

I would venture to suggest that the answer to this question can only be sought in the common ancestry that many of us share in the realm of the peoples' struggle, of popular movements. I was grateful, on the first day of the conference, to see the typology of struggle that David Legge had talked about. Any changes in governance that we are able to bring about can only be a bonus -- a side effect. Our real efforts have to be concentrated on the terrain of popular consciousness regarding the real determinants of health and healthcare. If we are able to make this change of focus, then we will see that conditions for change are more promising today.

Despite its recent dominance, neoliberalism, based on the theory that economic growth solves all problems, has lost its credibility. The hegemonic status of neoliberalism, the ideology

and practice of the dominance of markets over society has been seriously undermined.

Class mobilisation and politics are critical for health and tackling health inequalities because progressive social and class movements and parties are the dynamic forces pushing for improvements in the human condition.

This paper is based on Dr Binayak Sen's keynote address at the Third National Bioethics Conference on November 19, 2010. On December 24, 2010, Dr Sen was held guilty of sedition and sentenced to life imprisonment. Dr Sen has worked for over 25 years with the most marginalised people in India, devoting his life to the welfare of the least fortunate. We join the many organisations and thousands of individuals in questioning the judgment, and call for his immediate release.

Conference report

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The theme of the Third National Bioethics Conference was governance of healthcare, addressing issues of ethics, equity and justice. The conference that took place in New Delhi, the fulcrum of policy making in India, attracted over 350 participants from 7 countries. In all there were 58 papers in 25 parallel sessions, and 12 workshop sessions spread over four days from November 17 to 20, 2010.

The inaugural function began with a short film on NBC 1 and 2, followed by the welcome address. Dr George Thomas, Editor, *IJME*, described the work leading up to the conference and called for the collaboration of individuals, groups and alliances for the ethical care of human beings in a multi-disciplinary effort towards constructive debates. Justice Leila Seth (retired) inaugurated the conference and Dr KB Saxena, former Health Secretary, released the conference programme.

In his keynote address, "Ethics, equity and justice: a view from the belly of the beast", Dr Sanjay Nagral, one of the founding members of the Forum for Medical Ethics Society, described trends in healthcare and medical practice in India to locate the debate on ethics and regulation and to identify the response. As a part of the "beast of modern medicine" with an insider's view, he asked himself four questions: How has modern medicine changed in India? How has the medical system viewed these changes? What is the role of governance in it? And what can the movement for ethics do to sensitise people about equity, justice and ethics? The rise in private healthcare and education, the withdrawal of the state from healthcare,

the view of the entire healthcare sector from education to practice to insurance, as an "entrepreneurial opportunity"; is giving rise to new conflicts, and unethical practice is rooted in this context. Professional self-regulation has failed. The state has failed to regulate medical practice though we have seen that a determined government can implement the Prenatal Diagnostic Techniques Act if it wishes. He identified the "biggest failure" as the failure to sustain the ethical debate among the healthcare community. Corrupt medical professionals can survive only because their colleagues allow them to do so. He pointed out that all of us are part of this - we need to constantly flag this menace of market medicine, and we need to work with the state on governance, and create a critical base of medical professionals. So, there is a need to bring back public medicine and participate in the process of restoration of public credibility- that will maintain patients' rights and physicians' rights.

Dr David Legge of the People's Health Movement spoke on the "microethics of activist practice" the small choices that we make in everyday life. He described the larger context of healthcare activism: a global health crisis due to social inequities that are reflected in greater morbidity and mortality among the poor. The People's Health Movement, consisting of an international coalition of organisations and networks, has pointed to the social determinants of health, and the political economy of health. It views health as a human right, and has fought for equity sustainability. It views change as being driven

by social movements: delegitimising the prevailing regime and projecting an alternative vision. A core element in the strategies for social movements is working with communities, working across differences and effective communication. Dr Legge also described the International People's Health University training programme for health activism.

Justice Leila Seth spoke on the need for a social ethical movement in response to unethical medical practice that fuels and is fuelled by social inequities: "Female foeticide" is an example of the misuse of advanced technology on a large scale. The rich are using it and creating an imbalance. Laws- banning this practice as well as dowry -are not enough. A strong ethics movement is needed and doctors should be in the habit of reporting ethical violations.

The inaugural function ended with the felicitation of people who have made major contributions to the field of healthcare ethics in India. Dr Vasantha Muthuswamy, retired senior deputy director general of the Indian Council of Medical Research, has helped lay a foundation for research ethics and bioethics education. Dr CM Gulhati, editor of *Monthly Index of Medical Specialities*, has played a critical role in the campaign for regulation of the pharmaceutical industry and drug research. Dr Sunil Pandya has set an example of ethical behaviour in his clinical practice as well as in his founding of *IJME*.

Equity and ethics

Governance of healthcare includes using a rights framework to bridge equity gaps and this was the focus of the presentations on equity, rights and ethics.

Examining the structural factors that affect equity, Dr Gita Sen, Professor, Centre for Public Policy, Indian Institute of Management, Bangalore, talked of the conditions that result in chronic poverty conditions in Koppal, Karnataka, where health systems are largely absent or inadequate to meet healthcare needs. Such adverse conditions serve to normalise the drudgery of everyday living and the gender inequities that mark health outcomes in this region. She mentioned the restricted access that women have to maternal care in the region partly due to the impact of cultural beliefs and practices that constitute the context of maternal health. This belief system finds local temples and exhortation rituals more suitable than appropriate maternal healthcare. Culturally determined maternity care practices include poor nutrition during pregnancy and dangerous intra-partum practices during delivery; one of the latter is the practice of ignoring post partum haemorrhage due to the belief that it was "letting of bad blood". Ethical research and practice for researchers in this setting means involvement in the politics of engaging with multiple systemic inequities and bringing the "truth of evidence" back into focus for maternal health policies and programmes.

Dr Yogesh Jain from the Jan Swasthya Sahyog in Bilaspur, Chhattisgarh, picked up on the inequities in healthcare provisioning in terms of rural vs urban/rich vs poor and pointed out that attempts at cross subsidisation through differential

pricing for different groups do not address the basic reasons for differential access in a society. The provisioning of tertiary care curative facilities in urban areas and only preventive primary and secondary care in rural areas was based on the assumption that rural areas have simpler health problems. But the collective effects of poverty and the lack of functional health systems result in a greater burden of diseases with a clear gradient of morbidity and mortality for the poor, particularly in rural areas. Dr Jain highlighted the need for universal healthcare coverage as part of the plea for justice in healthcare provisioning.

Dr Angus Dawson, Senior Lecturer in Ethics and Philosophy, Keele University, UK, continued on the theme of justice and inequities by extending the understanding of the social determinants of health to research ethics. He pointed out that an inclusive agenda for research ethics would take into account the goals of public health and epidemiological research. Such processes built with a focus on justice would assess the tradeoffs between risks and benefits and consider post trial benefits for communities as part of the ethical requirements.

Speaking on the need to broaden the agenda for research ethics, Dr Dawson observed that there was an obsession with an individual focus and informed consent in research ethics. There is more to oversight of research ethics than correcting typos on a patient information sheet. In reality, the informed consent process is often a charade as it is difficult to evaluate how well a potential trial participant has understood the content of these forms. The standard declaration in the journal article reporting on the research states only that "written informed consent was taken from all participants". Since informed consent alone is not sufficient to protect participants, other forms of protection, such as a strong ethics review committee, are very important. Dr Dawson called for a broader agenda for research ethics which should include the goals of epidemiological and public health research, focusing on populations or groups rather than individuals. Research ethics should also be built around the value of "justice", including access to trial benefits and sharing of risks and burdens.

The theme of structural inequities in provisioning for healthcare referred in part to the inequity in regional distribution of medical education in India, where there is a concentration of institutions for medical education in south India and absolute deficits in the north-eastern part of the country. Such inequities were taken up in a panel discussion on regulation of medical education and practice.

Dr Ananthakrishnan, retired Professor of Surgery, JIPMER, Pondicherry, spoke of the rampant privatisation of medical education and the proliferation of medical colleges that resulted in a serious shortfall in faculty for teaching various medical disciplines. He pointed out the inequities in the distribution of medical colleges across the country; there is an excess of facilities for medical education in the southern part of the country and a paucity of these in the north eastern regions. Commercial potential and business interests, and not patient needs, were at the core of this disproportionate allocation.

Dr Sreekumari Sudhakaran, retired Professor of Biochemistry, Trivandrum Medical College, spoke of the efforts to improve healthcare that have been a part of the history of public policy from the time of independence with the Bhoré Committee's recommendations. She pointed out that the emphasis on rural doctors or the public health physician was part of this legacy. Yet, today one finds that most of the young students in medical colleges have a strong urban orientation and are disinclined to take up rural practice. In 1997, the Medical Council of India came out with regulations that would have helped to train doctors to serve as primary care physicians. But this goal has not been achieved. The training received currently does not inspire sufficient confidence in students to practise alone in rural areas; they have a great fear of being alone without the support of their seniors where they would be solely responsible for patient welfare. She called for a reversal in policies that would enable young medical college students to take up rural service.

Ms Kajal Bharadwaj, speaking on behalf of Mr Loon Gangte of the Delhi Network of Positive People, reiterated the need to realign medical education to a perspective that views patients as rights holders. Such a realignment will not be easy as it calls for orienting young medical students to community needs in rural India. There is a need not only to focus on medical education but also to monitor subsequent practices that could be discriminatory. This observation was based on the extensive work done among people living with HIV/AIDS in Delhi where healthcare workers were often found to refuse to treat PLWAs, delay treatment, and discharge them earlier than needed.

Dr NK Sarin, chair of the panel currently governing the Medical Council of India, described the efforts being made to address medical malpractice and other unethical practices within the profession. The Council has developed Standard Operating Procedures to deal with negligence, ignorance and errors in medical practice. He also highlighted the efforts being made to revise the undergraduate and postgraduate curricula in medicine. Efforts were also on to streamline the examination process and ensure fair remuneration as a means of preventing corrupt practices.

Various forms of vulnerability were examined in the parallel sessions. These vulnerabilities came not only from group identities but also from contexts. Researchers described the complexities involved in undertaking research among women prisoners because of their multiple vulnerabilities and the context of incarceration. Similarly, there are problems of working among displaced populations, and sex workers, who are also traumatised by their experiences. The confidentiality needs of these vulnerable groups, and the difficulties of maintaining confidentiality, were described in the parallel sessions. The notion of vulnerability was explored further in these groups when examining the enhanced vulnerability of survivors of sexual assault; further, healthcare providers are inadequately trained to deal with the experiences. The poor quality of care also contributed to vulnerabilities experienced by users of the healthcare systems in India, where many practitioners are not qualified in any system of medicine.

The inequitable distribution of healthcare facilities and the failed promise of health planning in India due to the politics of investment in health were also taken up in parallel sessions on this theme. Enhanced disadvantages caused by policies that violated people's rights, such as the population policy focus on the two-child family norm that was being reiterated through policies for utilisation of the public distribution system, or accessing education, were also described. The use and misuse of medical procedures that violated the health rights of women were also discussed in this parallel session. Researchers examined the misuse of surgical procedures such as hysterectomies for profit in the coastal areas of Andhra Pradesh. In all, these parallel sessions examined a broad spectrum of forms of inequity.

Policy, law and ethics

The second point of focus for governance of healthcare was the ethics of health policy and law, and the second plenary at the NBC 3 focused on this. Ms Kajal Bharadwaj, an independent consultant and legal researcher, addressed global justice in access to drugs. The current regulatory regime is a project of the constant confrontation between market forces and peoples' struggles to enhance access. Under the existing international regulatory framework, countries do indeed have the option of "compulsory licensing" of specific drugs that are required for use in a public health emergency, but this option is not exercised because countries face frequent legal action in courts of law if they attempt it. The Indian constitution is strongly oriented towards justice and the Indian judiciary has, by and large, upheld this when challenged. But pharmaceutical companies are making efforts to restrict this strength through means such as incessant lobbying with the judiciary, executive and legislative arms of the state.

Generic drug production in India grew in the 1980s and '90s because process patents, and not product patents, were the mainstay of our intellectual property rights policy. This facilitated the growth of the indigenous pharmaceutical industry and resulted in lower prices for drugs when compared to the international markets. This strength has been undermined by India's acceptance of the regulatory framework of the agreement on Trade Related Intellectual Property Rights (TRIPS) and also by the global players taking over Indian pharmaceutical companies. The call for re-examining the policy framework for drugs comes from this experience of learning that the emphasis on intellectual property restricts access to drugs for those most in need.

Policies in research ethics regulation need to focus on harms to the collective identity as much as they focus on individual autonomy. This was the thrust of the argument for understood consent and community as a unit of focus for public health research by Dr Richard Cash, with the Program on Issues in Global Health Research, Harvard School of Public Health and the Public Health Foundation of India. His presentation made a plea for testing the utility of interventions that are less than optimally efficacious in settings where no care is actually available.

Dr Binayak Sen of the People's Union of Civil Liberties and the Christian Medical College, Vellore, spoke on the politics of inequity. The state has disregarded the constitution's directive principles which call for the removal of inequity and the promotion of equity. He referred to the structural violence inflicted by the state upon its own people in terms of ignoring the near famine like conditions that prevail among the scheduled caste and tribe groups. Alienation from land and lack of safety nets have rendered those dependent on the land without alternatives. The Indian state has ignored the World Health Organization's call for law and policy changes to address the social determinants of health. Using the example of tuberculosis, Dr Sen pointed out that despite evidence of the strong link between "macronutrient malnourishment" or starvation and tuberculosis, such evidence is not incorporated into policies and programmes for tuberculosis prevention and cure. The absence of a focus on the social determinants in health policy and planning is a concern reflected in people's struggles in India.

Parallel sessions on this theme at NBC 3 focused on the quality of healthcare services - in terms of providers' skills - or the lack of these skills -- to meet the needs of special groups like sexual assault survivors, transgenders or people living with HIV / AIDS. A presentation on bioethics theory discussed the notion of "human dignity" to address this concern, using philosophical perspectives from the Hindu traditions. A study of public policy aimed at improving maternal healthcare examined the ethics of using conditional cash transfers to achieve maternal health goals.

Continuing on this theme of regulation as policy, presentations at parallel sessions discussed the consequences of the lack of regulation: among these were the promotion of stem cell procedures using false claims about their benefits, and the collection of placental material for commercial purposes. Others examined regulatory guidelines for disaster management across the region, including India, to assess the extent to which they addressed equity and human rights, and found that these guidance documents were largely devoid of such concerns. On the other hand, health practitioners talked of the need to go beyond guidelines in balancing practical considerations and ethical choices in everyday practice.

Researchers examined the ethics of health research in the community or the need for careful forethought with regard to social experiments, using a biomedical model. The ethics of placebo controls in such trials was questioned, as much as was the design of such experiments.

From a public policy perspective, the relevance of a rights discourse in ethical analysis of health systems was highlighted in the valedictory address by Dr Upendra Baxi, Professor of Law and Development, University of Warwick, United Kingdom. "The right to health is the right to an integrated health system" was the message he reiterated and elucidated upon in his address. Such an integrated system will ensure universal access, empowering people to achieve their health rights.

Regulatory mechanisms for ethics

The third key theme of governance in healthcare was the regulatory mechanism for monitoring ethical practices. This aspect was discussed in the (earlier mentioned) panel discussion on regulating medical practice and education which looked at the need for regulation, partly in the context of inequities in provisioning of medical education and care. Self-regulation was the context of a pre-conference workshop on publication ethics and at another pre-conference meet on IRBs.

For research ethics the existing regulatory mechanism is the institutional review board (IRB). Dr Gagandeep Kang, Director, Research, of Christian Medical College (CMC), Vellore, described the challenges in undertaking such an exercise. Her address commenced with locating health research in the country in its context. There is potential for extensive research, given the changing disease profile which includes both communicable and non-communicable diseases. CMC is a private, not-for-profit institution with a 110 year history. Its mission aims at fostering a spirit of enquiry, commitment to truth and high ethical standards. While the institution has a dedication to research and healthcare, it also faces a key dilemma: is research a luxury or a necessity? The institution has chosen to work towards a balance between patient care and research.

A second dilemma was which form of research to focus on: sponsored research or investigator-initiated research. Despite the limited scope for sponsored research to push the institution's mandate forward, and despite the huge patient loads and high standards of care, it has been possible to leverage sponsored research to fulfil the institution's mission statement with respect to high ethical standards. One concern has been that some of the processes in sponsored research do not lend themselves to requirements for transparency.

Investigator-driven research, which requires spirit and energy to undertake, is more difficult because the researcher is involved and responsible from the research question to the outcomes and their evaluation. From the IRB's perspective this calls for building research capacity and undertaking training in research methodology using a systematic approach.

The parallel sessions on this theme described the legal framework for regulation in India, using case law. The need for building comprehensive care with careful attention to equity in care provisioning, such as for HIV patients in need of ART, was also taken up in these sessions. Other sessions called for regulating IRBs and meeting the training needs of IRB members.

The Third National Bioethics Conference concluded on this positive note reiterating the concern for equity in health and health care and for a legal framework rooted in social justice and a monitoring mechanism for ethics that respects both of these concerns.

Rapporteurs: *Sridevi Seetharam, Chhanda Chakraborti and Bijoya Roy reported on the plenaries and the chairpersons of each parallel session provided a summary of the session.*