

FROM OTHER JOURNALS

Mindset theory and informed consent

Several patients who participate in early phase cancer trials have been known to later reveal that they had expected positive outcomes from the trial. Given that these unreasonably high expectations were expressed by participants after being made aware of the experimental nature of the new treatment, serious concerns have arisen for research ethics and informed consent. Such expectations are part of therapeutic error, and this article explores how such error forms, especially among those in an early phase cancer trial.

The author draws on the concept of “mindset” from social psychology and elaborates on the distinction between deliberative and implementation mindsets to understand why people suffer from therapeutic error. When faced with two goals, while a person with a deliberative mindset will try to accurately assess the outcome of each and decide accordingly, a person with an implementation mindset will keep planning about the outcomes of the goals. So, it is the former who can make more accurate predictions about any future course of action. The author argues that chances of therapeutic error are higher among people with an implementation mindset, than among those with a deliberative mindset.

There is also a predecisional and postdecisional phase vis-à-vis trial participation. While the predecisional phase tends to trigger a deliberative mindset, the postdecisional phase triggers the implementation mindset. It thus becomes important to assess what cognitive state of mind a participant is in when the therapeutic error starts to appear. While assessing risks is one thing, appreciating the “experimental” nature of a trial outcome is a very different thing to accept, argues the author. It helps explain why a participant, having clearly understood the experimental nature of a therapy/trial, starts expecting positive outcomes after s/he has been on the trial for sometime – it is precisely because the mindset in which s/he gave consent has changed into a different cognitive mindset. This re-emphasises the need to make informed consent an ongoing process – rather than a one-time formality at the beginning – especially for participants with serious health issues enrolled in long-term trials. The author argues that informed consent is a “diachronic” or “deliberative” process that should offer several exit points to participants; it is the ethical imperative of the researcher to constantly evaluate if the cognitive mindset of the participant has shifted and s/he has started to expect unrealistic outcomes, and act accordingly.

Jansen L A. Mindsets, informed consent, and research. *Hastings Cent Rep.* 2014 Jan–Feb; 44(1):25–32. doi: 10.1002/hast.237

The rhetoric of women and children’s rights in Indian psychiatry

This paper analyses the differences of social and political status between elite professionals and their non-elite patients and families with a view to understanding the failure of psychosocial interventions in a North Indian public teaching hospital. Through participant-observations and unstructured interviews conducted at the department of psychiatry during 2001-2004, two main strategies were delineated in the practice of professional psychiatrists. The first strategy was that psychiatrists were seen to manipulate popularly held traditional beliefs “almost beyond recognition” and use them to alter those views of their patients which were not deemed to be liberal enough. It was noted that Indian psychiatrists were more preoccupied with individual rights of women and children in line with current human rights discourses and less with their rights as mentally disabled patients. This was explained by the view that western psychiatry is viewed as the “significant other” from whom Indian psychiatry tries to gain recognition. The second strategy was that of (usually) harsh and public exhortation of patient’s family members who were understood to be perpetrators of oppressive household conditions. It is recognized that relationships across class in North India are hierarchical. Superiors issue diktats and provide patronage and inferiors express compliance or praise. Given this model, the author emphasised that exhortation by elite psychiatrists proved to re-inscribe the dominant political and social structures in the community that they were trying to attenuate. In conclusion, a new communicative register needs to be developed across class status for there to be mutuality in therapeutic relationships, and interventions must be designed taking into account the specifics of history and politics of space.

Marrow J. The rhetoric of women and children’s rights in Indian psychiatry. *Anthropol Med.* 2013 Apr;20(1):72–84. doi: 10.1080/13648470.2012.747590. Epub 2013 Mar 20.

Ethics of research photography

Taking photographs for research is common practice, especially since they are rich teaching material, make for strong evidence, provide irrefutable context to a setting, and help raise awareness and also funding. There are issues of privacy and consent that can be at stake in the quest to obtain more photographs. The growing use of the internet, easy accessibility of digital photographs and the lack of ethics protocols for photography in research, especially in low-resource settings,

have raised serious ethical concerns. The authors conducted three focus group discussions with medical and non-medical health researchers. All the members of the groups were of the opinion that photographs have immense value and should be taken as per need; however, the need to be ethical and judicious in their dissemination and replication was intensely debated. As expected, much of the discussion focused on the need and problematic of consent, the connotations of "informed" consent, the limits of information, and written consent versus verbal consent. Since the focus was on photographs of children, the members also discussed how best to involve the guardian; who was to be seen as the guardian in a culture where the family was the same as the community; and the problems of applying the "western" idea of informed consent to overwhelmingly non-western situations were tabled repeatedly. The authors provide a "ladder of dissemination" which details the extent of dissemination of photographs across social media in an escalating manner and asks researchers to decide on the nature and modality of consent according to their need for dissemination. They recommend training sessions for researchers on the complicated nature of cultural issues in low-resource settings vis-à-vis taking consent and photographing. Taking consent, sharing information and making researchers ethical and responsible is processural in nature and there cannot be a one-time solution. However, it is important that we keep flagging these issues and discussing the associated concerns, challenges and possible solutions so as to keep alive the discussion for making research more ethical and sensitive.

Devakumar D, Brotherton H, Halbert J, Clarke A, Prost A, Hall J. Taking ethical photos of children for medical and research purposes in low-resource settings: an exploratory qualitative study. *BMC Med Ethics*. 2013 July 9;14:27.

The Anuradha Saha case and medical negligence

The recent Supreme Court of India judgment awarding Rs 6 crore with interest brought into the limelight the issue of medical negligence and compensation in the country. One of the main reasons for the keen interest shown by the media in the case was the amount of compensation which the court awarded on the basis of the income Anuradha could have earned in the US. Anuradha Saha succumbed to complications arising from Toxic Epidermal Necrolysis (TEN) 15 years ago, while she was on vacation in India. Her case was first treated as an allergy at a clinic and later at private tertiary care hospitals in Kolkata and Mumbai. Cases were filed on account of criminal negligence and before the National Consumer Disputes Redressal Commission (NCDRC) whose verdict was questioned on appeal in the Supreme Court which passed its final judgment in October 2013. George Thomas, in his commentary in the Economic and Political Weekly, elaborates on the medical questions involved in the case. TEN is an uncommon disease with a high mortality rate, the prognosis of which depends on a number of factors including the quality of nursing care. The author points out that many doctors may argue that the nature of the illness and lack of supportive care were the real causes of

death, and not the high dose of steroid that was administered to her incorrectly. The author brings to the fore the sorry state of affairs in the Indian medical system which lacks the physical infrastructure, human and other related resources to deal with life threatening conditions in our intensive care units. He further explains that while the government sector is riddled with issues ranging from physical and human resources, the condition in the private sector is also not particularly hopeful for managing rare and life threatening conditions and that the kind of care that Anuradha Saha would have required does not exist in India even today. He raises the issue of why this information about inadequate facilities was not shared with the patients' relatives. He blames it on the intense competition in the private medical sector, insecurity amongst doctors resulting in failure to refer patients to another doctor or higher centre of care and the "I know it all" attitude among Indian doctors. The most fundamental issue is the lack of a proper system of medical care in India on which the patient can depend for correct diagnosis and proper care. While poor patients are left to the mercy of highly inadequate government facilities, rich patients are forced to make a guess as to which hospital and what care should be sought for the ailment. The author opines that the blame for Anuradha Saha's death should be shared by the negligent society which failed to demand a minimum quality of care and a proper medical care system in the country.

Thomas G. The Anuradha Saha case and medical error in India. *Econ Pol Wkly*. 2013 Nov 23;48(47):12-4.

The Medical Council of India and self regulation

The Indian medical council has been in the news for all the wrong reasons for a very long time now. The article draws attention to the 13th report of the Parliamentary Committee on Subordinate Legislation which stressed the need for refocusing on issues related to medical regulation in India. In this context, the article looks at the efforts at medical self regulation in Maharashtra state by examining the functioning of the Maharashtra Medical Council. Set up as a body to oversee the registration of allopathic practitioners in the state, the setting up a code of ethical conduct, and for the settling of complaints from its members, the council entered troubled waters in the early 1990s, when malpractices became very common during the election process for council members. The High Court appointed observers, in spite of which the sorry state of affairs continued to mar the MMC elections. The postal ballot was replaced by direct secret ballot on the directions of the High Court but the council did not elect members for nearly a decade, after which elections were held in 2009. Due to the failure of the Government to designate the nominated members who along with the elected members would constitute the council; the MMC was dysfunctional for another two years. While the council has become functional in 2011, it has many overwhelming tasks ahead of it including the updating and renewing of registrations, organising of continuing medical education (CME) programmes and taking action against erring doctors. MMC has taken the right initiatives by setting up a special ethics committee and by

taking stringent action against those doctors who violated the Pre Conception and Prenatal Diagnostic Techniques Act, 1994. The authors point out that the lack of transparency and knowhow about how to bring up a complaint before the council is an uphill task that patients and consumers face. Another overlooked area remains lay representation from the patient community, as the council now allows only for elected and nominated members. They conclude by stating that setting up a code of ethics for its functioning will be a good starting point for the relatively new MMC while contemplating on their way forward.

Panchmatia A, Ghoshal R, Ambhore V, Meherally S. Medical self regulation- a study of Maharashtra. *Econ Pol Wkly.* 2013 Dec 7;48(49):21-3.

Compiled with contributions from Rakhi Ghoshal and Anuradha Panchmatia

**e-mail: rakhi.ghoshal@gmail.com
anuradha_89@hotmail.com**

If you are looking for India’s finest medical journal, then here it is.

The National Medical Journal of India is a premier bi-monthly multi-disciplinary health sciences journal which publishes original research, reviews, and other articles relevant to the practice of medicine in India. The journal aims to instruct, inform, entertain and provide a forum for the discussion of social, economic and political health issues. It is included in the Index Medicus

SUBSCRIPTIONS

	One year	Two years	Three years	Five years
Indian	Rs 600	Rs 1100	Rs 1600	Rs 2600
Overseas	US \$85	US \$150	US\$220	US\$365

(Pubmed), Excerpta Medica (EmBase), BIOSIS, Current Contents/Clinical Medicine and Science Citation Index.

Personal subscriptions paid from personal funds are available at 50% discounted rates

Bank draft/cheque should be made in favour of *The National Medical Journal of India*. Please add Rs 75 for outstation cheques. Journals can be sent by registered post on request at an added cost of Rs 90 per annum. Requests to be made at the time of subscribing.

Please send your subscriptions, queries to:

The Subscription Department, *The National Medical Journal of India*, All India Institute of Medical Sciences, Ansari Nagar, New Delhi 110029.

Tel: 91-11-26588802 FAX: 91-11-26588663 E-mail: nmji@nmji.in Website: www.nmji.in



The National Medical Journal of India
On the frontline of Indian medicine