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Using unannounced standardised patients to obtain data on quality of care in low-income and middle-income countries: key challenges and opportunities

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Standardised patients (SPs)—also called patient actors, simulated patients or mystery clients—have a long history in medical education in high-income countries.[1–5] They are now increasingly being used in low-income and middle-income countries (LMICs) to measure quality of care in a variety of clinical and retail (drug shop/pharmacy) settings. SPs are healthy people, or people with stable conditions, extensively trained to consistently simulate the medical history, physical symptoms and emotional characteristics of a real patient to multiple healthcare providers, and subsequently to report details of those interactions. The SP approach has been referred to as the 'gold standard' for capturing actual provider behaviour in the healthcare setting.[6 7]

In a paper published in BMJ Global Health, Kwan *et al* discussed the different types of research questions that can be addressed using SPs, and the various methodological and analytical issues to consider.[8] In a recent complementary paper, King *et al* provide a step-by-step 'how to' guide for planning and implementing an SP study.[9] The two papers, and the detailed field manual provided by Kwan *et al* in their appendix, combine to make a valuable set of resources for researchers using the SP method. In this commentary, members of the Standardised Patients Working Group, comprising economists, epidemiologists and social scientists across nine universities and global health institutions, elaborate on five key methodological and ethical issues raised in the two papers, and discuss how these can be assessed.

SIMULATION

A key concern about SPs is that they are not real patients and therefore provider responses to SPs may not be valid. Researchers using this method in LMICs go to considerable effort to train SPs to act as real patients. SPs receive coaching to build their understanding of the background story and presentation, including the body language of ill individuals[10]—see the online supplementary appendix to the Kwan *et al* paper for examples of this process. Many studies also recruit SPs from the local communities where they are sent, as accents, language or other cultural characteristics are not easily replicated.[11]

Despite these efforts, concerns are often raised that providers may suspect that SPs are not genuine patients or carers. To allay these concerns, carefully designed studies include detection surveys where providers are contacted after an SP survey has been completed and asked about any suspected 'fake' patients (e.g. their symptoms, gender, age). In most studies, 5% or fewer of SPs are correctly suspected by providers of being 'fake' patients.[9]

TYPES OF CLINICAL CONDITIONS

An important challenge with SPs is the scope of conditions that can be investigated. The SP method is only feasible for conditions that

do not require physiological symptoms to be evident or invasive examinations to be performed: family planning request, cold, diarrhoea, tuberculosis or angina are examples of cases popular in SP studies in LMICs.[9] However, the spread of mhealth technology may allow SPs to show providers 'faked' results on a mobile phone, and therefore, allow for an expansion of SP cases.[12]

Another challenge is that SPs do not typically complete follow-up visits,[13] which excludes the assessment of continuity of care or chronic disease management. Studies from high-income countries highlight a 'first visit bias' that can skew assessment of quality.[14 15] A study in the USA found that quality of care for gastritis and hip pain was higher in two successive consultations compared with the first one, leading the authors to conclude that quality of care is underestimated when only the first visit is considered, and that SPs are more appropriate for cases requiring 'definitive clinical action' at the first visit.[16] While there are clear limits around the types of conditions that are suitable for SPs, the method has produced accurate measurements of the quality of care across a reasonably broad range of single encounters in LMIC settings.[17] That being said, there is a need, to find ways to extend the SP method for multiple, sequential visits to the same provider for chronic conditions.[8 9]

RECALL

One of the reasons behind the growing enthusiasm for SPs in LMICs is the wealth of data that this approach can help collect. SPs are typically asked to complete a structured questionnaire or checklist shortly after their consultation, capturing details of their interaction with the provider including: how long did the consultation last? Which questions did the provider ask? Which physical examinations did they do? What advice did they give? Which treatment did they choose? All of this information is invaluable in settings where electronic medical records rarely exist and paper-based patient files contain minimal information. SPs are partly chosen on their ability to accurately memorise clinical interactions, are carefully trained to do this and have been found to be much better at remembering the consultation than actual patients.[18 19]

One approach to empirically assessing the accuracy of SP recall involves covert audio recording of the clinical interaction and comparing this with the SP's report. Concealed recorders have been successfully used in one study in India which showed high quality recall by SPs.[17] However, the use of covert recording raises ethical issues and is limited to verbal communication. Another possible approach is for SPs to be accompanied by another fieldworker acting as a family member or friend, and to ask both individuals to answer independently the recall questions in order to measure inter-rater agreement.

STANDARDISATION

When comparing different types of providers, the SP approach can ensure comparability without concerns of patient selection issues, such as differences in patient socioeconomic characteristics (e.g., poorer patients more likely to consult public providers than private providers) or health status (e.g., sicker patients consulting more reputed providers). Standardisation allows researchers to alter one component of the patient–provider interaction at a time in order to estimate the causal impact of that component (e.g., estimating whether patient ethnicity has an impact on quality of care as investigated by Planas *et al*).[20] This ability to experiment with patient characteristics or attitudes is a key strength of the SP approach but researchers should also be alert to variations in the performance by SPs. Variation could arise if different individuals portray the same SP case in a different way, or if the same SP case is portrayed differently over time.

Measuring the consistency of SPs' portrayal of cases is done during training and sometimes during piloting (where SPs can be observed by a supervisor pretending to be a relative or friend), but it is more challenging during fieldwork. SP consistency can be measured indirectly by having multiple individuals portray the same medical case at the same healthcare provider. For instance, in their 2018 study using SPs to evaluate the quality of tuberculosis care in India, Kwan *et al*[21] found that providers delivered relatively consistent care, repeating all observed actions, including mistakes, approximately 75% of the time. Further examination of the same dataset showed that almost none of the variation in outcomes was predicted by personal SP characteristics such as age, gender, height and weight, suggesting that SP portrayals were sufficiently standardised.[6]

INFORMED CONSENT

A major ethical concern surrounding SPs is the deception of healthcare providers and whether or not informed consent should be sought from them. Since the objective of SP studies is to understand the unfettered interaction between provider and client, it has been widely recognised that seeking informed consent from a provider can jeopardise the scientific validity of the study by influencing the decision of providers to take part (creating selection bias) or influencing their behaviour (Hawthorne effect) if they think SP visits are imminent.[22 23]

King *et al*[9] discuss possible approaches to provider consent, such as obtaining consent well in advance to minimise Hawthorne effects, seeking consent from overarching authorities to minimise selection bias or obtaining a waiver of consent. Waivers of consent have been granted for minimally intrusive research in community pharmacies and other drug outlets[19 24] as well as a few large studies with providers.[6 21] Since results are reported at the aggregate level, the benefits of SP studies including the provision of objective data on quality of care must be balanced against risks posed to individual providers and facilities.

CONCLUSION

In summary, we would urge more research teams to report on the challenges and opportunities raised in this commentary. This information will enhance the uptake and generalisability of evidence from SP surveys and in turn, strengthen quality of care measurement in LMIC. Future investment in high-quality, accountable health systems relies on such information.

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