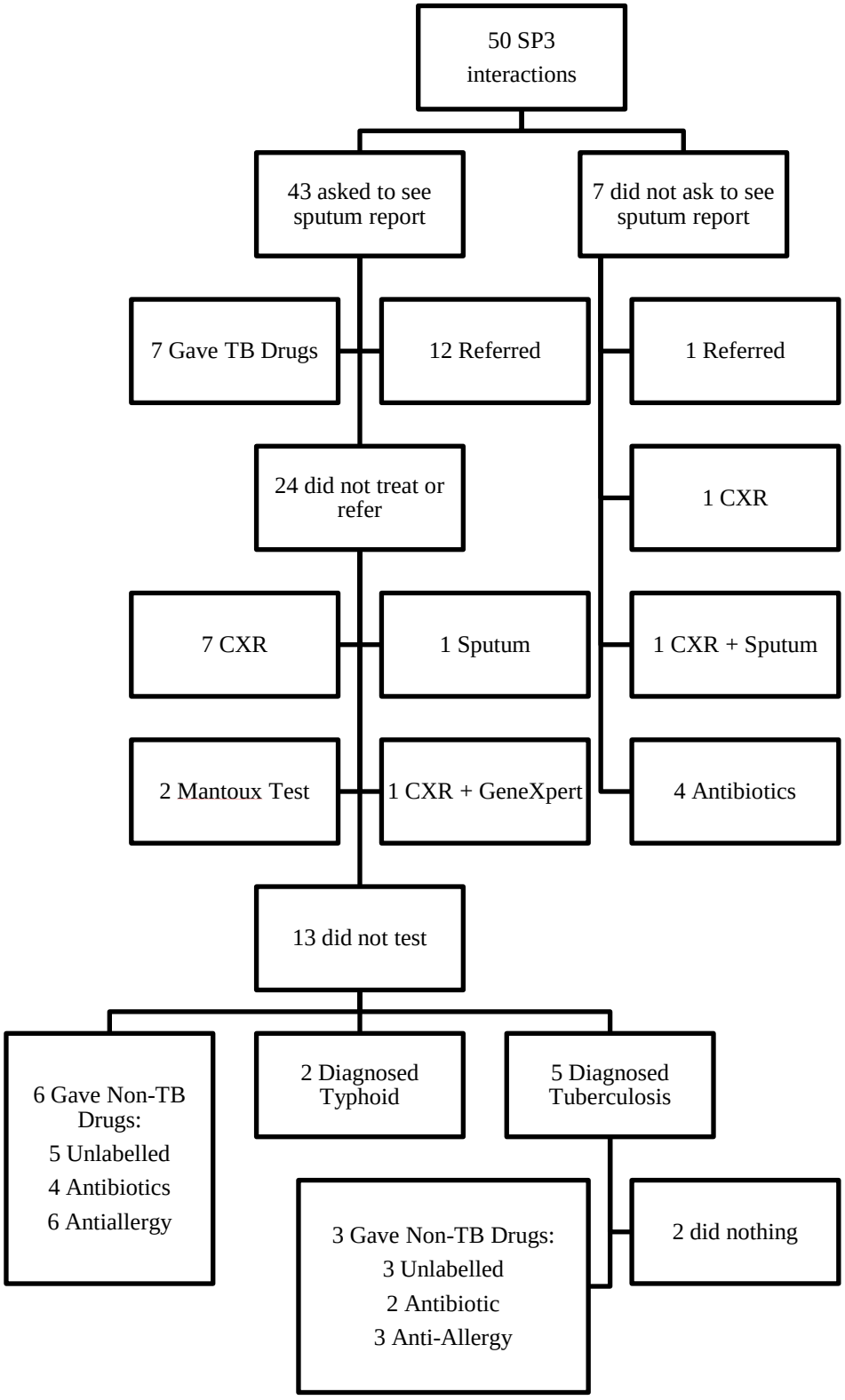
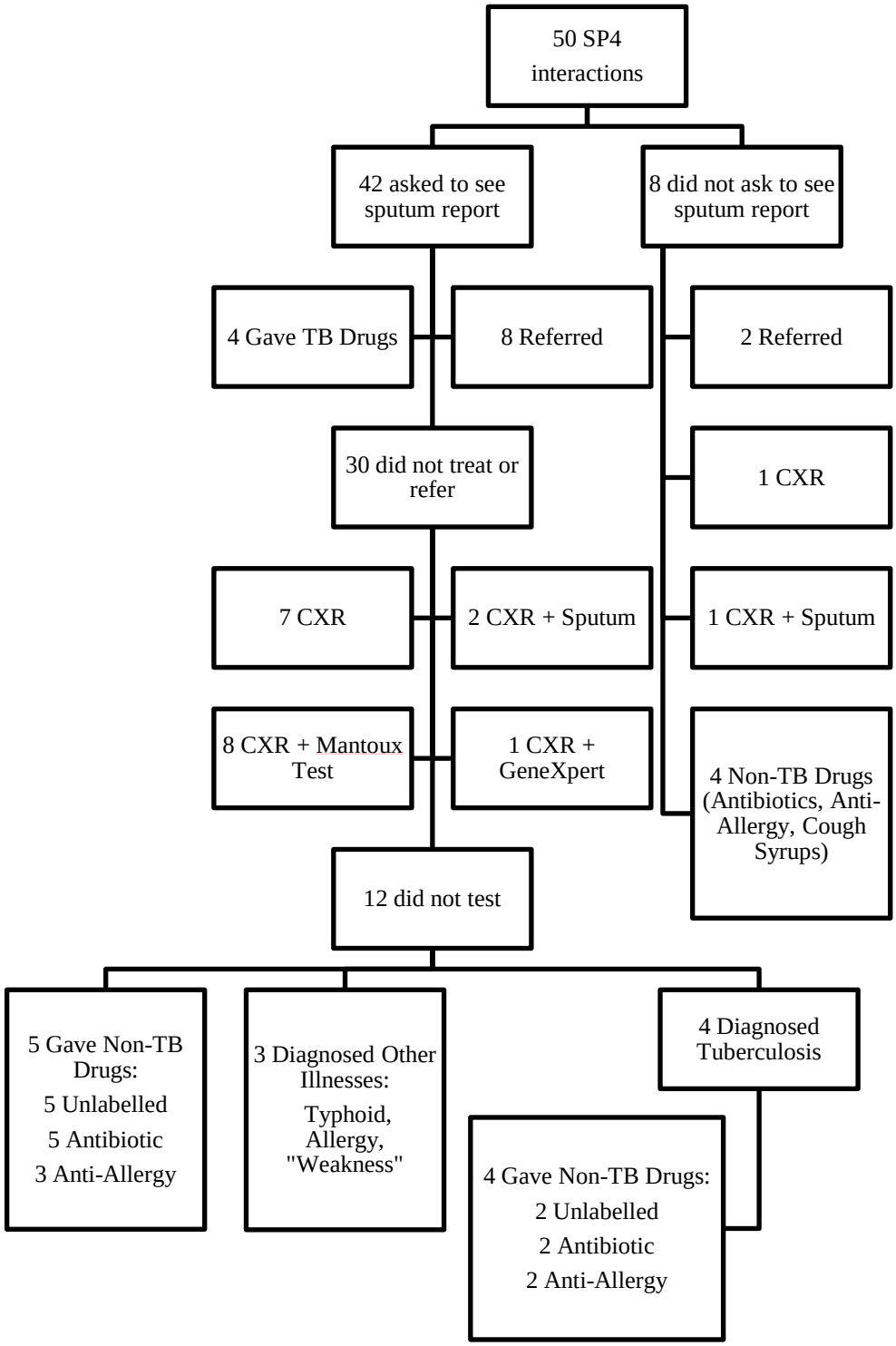


Figure S5. Case Management for SP4 (Chronic cough and a positive sputum smear report from a public health facility, and history of previous, incomplete TB treatment)



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