

# Conference Report

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The *IJME* Fourth National Bioethics Conference (NBC), organised by the Forum for Medical Ethics Society (FMES), Mumbai, in collaboration with the University of Hyderabad, Hyderabad, and the Council for Social Development, Hyderabad, was held from December 6 to 8, 2012, in Hyderabad.

The NBC saw the coming together of around 370 participants from different corners of the country and the globe. The participants included health practitioners, researchers, activists, social scientists, policy makers and students. The theme of the conference was 'Ethics and regulatory challenges in health research'. Over the three days of the meet there were debates, discussions and deliberations on various aspects of this subject.

## Inaugural session

Professor Ramkrishna Ramaswamy, Vice Chancellor, University of Hyderabad, Hyderabad inaugurated the conference with the release of a publication on ethics. '*Towards a history of bioethics in India (1980-2010): mapping the field*' by Maithreyi MR, Centre for Studies in Ethics and Rights, Mumbai, documents the trajectory of the bioethics movement in India. Professor Ramaswamy underscored the importance of organising NBCs in university settings as it opens up vistas for its students and faculty, besides offering an opportunity to engage with the evolving bioethics discourse.

## Ethics, morality and the law

The inaugural session focussed on the history of the conference, the rationale for its existence, and the relevance of the theme, especially as India is becoming a hub for international drug trials, a number of which raised ethical concerns.

In his address, Amar Jesani, Editor, *Indian Journal of Medical Ethics*, dwelt on the paradox that haunts research in contemporary India. Regulatory mechanisms are weak and insufficient in several places in the country; while in other areas, there is excessive scrutiny. This uneven quality of regulation is detrimental to good research.

Dr GVS Murthy, Director, Indian Institute of Public Health, Hyderabad, stressed researchers' ethical responsibility to report all study findings, including failures and limitations. We should not allow the research agenda to be hijacked by funders. It is our collective ethical duty to make research transparent. This point was reiterated by several others at the conference. Transparency in research, an ethical goal in itself, would ensure continuity in research and cut down duplication of efforts. Dr Murthy flagged the three 'R's of research ethics which he insisted should not get lost in oversight: respect for individuals/participants; rights of individuals/participants; and regulation

– both self-regulation and regulation by external mechanisms of the system.

Dr PM Bhargava, Chairman, Council for Social Development, Hyderabad, focused on the need to distinguish between ethics, morality and law. Ethics becomes important when there is a gap in the law and an absence of other regulatory mechanisms. To that extent, ethics and law are not synonymous. Dr Bhargava shared a 10-point agenda on how to make research more ethical: failures and limitations must be published; the increasing commercialisation of healthcare should be checked; touts should be banned from recruiting participants for trials; the influence of pharmaceutical companies on national governments should be monitored; researchers' funding with drug companies should be transparent; payment to research participants should be standardised; all institutional ethics committees (IECs) should be regulated by a higher body, possibly at the state level; there should be provision of fast tracking approval for drugs relevant to the local context; there should be more effort to ensure post-trial access for participants; political vested interests should not be allowed to influence research.

Dr GN Rao, Founder and Chairperson, LV Prasad Eye Institute, Hyderabad, pointed out that several professions have their own codes of conduct. Such codes are as important as self-regulation is. He urged the Indian Medical Association to take more responsibility for implementing the code of ethics.

Dr Rao noted that bioethics is not about clinical ethics alone. It refers to biotechnology, law, community, end-of-life issues, and other aspects of our daily lives. The purview of bioethics and its debates should extend further than they do today. An audience member suggested that while bioethics has focused on research ethics, clinical ethics cannot be overlooked; however, looking at clinical ethics in isolation will not solve the problem either. The need is to bridge this gap between research and clinical ethics that exists within the current bioethics movement.

Session co-chair Sunita Bandewar, member, Managing Committee, FMES, pointed out that even as the bioethics movement urges us to turn the focus back on participants in different capacities, participants themselves are yet to gain a strong enough voice even within this movement. Engagement with communities would help create 'ethics foot soldiers' and help prevent violation of ethical norms of research involving human participants.

Several themes of relevance to the contemporary discourse of research ethics and regulation emerged in the inaugural

plenary. These included: the scientific validity and social relevance of research contributing to justice and equity; the need to engage with larger systemic issues while navigating wide ranging ethics obligations; the integration of ethics into all disciplines, and strengthening of civil society. These set the tone for the Fourth National Bioethics Conference.

The three plenaries focussed on interdisciplinary approaches to research ethics; the regulation of research; and different issues within clinical trials. Speakers explored the politics of research from various vantage points: structural inequalities hidden in the research format and methodology; imbalances in knowledge and power; the problems of research being guided by the logic of the market, and the vested interests that have come to shape health research, particularly in developing countries like India.

### **Ethics of research methodology**

Dr Prathap Tharyan, Professor of Psychiatry, CMC, Vellore and Director, South Asian Cochrane Network and Centre, questioned three core suppositions of Evidence Based Medicine (EBM), a much hyped norm in research and practice. He argued that the evidence which is supposed to propel the practice of EBM is often doctored, manipulated and incomplete, supporting his analysis with data. He asserted that it is time the scientific community and civil society realised the inherent problems of EBM – especially as it is being practised – and reclaimed the research agenda.

Dr Vandana Prasad, Member, National Commission for Protection of Child Rights, asked if public health research is fundamentally opposed to the human rights paradigm. She suggested that the answer to this question would depend primarily on the way one understands the concept of public health research. Doing ethical public health research is possible provided one has acknowledged its latent power and taken adequate steps. She questioned the use of biomedical research models such as the use of a control arm; a cohort study might be a viable possible alternative. We should explore such alternatives instead of withholding proven interventions – the “placebo control” – which is an innately unethical practice.

The ethical issues involved in designing research methodology were discussed in several other sessions. Dr Purendra Prasad, Associate Professor, Department of Sociology, University of Hyderabad, acknowledged the importance of the social sciences in health research. This is because interdisciplinarity is inherent in the very notion of health and illness. Just as we cannot overlook the social and cultural determinants of health, we should address issues of equity, efficacy, justice and ethics in health research and healthcare from this multidisciplinary standpoint. Interdisciplinarity was emphasised by several speakers, who advocated a blend of social sciences and public health research, both as a more appropriate methodology and as an imperative for contextualising and politicising health. Dr Veena Shatrugna, Former Deputy Director, National Institute of Nutrition, Hyderabad, spoke on the politics of nutrition research; she used data to show how politics and vested

interests have come to inform and shape the understanding of nutrition. Prescriptions for addressing undernourishment are influenced by caste and religion; the recommended diets are often based on the habits of upper caste Hindus.

The theme of interdisciplinarity aroused much interest. Designing a relevant, appropriate and sensitive research methodology is as important – and a question of ethics – as deciding on the topic for research. Given the inherently social nature of illness and health, all trials – in public health as well as for new chemical entities – are rooted in the social context. In both cases, the study is of social beings, and the methodology cannot be borrowed from the laboratory without adequate reflection on the implications. Drawing on the models of social sciences like anthropology, public health and clinical trials should attempt to become more sensitive and humane. At the same time, it is necessary to adapt the methodologies to suit the specific purposes of medical research.

### **Informed consent**

A substantial part of the discussions at the NBC concerned informed consent: what it really means, whether it is possible, and if it is necessary in the first place.

One suggestion was that the requirement of written consent be waived and replaced by verbal consent in certain contexts. Insisting on written consent could actually result in a disregard of the complexities, nuances and sensitivities of people. One option suggested was to gauge the participant’s level of agreement from her body language before recruiting her. In some circumstances, this might be more appropriate than coaxing her to put her thumb impression on a sheet of paper. In India, the majority of trial participants are poor and often cannot read or write. They can be intimidated by repeated questions, demands for documentation, signatures, and thumb impressions. In some circumstances, these practices may actually make it difficult for the participant to develop trust in the researcher. One suggestion was to look for “concurrence” rather than consent in some cases. Another was to look at the cultural context of the research and modify the process of consent if required.

Researchers are known to limit the information provided to the participant on the ground that participants are illiterate and lack the ability to understand all the details. At the other extreme, some have argued that illiterate people should not be accepted as participants in any trials. However, data showed that illiteracy and agency are not directly related. Illiterate individuals can make rational decisions to give or decline consent. However, it is also necessary to think about how information should be disclosed; is ‘everything’ really to be disclosed? What is ‘everything’? Who decides on this?

Discussions also took place – both in the plenaries and in some of the parallel sessions – on group consent versus individual consent. In taking group consent, how far do we overlook the individual? It was pointed out that consent does relieve the researcher of further responsibility; no matter how detailed

a consent procedure is, a signature alone cannot protect a person's human rights and dignity. The development of trust between the researcher and participant is of crucial importance, as is a sense of responsibility in the researcher. At the same time, it was suggested that despite all the rules on paper, true informed consent is a rarity. The concepts of misinformed, partial and incomplete consent were also mentioned during several discussions.

In relation to consent, it was also stated that, especially in community-based research, the very idea of what constitutes a community should not be fixed in time and context; a community is a fluid and dynamic entity and researchers should develop their ability to decipher and appreciate its nuances because only then will ethical and truly relevant research become possible. The problems of dialects and translations were flagged as being of critical importance. Subsequently, an appeal was made for researchers to recognise the political nature of healthcare and health research (and of taking consent for research) and not reduce it merely to a positivist science.

### **Regulation of research**

Mr S Srinivasan, Managing Trustee, LoCost Standard Therapeutics, Gujarat, spoke on the challenges of regulation of research. He noted that many drug trials in India are "India only" trials, despite pharmaceutical companies' claims that their trials are multi-centric. New chemical entities which are not granted marketing approval in the country of origin also have their trials in India. He urged more monitoring of these trials and intervention on the participants' behalf, by the office of the Drugs Controller General of India. He concluded by demanding a code to regulate drug promotion practices.

The need to regulate research and the regulatory mechanisms received much attention; while regulation should ensure that the rights of research participants are not violated or compromised in any way, it is also important for regulatory mechanisms to be sensitive to the context, and to have a code of ethics giving priority to participants' well-being. Many private IECs have been known to be co-opted by vested interests which may lower ethical standards. At the same time, a workshop revealed that it is increasingly difficult to get the right people to become part of an IEC. The work is time-consuming and supposed to be voluntary. Further, at times the principal investigators feel that the ethics committee should review and not monitor the trial; when the committee tries to step in to address any divergence from protocol, conflicts ensue. It was pointed out that we need to train more people on the role of the IEC as well as those who would be willing to join an IEC. There was also a suggestion that we need to bolster the role of civil society organisations and community based organisations for better and more context-sensitive monitoring of existing regulations.

### **Parallel sessions...**

Researchers in a multi-centric collaborative study on biomedical and health experimentation reported on their findings on how

research groups understand collaborations in experimentation and their respective locations in the intersecting networks of knowledge and capital. Other papers focused on the ethics of doing certain kinds of research. The ethics of recruiting healthy volunteers for clinical trials generated much discussion among the audience, especially when trial participants shared their experiences. The topic of vulnerability was discussed from different standpoints in several presentations. How do we define a vulnerable population? Is there any truly non-vulnerable person? Can a vulnerable person not have any agency? How do we know we are not being patronising? A comment was made on the vulnerable positions of researchers in communities, questioning the argument that it is always the researcher who wields power over participants. Several papers explored the theme of the ethics of regulation in research: the need for regulation as well as the need to ensure that it does not interfere with good research or get co-opted by powerful lobbies. Speakers called for reflection on research methodologies – especially at a time when the trend is towards inter- and multi-disciplinarity. They stressed the need to learn from methodologies in social sciences, but with enough reflexivity. The rights of research participants were discussed in several papers: it was stressed that regardless of how much the participant is compensated, the important point is that s/he is taking a risk and the least society can do is to consider his/her act altruistic.

This year's conference had a separate session on ethics and traditional medicine that saw some lively debates. It was observed that traditional medicine should also be subjected to scrutiny and should necessarily evolve with research. However, it might not be ethical to apply the modern scientific requirements and research methodologies of western medicine to traditional medicine.

### **Workshops...**

The conference included eight workshops, each attended by an average of 25 participants. A workshop on intervention research in maternal health engaged with the issue of taking consent. Another explored the issue of understanding the challenges and complexities of working within an ethics committee. Yet another dealt with the role of the IEC, with vigorous discussions on the definitions of the 'lay' person or 'religious' person who is to be part of the body. A workshop on the ethics of biomedical and health experimentation focused on issues like accountability in drug trials, division of labour at the site level, capacity building, post-trial benefits, informed consent, quality of ethics committees, knowledge ownership, post-trial access and lack of information with regards to public health interventions. Relatives of trial participants spoke at a workshop and described how their family members had been used as guinea pigs.

### **And a film**

A short film on publication ethics was screened at the NBC. *Publish or Perish*, by the Centre of Biomedical Ethics and Culture,

Sindh Institute of Urology and Transplantation, Karachi, tells the story of young doctors who are forced to publish in order to move ahead in their careers. The easy solution: plagiarism, data fabrication, gifting authorship and more.

### Conclusion

After three days and nights of lively discussions and heated arguments, the fourth National Bioethics Conference ended, and participants dispersed with a renewed commitment take

forward the challenge of making health, healthcare and health research more ethical.

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We are pleased to bring to your notice that University College of Medical Sciences, University of Delhi and INFORMER are organizing the 6th International Medical Students' Research Conference **MEDICON 2013** from April 11th to 14th, 2013 in New Delhi

It has been 5 years since the inception of MEDICON and the conference has grown in popularity and magnitude with every edition. It has provided an unprecedented platform for young researchers and budding doctors, to show their contribution to research.

Medical ethics is the basis for all that is noble about the profession and hence assumes a great place in the lives of all doctors and Medical Education forms the basis of all medical practice prevailing today. The issue in question is of "medical ethics" one of the hallmarks of one's medical training, inculcated during one's graduation in the form of the ceremonial Hippocratic Oath. At a time when the prevailing Medical Education system is plagued by certain ills and is subject to a lot of cynicism, scrutiny and ridicule, it is only fit that this important issue be considered and steps taken to ensure that the illness can be nipped in the bud. It is on these central ideas of Medical Ethics and Medical Education, that MEDICON '13 will be based and would treat these all important issues as a platform to build on.

We would like to have the honor to invite one and all to University College of Medical Sciences in New Delhi for the 6th chapter of MEDICON and to undertake this beautiful journey with us.

We invite abstracts, registrations and participations from medical students and doctors from all over the country and would be happy to assist those of you who may require our help.

Looking forward to meet you at MEDICON 2013

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