

CONFERENCE REPORT

Reporting on the First National Bioethics Conference

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The First National Bioethics Conference, November 25-27, 2005 (NBC, 2005), organised by the *Indian Journal of Medical Ethics (IJME)*, brought together a diverse group of organisations and individuals in an effort to give a platform for bioethics discourse from across the country. The conference was organised around four issues: ethical challenges in HIV/AIDS; ethics of life and death in the era of high-tech health care; ethical responsibilities in violence, conflict and religious strife; and ethics and equity in clinical trials. Three cross-cutting themes that emerged during discussions were ethical challenges in biomedical and social science research, ethical responsibilities of clinical care providers, and the intersections of bioethics and public health/clinical medicine.

The conference comprised a mix of plenary sessions, parallel paper presentations and workshops. The inaugural session set the tone for the rest of the conference by situating the debate on bioethics in the context of those in need of care and those providing care and conducting research in India. Keynote speakers linked the global context of outsourcing of research, changing regulatory mechanisms and constrained resources in India, and the need for ethical guidance on the way forward.

Conference structure

Twenty collaborating institutions came together to constitute the organising committee of NBC 2005. In addition to a sizeable national contingent, the conference drew participants from countries within South Asia (Pakistan, Sri Lanka and Bangladesh) and beyond (Iran, Philippines, the US, Canada and Australia), and thus provided ample opportunities for regional and international comparisons.

The conference included five plenary sessions with eminent keynote speakers who put forth the ethical dilemmas in biomedical, social science and public health research and health care delivery. There were 17 parallel sessions in which 73 selected papers (of the 81 scheduled) were presented and discussed. Further, a series of posters was presented, and 11 workshops were run by experts on specific topics such as ethical dilemmas in everyday clinical practice. Pre-conference satellite sessions included a debate for medical students, and also a WHO workshop on ethics review processes (which continued during the conference), both of which attracted a lot of interest and participation. In this report, we first summarise the keynote addresses of the plenary sessions and then move on to describe the proceedings of the conference in terms of the three cross-cutting themes described above.

Day 1 - Plenary I: Inauguration

The inaugural session began with an introduction by the Executive Editor of *IJME*, Ms Sandhya Srinivasan, and the Coordinator of the NBC, Dr Amar Jesani. They cited a twofold rationale for the NBC: to give a platform for the various debates in the ethics movement within the country and to give an impetus to the process of scaling up of the nascent bioethics movement.

The NBC's emphasis on putting human beings' needs at the forefront was highlighted by the first keynote address by Ms P Kousalya of the Indian Positive Women's Network. She identified HIV-infected individuals' limited access to antiretroviral therapy and prevention of parent to child transmission programmes, particularly in rural areas, as especially important issues. In addition, she highlighted the need for research on drug resistance among women and infants participating in prevention of parent to child transmission programmes. Further, she emphasised that access to treatment and care needs to be examined within the context of new patent regimes and their effect on drug prices. Thus, Ms Kousalya's address focused on issues of critical relevance to the Indian bioethics movement – those of equity and justice. She also released the *IJME* special conference supplement containing details about the conference including abstracts, and an anthology of selected readings from *IJME* for the period 1993-2003.

Dr Vasantha Muthuswamy of the Indian Council of Medical Research (ICMR) described four ethical challenges in the global context: the problem of inequities between and within countries that resulted in unethical practices; developing mechanisms to engage with communities in health priority setting; creation of public awareness and education about the ethical challenges confronting human kind and – a challenge of particular importance in the Indian context – converting existing ethical codes to legal regulatory mechanisms that would govern biomedical research.

The third keynote speaker, Dr Sunil Pandya, Editor Emeritus of *IJME*, reflected upon bioethics in the Indian context. He outlined numerous unethical medical practices and traced them to the lack of inculcation of ethical values at home, in medical education, and in public life, and to a transformation of medicine from a vocation to an industry. He noted that although the participation of large numbers of professionals in the NBC gave hope, much had to be accomplished by the bioethics movement to bring ethics back into medical practice. In conclusion, the

Chairperson, Prof P N Tandon of the National Brain Research Centre, Manesar, identified six fundamental areas that were fraught with ethical dilemmas and required attention: end of life, human values, health care access, professional conduct, scientific research and human rights.

Plenary II: Ethical challenges in biomedical and social science research in health

In the second plenary session, Dr V I Mathan, Christian Medical College, Vellore, reiterated the concern about transformation of medical practice from a vocation to an industry, and from duty and responsibility towards patients to duty for wealth creation. Dr Parasuraman of the Tata Institute of Social Sciences dealt with the ethics of research on displaced populations and focused on the skewed priorities that shaped the sponsorship of such research. Currently, such research is more often commissioned by the promoters of displacement than by the government or communities themselves. He highlighted the problems of research among displaced populations, particularly those arising from a lack of enforcement of protective regulations and limited state accountability. In conclusion, he made an appeal for ethical research to deliver justice to these populations.

Dr CM Gulhati, Editor, *Monthly Index of Medical Specialties India*, outlined regulatory mechanisms to oversee monitoring of drug development – both new drugs and re-formulations of old drugs. He questioned the ethics of trials of drugs that were not relevant to the Indian context and noted that guidance for ethics committees on these issues is needed. In addition, he recommended national level regulation of clinical trials through registration. This would help ensure that negative results are reported, and that resources are effectively used by preventing trials of the same or similar drugs (me-too drugs). Finally, the Chairperson, Dr Muthuswamy, noted that ICMR is raising funds to support research on high priority issues in India that have not attracted private sector attention.

Day 2 - Plenary III: Ethical responsibilities of providers in clinical practice and research

The plenary sessions during the second day focused on ethical issues in HIV/AIDS care provision and policy formulation as well as on the ethical responsibilities of researchers conducting clinical trials. Dr Suniti Solomon of YRG Care, Chennai, noted that stigma and discrimination against HIV infected individuals in India are widespread and pervasive. Gender inequalities limit women's access to care, and even when care is accessible, women may opt out in favour of treatment for their husband or other family members. Dr Jayashree Ramakrishna of the National Institute for Mental Health and Neuro Sciences, Bangalore, spoke about the fact that principles of ethics may be understood easily and intuitively, but their application, particularly in the context of policy-making, may be extremely complicated. The following questions emerge: Which principles should take precedence? Which are most important? How can seemingly conflicting principles be reconciled? For example, in the case of HIV/AIDS treatment policies, policymakers are confronted with the question of whether resources should be used to provide treatment to those who may benefit the most clinically,

those who are most vulnerable, or those who are the most "productive" members of society. The application of different ethical principles would lead to different choices being made. Lastly, Dr Ramakrishna noted that what appears "ethical" may change when examined from varying vantage points by different stakeholders.

Next, Dr M D Gupte from the National Institute of Epidemiology, Chennai, presented ethical concerns in clinical trials, including conflict of interest arising from sponsors directly engaging in research and implications of participant eligibility criteria for justice. Dr Gupte echoed concerns raised by Dr Gulhati in the earlier plenary, namely those related to the multiplicity of trials both nationally and globally and the need for standardisation, registration, and regulation of clinical trials in order to ensure ethical conduct and scientific merit. Finally, he reiterated an observation made by Dr Ramakrishna that what is "ethical" is dynamic and changing over time.

Day 3 - Plenary Session IV: Bioethics and public health

This session was chaired by Prof Ghanshyam Shah, former Director, Centre for Social Studies, Surat. It began with a presentation by Dr T Jacob John from the Christian Medical College, Vellore, on "Ethics, human rights and public health." He dwelt on the difference in the ethics of the human rights approach and the public health approach and how often the public health approach may seem to encroach upon individuals' rights. In public health, the rights of the community were often privileged over those of the individual. However, he noted, the HIV/AIDS epidemic has challenged this practice, and, contrary to the norm, the victim or the patient has been seen as a collaborator in public health efforts rather than as "the other" who needed to be controlled.

The second keynote speaker, Ms Manisha Gupte from MASUM, Pune, discussed violence as a public health issue and highlighted the ways in which social and cultural inequities facilitate violence. She concluded that fundamental to the elimination of violence is the elimination of discrimination and the dismantling of social and cultural structures that foster power hierarchies and discriminatory practices.

Plenary V: Valedictory session

The valedictory address was delivered by Prof Abhijit Sen, Member, Planning Commission, Government of India, in a session chaired by Prof B Ekbal, former Vice Chancellor of the University of Kerala. Prof Sen noted that a fundamental tension within ethics is a tension between the achievement of "good" for many and the need for a strong basis for individual rights. He pointed out that the issues raised by the conference called for a more nuanced understanding of civil and political rights as guaranteed in the United Nations Charter for Civil and Political Rights and required national discussion and debate. He stated that the current political context was conducive to a rights-based approach to legislation and called upon the participants at the NBC to facilitate such a national process. Prof Sen also released a book titled *Ethics in Health Research: a Social Science Perspective* on the occasion. The chairperson commended the efforts of the

organising committee in bringing together a diverse group to a common platform for discussions on bioethics.

Theme 1. Ethical challenges in biomedical and social science research

A number of ethical challenges in biomedical and social science research were identified during the paper presentations and workshop sessions. Researchers highlighted the need to be cognisant of the potential power imbalances between the researcher and the researched. For example, in disaster settings, researchers' ability to provide care and offer access to meagre resources may tip the balance of power in their favour and may lead to undue inducement of potential participants. Presenters also emphasised the difficulty in evolving ethical consent processes when there was a lack of a culture of consent-taking in health care settings. Further, they argued that participant empowerment in low literacy settings may be achieved by moving beyond informed consent to "understood" consent with the participants' comprehension being verified through tests and other means.

Social inequities, particularly those arising from gender, caste and age, were highlighted as an important source of ethical challenges. For example, in a session on ethics in sexual and reproductive health research, presenters argued in favour of recognising the "mature minor" and developing legal and ethical mechanisms for reproductive health research among adolescents in India. Challenges in obtaining truly voluntary, autonomous informed consent and maintaining confidentiality as a result of gender inequities were highlighted in sessions on clinical trials. To illustrate, in clinical trials of vaginal microbicides, researchers were confronted with the problem of balancing the need to maintain confidentiality regarding a woman's participation in a trial and use of a microbicide, with the potential risk of discord between partners as a result of trial participation and microbicide use.

Cultural particularities and differences also contributed to ethical challenges in research. Researchers faced the task of reconciling scientific rigour, the need for respect for individual autonomy, and the need for respect for culture, particularly while working with vulnerable, marginalised groups. Innovative strategies are required to ensure that individual rights are respected within a community context, said participants in a session on disaster research. One response is to initiate and maintain dialogue with communities through community advisory boards or community-based institutions.

Global power inequities were also identified as a source of ethical challenges in research, particularly clinical trials. Dilemmas emerged when research was conducted in developing countries but key decisions were controlled by developed country sponsors. Improved review mechanisms and vigilant community advisory boards may be effective means to monitor international research collaborations and protect participants in clinical trials.

Theme 2. Ethical responsibilities of clinical care providers

In multiple sessions that spanned the four focal themes of the conference, participants reiterated the need to institute rigorous

training in ethics and establish guidelines and regulatory mechanisms for ethical research and health care provision in India. In the case of new reproductive and genetic technologies, they noted that further debate and reflection on the Indian situation were required prior to the identification of guidelines and standards. Speakers also observed that since it is primarily a privileged few who have access to these technologies, we need to grapple with the fact that socio-economic inequities may be worsened by the introduction of these technologies. Similar sentiments regarding the need for greater dialogue and introspection were expressed during discussions on palliative and neonatal care. Participants called for the creation of spaces in which physicians could debate and come to terms with how to provide options and advice in the context of such care.

In contrast, presenters noted that despite the many ambiguities that surround ethical dilemmas in end of life care, guidelines such as the consensus document from the Indian Society of Critical Care Medicine on the End-of-Life Issues for Critical Care Practice were already available and needed to be implemented. This was not the case with stem cell research, an area in which global lack of consensus made it difficult to determine ethical practice and responsibilities.

In a workshop on ethical controversies in everyday practice, four key issues were debated. While differing opinions dominated the discussion on the ethics of advertising by physicians, consensus emerged on the remaining three issues. Participants agreed that the following problems merited urgent action: fee splitting, which drives up health care costs and lowers quality of care; the casual nature of the informed consent process in health care settings; and lack of proper training and continuing education among physicians. Those who attended felt that the provision of health care by inappropriately trained individuals is ethically problematic. They concluded that in order to mainstream ethics in medical practice, it must be made an integral part of medical education.

The need for sensitivity to, and skills in handling, ethical and legal dilemmas in care provision were powerfully described in sessions on gender-based violence and sex selection. Health care providers were often the first line of care for victims of domestic violence. The one stop crisis centre for victims of gender-based violence in Mumbai was offered as an illustration of ethical care provision. Care providers were also confronted with and at times participated in perpetuating a demand for sex selection. Participants stated that responses to such situations also need to be framed recognising that women who request sex determination are acting within and because of social pressures and as a result are vulnerable.

Theme 3. Intersections of bioethics and public health/ clinical medicine

The conference also provided an opportunity to examine a number of the intersections between bioethics, public health and clinical medicine. Ethical challenges in public health were examined from multiple religious perspectives, and the role of faith-based organisations in this sector was discussed. In another session, researchers and clinicians shared a range of

issues facing ethics committees and review processes in India and the region more broadly. For example, one presenter suggested the need to consider bringing not only public health research but also public health interventions under the purview of ethics review committees. Another described the threats to ethics, and particularly integrity, arising from the increasing commercialisation, especially of public health research. And a third offered an example of effectively handling the ethical dilemmas of everyday practice through clinical ethics committees. Finally, a diverse range of issues such as access to and dissemination of public health evidence, the development of appropriate legal frameworks, policies and protocols for clinical practice, and better access to drugs through regulation of drug prices were debated.

Implications and the way forward

The participation of nearly 350 health care providers (working at the primary, secondary and tertiary care levels), medical educators, biomedical and social science researchers, and programme planners and implementers, affiliated to around 140 organisations/institutions and considerable media interest in the NBC are indicative of the growing relevance of and commitment to bioethics in India. The fact that nearly all those who attended the conference participated as presenters and active listeners and stayed until the end of the conference is noteworthy. Further, a distinguishing feature of the NBC was the absence of the commercialisation and tired

cynicism that characterises many contemporary professional conferences.

However, a number of gaps that may be addressed in future meetings were identified. Participants expressed the need for space within the programme for less structured, more spontaneous discussions. A range of issues like the ethics of research on development, with vulnerable populations like the disabled populations, and of public health policy, and the philosophical bases of ethics remained largely unexamined. Finally, participants noted the importance of devoting time at future conferences to developing concrete guidelines for ethical public health practice.

Although the content of a number of the debates and discussions at the NBC was not necessarily new, the act of coming together to engage in a passionate and committed dialogue and the plurality of voices present made the NBC a landmark event, giving much cause for hope by illustrating the enormous potential for sincere thought, passionate concern and careful action on bioethics in India.

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