

finished product. There is still no clarity on how the new regime for examining injuries and deaths in drug trials would function in a transparent and accountable manner. The issue of how the quantum of compensation would be calculated still remains undecided.

Besides, the panel and committees of independent experts formed to examine SAEs (2) are strangely charged with investigation of only those SAEs that resulted in deaths and not others. It is also not clear whether they will be examining the tens of thousands of SAEs of the last eight years. It is indeed very important that justice for those who have already suffered should constitute the foundation of new regulations.

All those with the ethical commitment to provide protection, benefits and compensation for drug trial participants will need to show a high level of vigilance to propel the system forward and not allow it to regress.

References

1. Central Drugs Standard Control Organisation [Internet]. New Delhi: Ministry of Health and Family Welfare, Government of India;2013. *Gazette of India, Extraordinary*. Part II-Section 3-Sub Section (i);2013 Jan 30 [cited 2013 Apr 22];17p. Available from: [http://www.cdscsco.nic.in/GSR%2053\(E\)%20dated%2030.01.2013.pdf](http://www.cdscsco.nic.in/GSR%2053(E)%20dated%2030.01.2013.pdf)
2. Central Drugs Standard Control Organisation [Internet]. New Delhi: Ministry of Health and Family Welfare, Government of India;2013. Panel of experts for constituting independent expert 22]. 130p. Available from: http://www.cdscsco.nic.in/panelof_exprt.pdf
3. Central Drugs Standard Control Organisation [Internet]. New Delhi: Ministry of Health and Family Welfare, Government of India;2013. *Gazette of India, Extraordinary*. Part II-Section 3-Sub Section (i);2013 Feb 8[cited 2013 Apr 22];13p. Available from: [http://www.cdscsco.nic.in/html/G.S.R%2072\(E\)%20dated%2008.02.2013.pdf](http://www.cdscsco.nic.in/html/G.S.R%2072(E)%20dated%2008.02.2013.pdf)
4. Drugs Controller General of India. Additional affidavit submitted in the Supreme Court of India. Writ Petition (Civil) No. 33 of 2012. Swasthya Adhikar Manch, Indore, and Another v. MoHFW and Others.
5. Ministry of Parliamentary Affairs. Committee on Government Assurances (of Parliament). Document "Post-Evidence Notes", reference No. SQ 71/22/102008-CGA, dated May 9, 2011, in relation to the Assurance given by the government in reply to Lok Sabha Starred Question No. 71 dated October 22, 2008. See Annexure B of the "Office Memorandum" dated April 26, 2011, signed by undersecretary to the government of India.
6. Srinivasan S, Jesani A. Standing committee report on CDSCO: Hard facts confirm an open secret. *Indian J Med Ethics*. 2012 Jul-Sep;9(3):148-50.
7. Vaidya M. Indian apex court raps govt over clinical trial data. *BioSpectrum* [Internet]. 2013 Jan 10 [cited 2013 Apr 22]. Available from: <http://www.biospectrumasia.com/biospectrum/analysis/155515/indian-apex-court-reaps-govt-clinical-trial#.UXAUgEpWLbc>
8. Elliot C. Justice for injured research subjects. *N Eng J Med*. 2012 Jul 5; 367(1);:6-8.
9. Chen DT, Miller FG, Rosenstein DL. Clinical research and the physician-patient relationship. *Ann Intern Med*. 2003 Apr 15;138(8):669-72.
10. Mukherjee S. Compensation conundrum. *Perspect Clin Res*. 2012 Jan;3(1):4-7.
11. Munshi R, Thatte U. Compensation for research related injuries, *Perspect Clin Res*. 2013 Jan;4(1):61-9.

Trust in healthcare: an evolving concept

VIJAYAPRASAD GOPICHANDRAN

Doctoral Research Scholar, School of Public Health, SRM University, Kattankulathur, Kanchipuram District 603 203 INDIA e-mail: vijay.gopichandran@gmail.com

Introduction

There has been increased interest over the past couple of decades in the public's trust in doctors and in the health system. The fundamental basis of a healthcare relationship is trust, which is the patient's voluntary acceptance of his vulnerability in the expectation that the healthcare provider will do the best for him (1). The changing socio-political and healthcare environment in India may be creating different types of provider-patient relationships. There is a need to look at what 'trust in healthcare' means in today's context. Do patients still have (a possibly naïve) complete faith that providers will give them correct treatment that is in their best interest?

In this essay, I will explore the notion that advances in medical technology and their diffusion through corporatisation of healthcare have affected the character of people's trust in healthcare providers and the system. Patients may have a modified trust in their physicians. I describe four types of trust in addition to what some have described as "blind trust": patients may weigh their options: they may verify the doctor's decisions; they may remain sceptical of the doctor, and they may place their trust in protocol-based treatment.

Trust in healthcare

First, we have to understand what trust in healthcare is. Some have defined patient trust in the physician as a collection of expectations that the patients have from their doctor (2). Others have defined it as a feeling of reassurance or confidence in the doctor (3). Yet another definition of trust, which is apt for the healthcare setting, is "an unwritten agreement between two or more parties for each party to perform a set of agreed upon activities without fear of change from any party"(4). A fourth definition of trust in healthcare is "an optimistic acceptance of vulnerability of the patient that the physician will do the best for their treatment

with good will”(1). Thus trust is a set of expectations that the healthcare provider will do the best for the patient. It acts as the fundamental basis on which autonomy and informed consent are based.

The changing socio-political environment in healthcare

There has been a rapid growth in technology in the medical field starting from the late 20th century. This has resulted in major advances in the understanding of disease processes, and in the diagnosis, treatment and course of diseases (5). The evidence-based medicine movement which evolved over the past four decades is accepted as the *sine qua non* of good quality medical care (6). Alongside this development is the growth of business models in healthcare. Corporatisation of medical care has given an impetus to the advancement of technology in medicine in India(7). Healthcare of international standards has reached remote corners of the country. Yet, large segments of the population still do not have access to even basic healthcare. There has been much debate on the health disparities in the country (8). National task forces have been set up on how to make access to healthcare universal (9). The development of the human rights movement post World War II, and the more recent discourse on realising health as a human right, has significantly contributed to the understanding of these health inequities and the need for universal healthcare access in countries like India.

At the same time, the era of information technology, heralded by the development of the Internet, and communication technologies like cellular phone services, has significantly shrunk the world. Communities are being defined differently, with fewer personal and more virtual interactions. People seeking healthcare may also visit the Internet for information.

These developments have affected people’s trust in healthcare in various ways.

It has been suggested that developments in the socio-political scenario of healthcare have affected people’s trust in healthcare providers (10). I would like to describe four types of trust in health care, in addition to the “blind trust” which has been implied in the historical descriptions of the physician-patient relationships (11). These are: calculated trust, trust but with verification, sceptical trust and impersonal trust. These describe distinct approaches, but with some overlapping features.

Autonomy and patient participation in treatment – “calculated trust”

From historical times, the doctor-patient relationship has been given a special status and several measures such as various codes of conduct from the Hippocratic Oath to modern biomedical codes of ethics, have been adopted to protect its sanctity. Trust in the physician and healthcare was unquestioned and implicit (11), based on an expectation that the physician followed professional ethics.

This trust in healthcare and providers changed with growing evidence that physicians sometimes acted against their patients’ interests. The evidence presented at the Nuremberg trials after World War II provided sufficient grounds for mistrust in the profession. As a result, greater emphasis was placed on autonomy and self determination of individuals, by the international organisations which emerged to codify the conduct of doctors. It was emphasised that patients should be made equal partners in medical decision-making. Some studies found that when patients actively participated in the decision-making, the outcomes were better (12). In this period, it became an ethical requirement for physicians and researchers to obtain voluntary informed consent for participation in medical research as well as for treatment and procedures.

As patients become increasingly able to make informed decisions, their trust in doctors may reduce as they start suspecting that doctors might act in their own self-interest rather than the best interest of patients (13). Lack of adequate information to patients, poor communication skills of doctors and suspicions about conflicts of interest naturally lead to doubts.

There is another facet to the interaction between trust and autonomy. Patients who have blind trust in their physicians tend to participate less in the clinical interaction and allow physicians to make most decisions. This can have negative consequences. Physicians may fail to do the best in the circumstances as they may not feel accountable for their actions. There is also potential for exploitation as doctors know that their decisions will not be questioned.(13)

Thus with the rise in importance of autonomy in the patient-physician interaction, patients’ trust may no longer be “blind trust”. Autonomous patients may choose to have “calculated trust” in which they weigh their choices and make a calculated choice to trust the doctor.

Ready access to information – “trust but verify”

The latter part of the 20th century heralded a rapid growth in information technology. While the Internet is a powerful source of information, the ease of access to information can be a double edged sword (14). There is a proliferation of information on the Internet, without regulation to ensure its accuracy, and some of it can be misleading. The ease of access to information has empowered patients to ask questions, but may also have led to a decrease in trust.

When patients have unlimited access to information, their trust in the doctor should be understood as a dynamic phenomenon. Patients expect that the doctor will do what is best for them. But they are also alert enough to ask questions and verify the doctor's advice if need be. This relationship has been described as "trust but verify" (15). Such trust would not imply a compromise in autonomy and the need for full information.

The development of information technology has given rise to readily verifiable trust. The patient has access to information and thus can verify the doctor's decisions.

Profit-motivated healthcare – "sceptical trust"

The growth of the private sector in healthcare has led to significant improvements in the quality of healthcare and technology, but has also caused glaring disparities in health. The business model of healthcare has led to scepticism among patients (4). Patients who pay large sums of money out of their pocket may wonder if their doctors are doing all that is best for their treatment. They may wonder whether their doctors' decisions are motivated by money. At the same time, there is some evidence that in developing countries, trust in private doctors is higher than in the public health system (16). They may believe that paying money buys them trustworthiness in the private health system, whereas the public system is not trustworthy since no money is paid. This can be described as a 'sceptical trust' -- the patient's strategic acceptance of his vulnerability while remaining sceptical in the belief that money determines trustworthiness.

Protocol-based medicine – "impersonal trust"

Another important development which has a significant impact on patient-physician trust is the growth of evidence-based medicine (EBM). The evidence-based medicine movement has been criticised for disrespecting the value of clinical experience and expertise. Its protocol-driven practices ignore patient preferences and can increase healthcare costs (3). However, the presence of standard treatment protocols which are publicly available may also lead to increased accountability. By demystifying medical treatment, EBM also leads to a reduction in blind trust in the doctor. Patients gather information about the disease and treatments, and the trust they develop is more in the standardised protocols and treatment procedures than in the physicians. This makes the trust impersonal.

Thus the original "blind trust" can be seen to have evolved into 'calculated trust', 'verifiable trust', 'sceptical trust' and 'impersonal trust' over time, facilitated by socio-political developments in healthcare.

Trust is still an important value in healthcare

Given this metamorphosis of trust in healthcare from blind faith into a calculated, strategic approach, is there still a role for trust as an intrinsic value? I would like to argue that though trust has evolved over the years because of the various influences as described above, there is a strong undercurrent of ethics in the construct of trust which has stayed intact. The principles of medical ethics lay emphasis on autonomy, beneficence, non-maleficence, and justice (17). Medical ethics advocates for respect to the individual moral agency of patients and their rights. Therefore, good ethical practices express the doctor's sense of commitment to the profession and respect for the patient. It is my argument that this commitment and respect will nurture trust of a different form in the current socio-political scenario in healthcare.

A trusting doctor-patient or doctor-system relationship has several instrumental values. A patient who has greater trust in the doctor is more likely to comply with advice on treatment and follow-up, disclose relevant sensitive and personal information, and also derive a placebo effect – which has its own value – from the clinical encounter. Greater trust in the physician has also been reported to increase self-reported good health among patients. A patient who has greater trust in the physician tends to elicit positive behaviour from the physician and the system itself, thus creating a positive feedback loop of trust and benefit (18).

The model of trust in healthcare has evolved significantly, as described in the previous paragraphs. However, any doctor-patient relationship necessarily exposes the vulnerability of the patient to the doctor, with patients giving their body to the doctor in the good faith that they will be taken care of. The models presented here only describe the extent to which the trust is blind or well informed.

Some western studies have reported diminishing levels of trust in healthcare (19). In my opinion this assessment is flawed because it does not consider the dynamism of trust as a concept. The dynamism referred to here is the responsiveness of the nature of trust in healthcare to the social situation. Assessment of trends of trust in healthcare over time should take into consideration the interaction of variables such as the social environment, political circumstances and scientific developments. It is more likely that the form of trust has changed, not trust itself.

A true loss of trust in healthcare is reflected as a reduction in trusting behaviours (20). A typical example is the adverse event following immunisation for measles in Tamil Nadu (21). Following the death of four children after administration of the measles

vaccine, the measles vaccine coverage rate reduced drastically. This is a direct reflection of loss of trust in the measles vaccine and the system. But reports of reduced trust in the public health system have to be assessed with care as they are not associated with a concurrent distrustful behaviour.

Currently patient satisfaction is extensively used as a measure of healthcare system performance and quality. This could be effectively complemented with measures of trust. Since trust is forward looking, it gives a prospective assessment of quality (22). It complements satisfaction measurement and completes the loop of patients' perceived assessment of healthcare. As a measure of quality of care, trust is still an important value in healthcare.

Directions for research on trust in healthcare

There is little empirical work on the nature of trust in healthcare, its dimensions and determinants (10). The understanding of trust in healthcare has evolved slowly. But most research has emerged from developed country settings. We know that the healthcare setting is very different in India and other developing countries. There is a need to develop models of trust in healthcare grounded in developing countries like India, where solidarity and social cohesion play an important role.

Acknowledgement: Vijayaprasad Gopichandran is supported by the INSPIRE Fellowship, from the Department of Science and Technology, Government of India.

References

1. Hall MA, Dugan E, Zheng B, Mishra AK. Trust in physicians and medical institutions: what is it, can it be measured, and does it matter? *Milbank Q.* 2001;79(4):613-39.
2. Anderson LA, Dedrick RF. Development of the Trust in Physician Scale: A measure to assess interpersonal trust in patient-physician relationships. *Psychol Rep.* 1990 Dec;67(3 Pt2):1091-100.
3. Caterinicchio RP. Testing plausible path models of interpersonal trust in patient-physician treatment relationships. *Soc Sci Med Med Psychol Med Sociol.* 1979 Jan;13A(1):81-99.
4. Shore DA. Communicating in times of uncertainty: the need for trust. *J Health Commun* 2003;8 Suppl 1:13-4.
5. Cutler DM, McClellan M. Is technological change in medicine worth it? *Health Aff (Millwood)* 2001 Sep-Oct;20(5):11-29.
6. Straus SE, McAlister FA. Evidence-based medicine: a commentary on common criticisms. *CMAJ.* 2000 Oct 3;163(7):837-41.
7. Jindal S. Privatisation of health care: new ethical dilemmas. *Issues Med Ethics* 1998 Jul-Sep;6(3):85-6.
8. Bajpai V, Saraya A. Socioeconomic inequalities and health outcomes in India. *Natl Med J India* 2012 Jan-Feb;25(1):38-42.
9. Reddy KS. Universal health coverage in India: the time has come. *Natl Med J India* 2012 Mar-Apr;25(2):65-7.
10. Pearson SD, Raeke LH. Patients' trust in physicians: many theories, few measures, and little data. *J Gen Intern Med.* 2000 Jul;15(7):509-13.
11. Conti AA, Gensini GF. Doctor-patient communication: a historical overview. *Minerva Med.* 2008 Aug;99(4):411-5.
12. Fraenkel L, McGraw S. Participation in Medical Decision Making: The Patients' Perspective. *Med Decis Making.* 2007 Sep-Oct;27(5):533-8.
13. O'Neill O. *Autonomy and trust in bioethics.* Cambridge: Cambridge University Press; 2002. p 228.
14. Takahashi Y, Ohura T, Ishizaki T, Okamoto S, Miki K, Naito M, Akamatsu R, Sugimori H, Yoshiike N, Miyaki K, Shimbo T, Nakayama T. Internet use for health-related information via personal computers and cell phones in Japan: a cross-sectional population-based survey. *J Med Internet Res.* 2011 Dec 14;13(4):e110.
15. Lee YY, Lin JL. Trust but Verify: The interactive effects of trust and autonomy preferences on health outcomes. *Health Care Anal.* 2009 Sep;17(3):244-60.
16. Russell S. Treatment-seeking behaviour in urban Sri Lanka: trusting the state, trusting private providers. *Soc Sci Med.* 2005 Oct;61(7):1396-407.
17. Beauchamp TL, Childress JF. *Principles of biomedical ethics.* 5th edition. New York: Oxford University Press; 2001.
18. Lee YY, Lin JL. The effects of trust in physician on self-efficacy, adherence and diabetes outcomes. *Soc Sci Med.* 2009 Mar;68(6):1060-8.
19. Mechanic D. Changing medical organization and the erosion of trust. *Milbank Q.* 1996;74(2):171-89.
20. Hall MA, Camacho F, Dugan E, Balkrishnan R. Trust in the medical profession: conceptual and measurement issues. *Health Serv Res.* 2002 Oct;37(5):1419-39.
21. Amdekar YK, Singhal T. Committee on Immunization, Indian Academy of Pediatrics. Measles Vaccine Deaths—The IAP-COI Stand. *Indian Paediatr.* 2008 Jun;45(6):479-80.
22. Thom DH, Hall MA, Pawlson LG. Measuring patients trust in physicians when assessing quality of care. *Health Aff (Millwood).* 2004 Jul-Aug;23(4):124-32.

Be a part of IJME

IJME invites readers to submit research studies, comments, case studies, reports, reviews, letters, as also poems, short stories, original paintings and photographs of print quality (both in colour and B/W) to be considered for publication.

All submitted matter is subject to peer review.

Contributors are neither paid nor charged any fee for published matter.