

## Standardized patient method in tuberculosis research

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Satyanarayana S, Kwan A, Daniels B, Subbaraman R, McDowell A, Bergkvist S, Das RK, Das V, Das J, Pai M. (McGill International Tuberculosis Centre and Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montreal, QC, Canada; Manipal McGill Center for Infectious Diseases, Manipal University, Manipal, India; Development Research Group, The World Bank, Washington, DC, USA; Division of Infectious Diseases, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA; ACCESS Health International, Hyderabad, India; Institute for Social and Economic Research on Development and Democracy, Delhi, India; Department of Anthropology, Johns Hopkins University, Baltimore, MD, USA; Center for Policy Research, New Delhi, India.) Use of standardised patients to assess antibiotic dispensing for tuberculosis by pharmacies in urban India: A cross-sectional study. *Lancet Infect Dis* 2016;**16**:1261–8.

### SUMMARY

India contributes to almost a quarter of the global burden of tuberculosis (TB).<sup>1</sup> The majority of patients are treated either in the government sector or in the highly unregulated private sector.<sup>2</sup> Using the technique called 'standardized patient' (SP), Das *et al.* and Satyanarayana *et al.* assessed the practices of healthcare providers and pharmacies when patients with symptoms suggestive of TB consult them. The first study used the SP method to assess the quality of care delivered to patients with TB. The SP method has been used for diseases such as diabetes and pneumonia. Das *et al.* were the first to use this approach for TB. This pilot study aimed to validate the SP method to assess how healthcare providers manage patients presenting with symptoms of TB. Individuals were recruited as employees and trained intensively to present as SPs to different types of private practitioners. This study was done in low- and middle-income areas of New Delhi. The convenience sampling method was used to recruit 100 private healthcare providers, of which 40% were practitioners of alternative medicine, 29% were practitioners of allopathic medicine and 31% were informal healthcare providers. The authors developed four types of case scenarios: (i) patient of presumed TB; (b) patient of presumed TB not responding to a course of antibiotics; (iii) patient presenting with evidence suggestive of bacteriologically confirmed TB such as a positive sputum smear result; and (iv) recurrence of TB in a previously treated patient. Correct case management was defined as per the Standards for TB Care in India. Of the 250 SP healthcare provider interactions, correct case management was seen in only

21%. The detection rate of SPs by private practitioners was minimal (5%) in this study. The authors recommend that the SP method can be used successfully to assess the quality of healthcare provided to patients with TB.

The authors used a similar technique in another study to assess the practices of pharmacies when patients with symptoms suggestive of presumed TB and microbiologically confirmed TB approached them for advice and medicines. Satyanarayana *et al.* conducted this multi-centric survey in Patna, Mumbai and the initial validation phase in New Delhi. Expected case management was defined as per the guidelines from the Indian Pharmaceutical Association and Central TB Division, Government of India. Similar to the first study, SPs were trained intensively. Mock interviews and dry runs were conducted in the field under supervision. Two case descriptions were adopted to assess the guidance given to the patients and medicines dispensed to them by the pharmacists. Case 1 SPs were trained to present to the pharmacist with 2–3 weeks' duration of cough and fever. Case 2 SPs had a positive sputum smear result for acid-fast bacilli (in addition to the presentation of symptoms). Convenience sampling was used for the pilot phase in Delhi and random sampling for the pharmacies in Patna and Mumbai. Of the 622 pharmacies sampled, 93% of the scheduled SP-pharmacist interactions were completed for both case scenarios. Ideal case management was noted in 13% of case 1 presentations and 62% of case 2 presentations. First-line anti-TB drugs were not dispensed to any of the SP. The fluoroquinolone group of drugs was given to 7% and steroids to 5% of the total interactions; this has relevance not only for TB, but also for other community-acquired infections. The second study complemented the first one by using the SP technique to assess inappropriate use of antibiotics by pharmacists.

### COMMENT

The term 'standardized patient' was coined by Geoffrey Norman, a Psychometrician from Canada.<sup>3</sup> In 1963, Dr Howard S. Barrows, a neurologist at the University of Southern California, introduced the use of simulated patients in medical education. He faced harsh criticism for comparing SPs with 'actors'. He had a tough time convincing the medical community that the SP technique was a legitimate educational tool. Later in the 1970s and 1980s, the method got gradual acceptance to evaluate the clinical skills of medical students, which needed a more rigorous method.<sup>4</sup> In medical education, SPs have been used to test a broad range of skills including history taking, physical examination and counselling, and have been proved to be valuable educational tools for medical students.<sup>4,5</sup>

Apart from medical education, this method was later adopted to assess performance of physicians as well as medical professionals. SPs are also known as 'pseudo patients', or 'simulated patients'. They are individuals who are trained to present as a particular case or with particular symptom to a healthcare professional and to record the details of the encounter. The major advantage of the technique is that the patient's presentation to each medical student/intern/physician is more or less the same.<sup>4</sup> Doctors' performance in medical field was generally assessed by two methods: direct and indirect. Direct methods include simulated or SPs, and audiovisual recording of consultations. Indirect methods include review of clinical notes or case records.<sup>6</sup> Few studies have used the SP method to assess efficacy of intervention trials. Li *et al.* used this approach to evaluate the outcome of an intervention on stigma reduction associated with HIV in a hospital-based study in China.<sup>7</sup> Especially for surveys on sensitive issues, where social desirability is a major challenge in self-report assessments, SPs were of great use in

reducing the reporting bias. The SP approach has many advantages compared to other methods of performance assessment. Review of clinical notes is an indirect method and is still practised in many countries. However, this method is not highly reliable as all the information may not be recorded by medical professionals. Hence, the validity of case records in assessing actual performance of medical practitioners is questionable.<sup>8</sup> Whereas SP method is a reliable and accurate method if individuals are trained extensively to present as pseudo patients and interviewed soon after the interaction to minimize recall bias.<sup>5</sup>

The SP method also has its limitations. The foremost concerns are the time and cost involved in training them.<sup>9</sup> Generally, individuals are recruited and trained as pseudo patients to present with symptoms of the disease of interest. The individuals are paid a stipend for the period they are employed.<sup>10</sup> Extensive training needs to be given to them to present the scenario with perfection.<sup>11</sup> All these require a lot of resources and hence limit the use of this approach in research. SPs may not be able to simulate all relevant symptoms and emotional states. Symptoms of acute diseases such as asthma, myocardial infarction, heart failure and seizure cannot be simulated realistically without supporting findings in clinical examination of the body systems.<sup>11</sup> There are also ethical concerns in using SP methodology. The time spent by practitioners with SPs is crucial and might delay consultations of real patients. In many studies, healthcare providers were informed of the possible SP observation before the study initiation and were free to opt out of the study. Some researchers ensured that individuals recruited as SPs underwent training in research ethics.

Das *et al.* implemented the methodology of using SPs in the field of TB research. Even minor details were taken into account while designing the study. The SPs recruited were both new as well as experienced individuals. The SPs were a diverse group by age, sex and anthropometric parameters. The authors took the guidance of an anthropologist in designing the scripts. The most important factor is that the SPs themselves were involved in script development and their inputs on social and cultural contexts were taken into consideration. One of the greatest strengths of the study was that the SPs were given extensive hands-on training to standardize the case presentation. The authors had made the scripts relevant to the social and cultural contexts of the study areas. Mock interviews were conducted and the study team physicians provided feedback to the SPs on their case presentations. For each of the four cases, the authors developed essential and recommended questions to be asked by healthcare providers during history taking. Only 5% of healthcare practitioners were able to detect the SPs as fake patients and the authors recommend the SP method as a successful approach to design indicators for monitoring the quality of TB care delivered by the national programme. On the other hand, only private practitioners were included in the study, which might have influenced the results. As a first of its kind study in quality of TB care assessment, the study highlighted the big know-do gap that existed among healthcare providers in managing patients presenting with symptoms of TB in India.

Satyanarayana *et al.* adopted the same approach to assess the dispensing of antibiotics to SPs presenting with symptoms of TB. With the first pilot study, the authors established that SPs or healthcare providers had minimal issues in participating in the study. The ability of pseudo patients to recall the details of the SP-

provider interaction strongly correlated with recordings of the interaction. Similar to the first study, the scripts for the case scenarios were developed under the guidance of anthropologists, physicians and TB experts. The individuals recruited as SPs were assigned to only one of the case presentations to avoid detection by pharmacists. The study team also made sure that the gestures, way of talking and outfit of the SPs were close to the people ordinarily residing in the study areas. The team recruited individuals from low-income settings to minimize detection during interaction with the pharmacists. This is the first study in India to use SPs for assessing pharmacy practices for patients with symptoms of TB in India. The authors highlighted the inappropriate use of antibiotics and steroids by pharmacists, though anti-TB drugs were not dispensed to any of the SPs.

The major strengths of both studies were intensive training for recruited individuals in correctly presenting as patients, development of scripts keeping in mind the sociocultural background and conduct of mock interviews and dry runs to minimize detection. To conclude, the SP method seems to be a promising and effective approach to assess the quality of care given to patients with TB. Similar techniques can be used in future studies to assess practitioners, pharmacists and other healthcare service providers. With the huge burden of TB in India, there is an urgent need for newer strategies to end TB and the SP approach can be a useful tool to assess the standard of TB care in the country.

*Conflicts of interest.* None

## REFERENCES

- 1 World Health Organization. *Global Tuberculosis Report 2016*. Geneva:WHO; 2016. Available at [www.apps.who.int/iris/bitstream/10665/250441/1/9789241565394-eng.pdf?ua=1](http://www.apps.who.int/iris/bitstream/10665/250441/1/9789241565394-eng.pdf?ua=1) (accessed on 1 Mar 2017).
- 2 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.
- 3 Collins JP. AMEE Medical Education Guide No. 13: Real patients, simulated patients and simulators in clinical examinations. *Med Teach* 1998;**20**:508–21.
- 4 Wallace P. Following the threads of an innovation: The history of standardized patients in medical education. *Caduceus* 1997;**13**:5–28.
- 5 Beullens J, Rethans JJ, Goedhuys J, Buntinx F. The use of standardized patients in research in general practice. *Fam Pract* 1997;**14**:58–62.
- 6 Rethans JJ, van Leeuwen Y, Drop R, van der Vleuten C, Sturmans F. Competence and performance: Two different concepts in the assessment of quality of medical care. *Fam Pract* 1990;**7**:168–74.
- 7 Li L, Lin C, Guan J. Using standardised patients to evaluate hospital-based intervention outcomes. *Int J Epidemiol* 2013;**43**:897–903.
- 8 Mansfield BG. How bad are medical records? A review of the notes received by a practice. *J R Coll Gen Pract* 1986;**36**:405–6.
- 9 Adamo G. Simulated and standardized patients in OSCEs: Achievements and challenges 1992–2003. *Med Teach* 2003;**25**:262–70.
- 10 Hasle JL, Anderson DS, Szerlip HM. Analysis of the costs and benefits of using standardized patients to help teach physical diagnosis. *Acad Med* 1994;**69**:567–70.
- 11 Duffy FD, Gordon GH, Whelan G, Cole-Kelly K, Frankel R, Buffone N, *et al.* Assessing competence in communication and interpersonal skills: The Kalamazoo II report. *Acad Med* 2004;**79**:495–507.

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