# Clinical trial ethics in India: One step forward, two steps back

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Clinical trials in India continue to be in the news, unfortunately a fair bit being negative coverage. Over the last few years, there has been continuing outrage on the issue of rising outsourcing of clinical trials to India,[1] with concerns about little benefit or relevance to the public health needs of the country. While this dust has not even settled, allegations of unethical conduct in clinical trials[2-4] have again brought a focus on the need for regulatory reform and stringent ethical safeguards.

## THE CONTROVERSY ON TRIALS IN INDORE

The recent reporting of controversial drug trials being conducted by doctors of the government medical college and private practitioners on 'mentally challenged' patients in Indore has caused uproar.[5] It was alleged that for more than two years, from 2008 to 2010, trials were conducted flouting ethics guidelines. The Madhya Pradesh government levied a fine of Rs 5000 each on the doctors involved, and this was seen widely as being paltry and insufficient punishment.[6] As details emerged, questions were raised about the role of independent or commercial (as compared to institutional) ethics committees, improper documentation of consent, vulnerability of research participants as well as the thorny issue of private practice (and in this case, research in private clinics) by government doctors.

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## GROWTH OF THE CLINICAL TRIAL INDUSTRY IN INDIA AND ETHICS VIOLATIONS: IS REGULATORY REFORM ENOUGH

Research being conducted by pharmaceutical and biotechnology companies in India has been on the increase. Added to this, has been the mounting quantum of outsourced research facilitated by Contract Research Organizations (CROs) with the promise of cheaper and faster conduct of trials as compared to the west.[7] From 40 to 50 trials in 2003, the country saw around 1850 trials registered with the government registry in June 2011.[8] Mushrooming clinical research courses, often unregulated,[9] have sprung up with an aim of servicing the need of personnel for conducting clinical research.

While the escalating research quantum has, to some extent, served to benefit the Indian population which now is undergoing a demographic transition with both infectious and non-communicable diseases being commonplace, it has also raised concerns that ethical conduct is often forgone when the primary interest increasingly is profit generation. The specter of unethical trials being frequently reported is a reflection of an ailing and substantially ineffective research regulation system in India. While biomedical research in the country has increased exponentially in the last decade, reforms in regulations have only occurred at snail's pace. Intent has been demonstrated towards such reform,[10] but needs to be substantiated with priority policy changes. Regulatory progress is only one element of the solution—other steps are also needed to move forward in this area.

## WHAT NEEDS TO BE DONE?

It's quite clear that there is a need for reform. Improvement has

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already been seen in certain areas, such as the stress on clinical trial registration in India through the medium of the Clinical Trial Registry -India (as well as Indian journals insisting on such registration for accepting resultant manuscripts).[11] The increasing awareness about ethical requirements in research, as well as the role of activists in questioning trial conduct when deemed exploitative, has also resulted in a positive change to some extent. However, a lot still needs to be done. This requires a multi-faceted approach and involvement of all the stakeholders with an aim for more robust science, which incorporates a strong commitment to ethics.

### Stringent regulations and laws

The role of stronger legal oversight, in light of the guidelines[12] not serving to be enough in curbing deviant research conduct, cannot be emphasized enough. Advocacy is needed, so that the draft bill on Biomedical Research on Human Participants (Promotion and Regulation) prepared by the Indian Council of Medical Research is put in the public domain for discussion and refinement, and is then tabled in the parliament on a priority basis. Such a law can provide mechanisms for legal remedy in the case of questionable and/or exploitative research.

The number of Ethics Committees (ECs) in the country is rising, but there is no clear estimation of the total numbers. The quality of conduct of ECs is often quite variable, and also there is no standardized training or orientation for members. Unless there is *mandatory registration* of ethics committees and an *accreditation* process, it would be difficult to ensure that ECs are optimally focusing on their core duty of protection of research participants. In a positive development, some ECs in India have voluntarily undergone accreditation through the Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP), and the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRP). Indian EC members who were surveyed in the past, also felt that there is a need for formal training of EC members in ethics, and networking of ECs.[13] The Forum for Ethics Review Committees in India (FERCI), which recently conducted its first national conference, could serve as a platform to respond to these needs. E-groups and online discussion forums have also helped in providing avenues for sharing of experiences and updates. ECs also need to proactively engage researchers and conduct on-site monitoring of projects; this can help in identifying and addressing transgressions.[14]

The role of *mentorship* is crucial in training research investigators. If the mentors demonstrate and require that trainees conduct research of a high standard, it can help a great deal in producing researchers for the future, who do not cut corners and believe strongly in scientific integrity.

*Transparency* is one of the core guiding principles in the ICMR Ethics Guidelines. Institutions and investigators need to put more information into the public domain: About the kind of research they are carrying out, the rationale for choosing a certain set of participants and the interventions, the standard of care in the research, ancillary care and post-trial obligations etc. While it might not be possible to always disclose proprietary information related to the intervention or some elements about the research, the relevant ethics committee should at least insist on full information being provided. Another area where enough attention is not often paid is the EC demanding to see the budget of the study, the details of any MoUs signed with the sponsors, as well as details of other sites (in a multi-site study).

Global attention is now being paid to the need for *public engagement in science*. There is a need to enhance the public understanding for research, and to develop a civic dialogue around what kind of research is necessary. This will help in creating widespread support for scientific endeavors. Mechanisms of communication being present between research participants and the communities they belong to, and between the researchers and ECs will help avoid misunderstandings developing due to a trust deficit. Scientists should also use the media at local and national levels to explain the rationale for the research which is being conducted, and how it relates to the health priorities in that context.

## CONCLUSION

India, as an emerging economy needs to continue to promote a strong culture of research and development, including in the health sector. However, attention needs to be paid to ensuring that stringent quality checks are built in, and that investigators conduct research in an impeccable manner. Failure to do so will dent the credibility of the research enterprise, affecting not just investigators or institutions conducting research, but also those planning to do so.

## REFERENCES


1. Nundy S, Gulhati CM. A new colonialism?--Conducting clinical trials in India. N Engl J Med 2005;352:1633-6.
2. Bagla P. Clinical research. India acts on flawed cancer drug trials. Science 2001;293:2371-3.
3. Mudur G. Indian study sparks debate on the use of placebo in psychiatry trials. BMJ 2006;332:566.
4. Shetty P. Vaccine trial's ethics criticized. Nature 2011;474:427-8.
5. Rajalakshmi TK. Criminal Trials. The Frontline. 2012 Jan-Feb. 29(2). Available from: http://www.frontlineonnet.com/fl2902/stories/20120210290203300.htm [Last cited on 2012 Mar 10].
6. Ghatwai M. Drug trials: Panel for stringent action, doctors fined 5,000 each. The Indian Express. 2012 Jan 2. Available from: http://www.indianexpress.com/news/drug-trials-panel-for-stringent-action-doctors-fined-rs-5-000-each/894681/2 [Last cited on 2012 Mar 10].
7. Singh M. Should Clinical Trials be Outsourced. Time. 2008 Aug 7. Available from: http://www.time.com/time/health/article/0,8599,1830334,00.html [Last cited on 2012 Mar 10].
8. Yee A. Regulation failing to keep up with India's trials boom. Lancet

2012;379:397-8.
9. Bhan A. Need to regulate burgeoning clinical research courses. J Postgrad Med 2009;55:150.
10. Jayaraman K. India mulling stricter laws to curb unethical trials. Nat Med 2012;18:182.
11. Satyanarayana K, Sharma A, Parikh P, Vijayan VK, Sahu DK, Nayak BK, *et al*. Statement on publishing clinical trials in Indian biomedical journals. Natl Med J India 2008;21:105-6.
12. ICMR Ethical Guidelines for Biomedical Research on Human Participants, ICMR, 2006
13. Brahme R, Mehendale S. Profile and role of the members of ethics committees in hospitals and research organisations in Pune, India. Indian J Med Ethics 2009;6:78-84.
14. Shetty YC, Marathe P, Kamat S, Thatte U. Continuing oversight through site monitoring: Experiences of an institutional ethics committee in an Indian tertiary-care hospital. Indian J Med Ethics 2012;9:22-6.

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