

EXPLORING STANDARDIZED PATIENT TECHNIQUE FOR
MONITORING QUALITY OF CARE IN
HEALTH SERVICE DELIVERY

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ABSTRACT

The ever emerging thrust for quality improvement in health care practices often look forward to appropriate assessment scholarship. The need for newer approaches for assessment and continuation of older methods generally come into conflict concerning the uncertainties in quality improvement. Assessing quality care as well as gaps in knowledge and practice of healthcare providers, Standardized Patient technique is currently being used in developing countries. The technique employs well-trained field workers to take on the role of patients and visit a doctor just like an actual patient would. The Standardized Patient is expected to pay attention during the interaction and record all observations in form of notes or in an exit-tool; the central idea being simulation of an actual patient environment. Through standardization and simulation, it tries to analyse process quality and determinants of quality. Standardized Patient as a tool is compared with medical vignette and direct clinical observation. It has been argued that Standardized Patient could work as an efficient tool in minimizing the Hawthorne effect.

The purpose of the paper is to discuss Standardized Patient as an evolving health care monitoring tool. The paper thus focuses on the relevance of technique and ascertain current usage in monitoring health systems through secondary data and review of literature to enumerate the best practices. Drawing upon examples from projects implemented or currently underway, the paper also explores modalities for implementation of the technique in an Indian setting.

Keywords: Quality of health care, Standardized Patients, monitoring

INTRODUCTION

The degree to which health care encompasses range of quality assurance measures recognizes the likelihood of increase in desired health outcome. Variations pertaining to the desired outcome in line with the quality of service delivery has been the concern of policy makers, implementers as well as beneficiaries globally. The question which arises here is whether there is a set parameter through which the much discussed quality assurance could be measured. Quality of care, especially within the context of developing countries, has been encountering such strategic concern. Can we now say, quality assurance of developing countries can be measured along the similar lines at which it is measured globally? The standards at which quality of care is measured may vary contextually, nevertheless, the zeal remains the same. This leads us to critically look into the health systems and decision-makers concerned. Abiding by the range of health concerns, the quality of health care could be contextualized and screened through a process of rigorous monitoring. Thus, the quest towards establishing quality health parameters and improvement likewise, through monitoring will raise the boundaries at which the quality assurance could be measured.

Delving into India's Health care systems raises a concern which particularly revolves around quality of health care. The gap between desired health outcomes and the actual quality of care delivered is the decrease with which India's health system is suffering. The focus here therefore is to see how this gap can be measured and assessed so that quality assurance can be established when hypothetically policies concerning health care are formulated adhering to desired outcome. Several methods have been evolving to measure the gap between this desired and actual quality of health care. The pursuit may take several forms but will aim towards one goal; quality health care. This paper is a result of one such concern, looking into the existing health care monitoring methods and in particular the evolving Standardised Patients method.

MONITORING QUALITY OF HEALTH CARE

Monitoring India's health care system around quality of care at primary level corresponds majorly to two important indicators which are assessing the knowledge of the health service provider and the performance of the provider along with clinical, technical and interpersonal elements of health care. Results which are envisaged at this juncture do not only confine to the performance or knowledge assessment of the health service provider but also the overarching need of the health care beneficiaries in terms of access and appropriateness of services.

Knowledge and performance of the health service provider thus ensure that quality of care is *measured, monitored and improved* (IOM 1994).

Since knowledge and performance of the health service provider is monitored along the lines of clinical, technical and interpersonal elements of health care, the methods with which it is monitored will focus upon such comprehensive indicators. The constituents of quality health care as laid down by World Health Organization (WHO) are; *effectiveness* at which the health service is delivered, *efficient* use of resources while delivering health care, Delivering health care which is timely, geographically *accessible*, health care which is *patient-centred and acceptable*, health services which is equally delivered not varying in quality due to gender, race, ethnicity, geographical location and socio-economic status (WHO 2006).

Over the years, these dimensions of quality of health care are analysed and emphasised to overcome poor quality of health care. The third factor which plays a major role while assessing quality of care is that of competency. Competency is the skill of the provider to perform his or her activities keeping in mind the above mentioned dimensions of health care. Given the scope of quality health care at the primary level, based on knowledge, performance and competency, variety of methods are in place to assess the quality of outpatients care such as clinical observation, exit interviews, vignettes and chart abstraction. Lately, Standardized Patients is evolving as an efficient tool to over the existing tools.

Methods for assessing quality care in developing countries have been confined to vignette, chart abstraction, exit interviews and direct clinical observation. Review of records has not been able to provide validity due to lack of appropriate documentation. Direct observation is one of the method which is termed to provide most accurate and reliable information on quality care as it assess the undergoing performance of the health care practitioner at normal circumstances. However, most of the times the observer may tend to look track of the activities the practitioner is performing due to lack of understanding of clinical procedures. Direct observations is known as the gold standard while assessing quality of care but what it misses out it the behavioural consistency which the practitioner will have at varied encounter with the patients. Thus, direct observation will provide us an assessment of performance conducted at one point in time.

Chart Abstraction on the other hand are termed to be useful while assessing the competency of the health service provider. It derives the process through which a practitioner provides care to a patients. This method is mostly used for inpatients. Therefore, it will not be able to provide a wholesome picture capturing both in and

out-patients. Due to time constraints the out-patients recording bias may occur and since no iterative or multiple adjustments for treatments could be recorded through chart abstraction for outpatients, the method will not provide reliable information while assessing quality of care.

While assessing knowledge and awareness of the health service provider, vignettes or written case simulations are often used. Vignettes are helpful in providing aggregate knowledge and awareness scale of a practitioner or a group of practitioners. But despite this vignettes are not been able to provide validity and rigour while assessing quality of care and not much have been done to validate it. All the methods discussed above are tried and tested over a period of time however their scope and applicability in the field have been decelerating. The need for a more rigorous method of assessing quality of care is required. Given the condition, standardized Patients is evolving as a “Gold Standard” method of assessing quality of care.

SCOPE OF THE PAPER

Based on the need of exploring new approaches of looking into the performance of health systems and quality of care mechanisms at the primary level, this paper tries to search thoroughly through the existing methodological approaches and comparatively explore the potential of Standardized Patient approach as a quality of care assessment tool. The paper has also tried to summarize the use of various health care monitoring tools at varied points in India with the help of literature review. Nature and characteristics of Standardized Patients and its current usage in Indian setting mostly pertaining to the assessment of the quality of health care in rural areas will be highlighted. The scope of the paper therefore is, firstly it gives a comprehensive picture of all the existing health care monitoring tools and secondly, provides informative justification over whether or not Standardized Patients has evolved as a “Gold Standard” while assessing quality of health care.

The first part of the paper presents an overview on the existing methods of monitoring. Its evolution usage, current eminence and limitations. Similarly, in continuation to the previous section, the evolution of Standardized Patients technique, history, application and current eminence, advantages and limitations are discussed. The second part of the paper goes on to develop a comparison between standardized patients as “gold standard” and other monitoring techniques. The third part of the paper talks about current usage of Standardized Patients as a monitoring tool and its consideration for implementation in the Indian Context.

METHODS OF MONITORING QUALITY OF HEALTH CARE

A variety of methods have been used in various studies to assess the quality of care routinely provided to the patients. This section throws some light on four such methods, which include: chart abstraction, exit interviews, clinical observations and vignettes.

Chart abstraction

The medical records, if maintained adequately, provide detailed information about the care provided to various patients visiting a health care provider. The method of chart abstraction involves studying these medical records and extracting relevant data to assess the quality of care provided to the patients.

Chart abstraction has proved to be an efficient and cost effective methodology that can provide a retrospective assessment of routine provider performance. In comparison to other methods available to assess quality of care, this method is less time consuming and can cover a large number of cases coming to any medical provider. As different kinds of patients come to consult any provider over a period of time, studying the records over such time period gives an opportunity to get information on variety of cases of illness. Using this method, the quality of care for both common and severe illness can be assessed.

Though the method of chart abstraction may provide more information in less time and at low cost, this method is limited by quality and completeness of medical records. Especially in developing countries and that too in informal settings, the medical records pertaining to the diagnoses and treatment or instruction are rarely available. This may be due to time constraints during the patient visits or due to lack of any systematic method of maintaining such records. The only records maintained in such settings are prescriptions which are not available as they go with the patients or the registers at the health centers which have very limited information. Also, the results that we get from this method are not comparable for different providers due to the difference in patient load and patient type presenting with different disease.

Exit interviews

The methodology of patient exit interview includes interaction with the patients coming out of the provider clinic. The exit interviews are designed and conducted to get information on the procedure that the provider followed to diagnose the illness and provide treatment to the patient.

This method helps in assessing the routine performance if it is conducted without provider knowledge. Many studies have shown that exit interviews are capable of gathering valid information about many activities performed during the interaction between the provider and the patient. It is particularly efficient in assessing the normal performance of provider on specific activities of asking history questions, physical examination and counselling task. As the observer is not present during the consultation process, the provider performs all the activities, as he/she would have done under normal conditions.

Though, the exit interviews provide a good means to assess routine behavior of a provider, the reliability of data collected by this method is affected by various factors, the first being the memory of the patient. After the consultation, the patient may not remember all the details about the questions asked and activities performed by the provider. Second, the patient might not be comfortable in giving all the information to an interviewer. Third, the patient might not have paid attention to the various activities done by the provider. Lastly, the patient doesn't know the mental activities and thoughts that were going in the provider's mind during the consultation process. Apart from these factors, the correctness of the diagnoses done by the provider cannot be commented on by using this method. This can be done by employing a medically trained interviewer, which will increase the cost of conducting the interviews. This method is also dependent on the patient load and variety and thus is incapable of carrying out any comparison between different providers.

Clinical observation

Clinical observation provides an opportunity to collect rich data about the processes followed during a medical consultation. In this method a trained observer spends some pre decided time, say a day, in provider's clinic and observes the whole process of disease diagnoses and treatment. The observations are recorded in a form designed to capture the complete information pertaining to various activities starting from presentation of symptoms by the patient to the prescription and suggestions by the healthcare provider.

The information gathered by this method is complete and is not limited by the memory of the patient. It helps in assessing the performance of the provider under normal conditions. The only difference is presence of an external observer. Many researchers believe that the presence of external observer tends to affect the performance of the provider. Under such condition the provider is believed to put in his best efforts while giving treatment. Thus this method is believed to assess BEST performance and not regular performance of healthcare provider.

Clinical observation provides information about every minute OBSERVABLE activity that is carried out during the treatment process but is unable to capture the performance of mental tasks. This method is dependent on the patient load, which in turn is affected by seasonal variations. Generally, in a day, majority of patients present with minor illness, therefore this method is unable to assess performance in case of severe illness if no such case appears on the day of observation. As in the case of chart abstraction and exit interviews, this method is also inapt to compare the quality of care provided by different providers as the types of patients that approach different providers may be different and suffering from different illness. Also, it is difficult to identify whether the course of treatment suggested by provider is appropriate for the symptoms presented by the patient. For doing so, medically qualified observers will need to be hired which may increase the cost dramatically.

Vignettes

Vignettes are stories or cases that present practical but hypothetical situations. In using vignettes to assess quality of care, the providers are presented with imaginary cases of patients presenting symptoms of specific disease. The provider is asked to react to the story considering it to be a real case of illness. The provider is supposed to follow the general course of diagnoses and treatment that he/she follows in routine conditions if encounters a case similar to the one presented in the vignette. Thus the provider's reaction to vignette gives the required data to assess the quality of care provided to the patient. Using vignettes we can control for type and number of cases that are presented to a provider and thus can get data to compare different providers and the quality of healthcare provided by them.

Vignettes measure the competence of the provider. Many studies show that the providers who have high competence may not always provide better quality of healthcare. There are differences in knowledge and practices of medical providers. As in case of vignettes, the providers know that they are being tested; they tend to give information to the best of their knowledge, which may be different from their routine performance. Thus vignette assess "What providers do" and not "what they do". Administering vignettes may be costly, as it requires well-trained enumerators who can memorize the answers to all the questions and examination that the provider may ask or perform. Also, the enumerator must be capable of repeating EXACTLY SIMILAR responses to all the providers.

THE STANDARDISED PATIENTS TECHNIQUE

The technique of standardised patients has essentially evolved from the field of medical education. The first simulated or standardised patient was born in 1963 in Los Angeles in the University of Southern California (USC). Howard S. Barrows first used this technique in training third year neurology clerks at USC. He was responsible for sourcing actual patients for the program. But, it was found that an actual patient had limitations. He could tire out easily for one and there were chances of his health being affected adversely. To wean out this problem Dr. Barrows started recruiting actors/people with normal health conditions and trained them as standardised patients. He was met with widespread resistance, many calling it an "invasion of Hollywood" in medical education. However, over the years the technique developed and gained popularity among the students as they got to practise their skills hands on without jeopardising the well-being of an actual patient. An SP feedback was used to better the skills of the students. The term began being generally accepted and adopted in evaluation of clinical performance from 1980s onwards hence bringing the methodology into research focus as being an unbiased tool for assessment of healthcare (Wallace, 1997).

Standardised patient is a person coached to reproduce the symptoms, conditions and mannerisms of an actual patient in front of a physician. The general idea is to allow a fair assessment of the skills of the physician by presenting to them a scenario which cannot be replicated by other means of assessment like oral examinations or paper based examinations. The technique captures other aspects of a physician's skills like patient handling. The term standardised patient was coined by a Canadian psychometrician Geoffrey Norman (Wallace, 1997). The term captures one of the most important features of the technique i.e. standardisation. This means that each and every research subject (student) is presented with the same set of conditions.

The process of using the standardised patient (SP) methodology starts with the enrolment of interested candidates. These people may or may not be trained actors. The enrolment happens according to the cultural context and it is of utmost importance that the patient be able to take characteristics of the usual clientele that the provider meets with. The aim is to minimise the identification of the SPs by the providers. After the enrolment of SPs, extensive training is done where the SPs are informed in detail about the disease that they are expected to portray. Personal data that they are expected to portray is also given to them. Personal data can include information on past disease history, name and background information of the patient, etc. After a case history has been created, standardisation is ensured

via repeated practice and debriefing to ensure that the patient's response is the same even upon repeated questioning.

Finally, the SP is informed of the risks of the job and advice is given on how to avoid evasive procedures. Visits to the providers are made after due consent. The SP is coached to pay attention and memorise the conversation with the provider and record his/her observations later on. Here as well there are different ways of recording observations. Some studies make use of audio tapes for recording the conversations (Luck and Peabody, 2002) while some used paper based formats. Even in the paper based formats either the SP could record his observation himself in a checklist tool or he might be interviewed by his supervisor who fills out the relevant details in a form. Such a tool is commonly called a post visit exit-tool where information on 5 sections (i.e. history, investigation, examination, recommendation/diagnosis and a patient feedback section) could be listed.

Some studies have been known to use the SP methodology to test quality of out of hour telephone consultations in primary care (Derx et al., 2009). Here the SP is trained to talk over the phone and convey his/her disease history.

ADVANTAGES AND LIMITATIONS OF SP

The standardised patient methodology has been used in various clinical settings for an assessment of quality of medical care. The prime advantage of the methodology is that it avoids the Hawthorne effect a term that warns that the knowledge of being in an experiment may have a more powerful impact on participants' behaviour than any single experimental variable (Broches, 2008). Further, the methodology allows for control in case-mix while measuring quality.

It is a great tool that allows observation in actual clinical setting as the doctor is unaware of the identity of the patient and behaves as he would with an actual patient. In terms of a monitoring tool it can be used not only to check the knowledge and actions of the doctor but allows observation of more sensitive skills like the doctor's behaviour and patient handling. Our exit tool in that case will have to cover questions on the aspect of the clinical environment that we want to capture. For example, if the basic assessment of the skills of the doctor is being done the exit-questionnaire can have questions based major areas of questioning that a doctor normally takes, these being:

- a) questions on the history of the patient,
- b) questions on investigation prescribed by the doctor,
- c) questions on the examinations performed by the doctor and

d) questions on the recommendation given by the doctor.

In such a tool the standardised patient can record his observation by dichotomous response of yes and no.

As far as the environment assessment goes the questionnaire can be changed to reflect parameters such as the clinic environment, behaviour of the staff, cleanliness of the waiting and the examination rooms, behaviour of the doctor, understanding on the treatment prescribed, etc. The answers of the patient can be a dichotomous or response on a 5-point scale.

The biggest limitation of the technique is that it is difficult to attribute the physical characteristics of an actual patient to the standardised patient in terms of pallor, signs of fatigue, etc. Further, more than one visit might be required to judge a doctor's skill sets adequately which might not be possible in every situation. Although, this has been attempted in some studies. Yet another limitation cited by some studies is the 'first visit bias' (Luck and Peabody, 2002). It raises question on the ability of the standardised to measure quality in a single interaction.

COMPARISON BETWEEN SP AND OTHER TECHNIQUES

The standardised patient technique has been called a gold standard by many studies. There are several advantages that it has over the other methods. In this section a comparison between this technique and other techniques of healthcare quality assessment has been attempted (MAQRI, n.d.). We are analysing just the advantages and the disadvantages here while it may be kept in mind that all techniques have their merit and applicability in different situations. The analyses is summarized in the table 1.

Table 1: Comparative analyses of different monitoring methods

Aspects of Monitoring	Standardized Patients	Vignettes	Chart Abstraction	Exit interviews	Clinical Observation
Aspect of bias	Hawthorne effect is minimised in this technique as the service provider (doctor) does not know of the identity of the patient.	The doctor is presented with a case and depending on his questions further answers are given to him. This could get biased if the investigator gives unsolicited information.	Ideally, this has to be performed by someone who has medical knowledge. His/her bias towards a particular treatment may make him biased in his opinion of the chart.	The assessment of the doctor's practice depends on the patient's views. Can't be compared across providers.	This is prone to Hawthorne effect, the doctor is aware of being observed and he may change his behaviour drastically.
Measures knowledge (what the doctor knows?)	No, the techniques does not measure knowledge of the doctor. It is just an observation of an interaction.	Yes, it is administered in a Q&A format and hence can be used as a test of knowledge of the provider.	No, it does not adequately measure knowledge.	No, by the means of this tool we are interviewing only the patients. Correctness can be judged later on.	No. this technique is more oriented towards measurement of action than knowledge.
Measures practice (what the doctor actually does?)	Yes, the standardised patient (SP) observes and records all information.	No, the doctor is trying to give the best possible response to this tool, may not be his actual practice.	Yes, it gives an actual picture of the prescription made by the doctor.	Yes, at some level. The patient is able to tell about the course of treatment adopted by the doctor.	Yes, the whole emphasis is observing the doctor in a real setting.

Aspects of Monitoring	Standardized Patients	Vignettes	Chart Abstraction	Exit interviews	Clinical Observation
Accounts for case-mix (different cases and diseases being presented to the doctor)	Yes, the SP can be coached to present the case of a patient as required.	Yes, case studies of different diseases can be created.	No. This is done only on the basis of availability of cases.	No, The case mix would solely depend on the type of patient the doctor specialises in.	No, same problem as that of exit interviews.
Accounts for patient-mix (refers to the patient characteristic other than the diseases, ex. sex of the patient, age, etc.)	Yes, any investigator with required characteristics can be trained as a SP.	Yes, depends on the case study presented to the doctor.	No, availability is the issue.	No, availability is the issue.	No.
Illnesses covered (types of diseases/cases that can be covered)	Any illness that does not have an invasive treatment/examination process can be taken up by using this methodology.	All illnesses could be covered.	The limitation here is the availability of required charts which even if available are poorly kept.	Limited to the interviewer knowledge and the patient awareness and understanding.	Limited, as the observer might not have full knowledge of the correctness of diagnosis made by the doctor.

CURRENT USAGE OF SP AS A MONITORING TOOL

Given the fact that despite certain limitations, standardized patients is still considered as a Gold standard in quality measurement. Use of SP as a monitoring tool is gaining popularity in the Indian context especially when it comes to assessing rural health systems. A study conducted in 2010 in rural Madhya Pradesh is one of the examples of where SP technique was adopted to assess the quality of provider's medical care (Das et al., 2012). The Medical Advice Quality and Availability in Rural India (MAQARI) component of the Health and Education in India project was multi-year study that seeks to close information gap and better inform policy by measuring the quality of medical care and piloting interventions that could potentially improve the delivery of care. The study found that SP technique was adept at capturing lack of provision of recommended care, low diagnostic care, poor adherence to treatment guidelines, and frequent use of harmful or unnecessary medications. All of these are some of the critical indicators while monitoring quality of health systems. The study also suggests that the case presented was convincing enough for the providers to need based health care provision. The cases simulated were asthma, dysentery and unstable angina. Likewise use of SP technique is gaining its influences over assessing quality of care provided to diseases like tuberculosis. The National Tuberculosis Control Programme in its national strategic plan recognizes the need for incorporating private providers using "Private Provider Interface Agencies" (PPIA) to enlist, sensitize, incentivize, and monitor diagnosis and treatment by private providers, to provide patient cost offsets such as subsidized diagnostics and free drugs to privately treated patients (Pai, 2014, March 24). The PPIA model is currently being implemented by Bill and Melinda Gates foundation along with other partners in the state of Bihar and Patna. SP technique is currently in place to assess the quality of care provided by the providers to TB patients.

The evolution of SP as a clinical teaching technique to a monitoring method has been seen in the developing countries. Given a specific condition, or illness in case of health studies, having predefined questions to be posed for a particular research purpose and a standard protocol is all that is required by a SP technique to produce results which makes it prevail over other health care monitoring techniques. Standardized patient's presentation and accurate recording of processes involved during the interaction with the health care providers are the milestones upon which the monitoring crux are based.

CONCLUSION

Measurement of quality in healthcare is an important issue. There are several ways that are being used and some new ones that are coming up. By this paper an attempt has been made to integrate the available information about the standardised patient methodology. The aim is not to compare and prove the method as the best but to bring out the points of comparison between this and other methods of monitoring. The SP methodology provides several advantages over the others while having some limitations no doubt. Given the flexibility with which it can be used the method can surely find a firm footing when healthcare monitoring exercises are being designed. Some questions have arisen on scale at which the methodology can be used. To cater to needs of different project situations the training and the recording of observations can be tailored accordingly. For example, when there is abundance of resources tape recorders can be used to record the SP interaction and when there is a paucity of resources a paper based exit interview tool with relevant points of data capture may suffice.

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