

NATIONAL BIOETHICS CONFERENCE 2007

Medicine, ethics and the law

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It was towards the end of the last century that medical ethics assumed the character of a distinct discipline in India, attracting the attention of professionals from both law and medicine. However, bioethics was not a major issue in professional discourse at that time. The focus was more on technological applications in medicine and healthcare, and their human rights implications. The concern was on medical negligence and the need for consumer protection.

Within two decades, the nature of the discourse changed considerably because of the progress in biomedical research and applications, including genetic engineering, assisted reproductive technologies and human cloning. The advent of biotechnology in a big way transformed Indian medical research, promising hitherto undreamt benefits to humankind. Legal regulatory systems were soon found to be inadequate to achieve the desirable balance between research procedures on the one hand and ethical standards on the other. The research community turned to law makers and leaders of public opinion to guide them with ethical and legal parameters in the pursuit of uninhibited scientific research.

What came out during the last two decades largely under the supervision of the Indian Council of Medical Research is a complex set of norms, standards and procedures, largely self-imposed and self-executed, which may conveniently be called the bioethics jurisprudence of India.

Given the infinite potential of human biology research, the various topics discussed in the Second National Bioethics Conference will become central to medical education, medical practice and medical research in future. Law schools have already started introducing medical law in their curricula, and a few lawyers and judges are seeking to specialise in this emerging area of jurisprudence. The promoters of the conference deserve to be congratulated for the initiative they have taken to advance the cause of ethics in research, education and healthcare services. I am sure this interactive process will be a recurring event in future, enabling us to build up our own standards of bioethics suited to the conditions and demands of our country.

Ethics and morals are everybody's concern. They keep changing as they constitute a compromise between liberty and security on the one hand, and progress and development on the other. Human rights are said to be universal, inviolable and indivisible; yet when it comes to applications in specific situations we

find standards of reasonableness varying at different periods and places. It is a matter of perception, interpretation and experience. This makes bioethics a fertile area for inquiry, comparison, conceptualisation and application for a long, long time to come. Conferences like the Second NBC at Bangalore help us take the debate outside our narrow professional circles into the world at large, where ideas get shaped into policies and practices globally.

Many in the medical world resent the intervention of law and courts in matters of professional ethics. They have a justifiable reason for that attitude. Lawyers know little of science and technology, particularly the frontier science of biomedical research. Therefore, the medical community would prefer issues to be settled within the peer group rather than outside the profession. However, law cannot be totally avoided so long as technology can be abused and exploitation can happen in the name of experimentation. Human rights have become central to governance, and no activity can escape the moderation of the human rights discipline. Wherever there are rights, there are duties as well, and implementing rights and duties is the business of law and courts. Of course, if ethics prevails, law becomes unnecessary. Though law and ethics have the same centre, that is, human beings in society, they have different circumferences. In a sense, law also is a moralising force, and we say in jurisprudence that law is the minimum of morals. Certain violations of ethics may not be violations of law, but all violations of law are violations of ethics as well. As medical practice assumes the character of any industry with tradable products and services, more and more ethical norms will change to legal rights and duties enforceable through civil and criminal courts. This is what is happening now in the fields of organ transplantation, assisted reproductive technologies and clinical trials of drugs and devices on humans. Many people are unaware of this transformation and its implications. Organisations like the Indian Council of Medical Research (ICMR) and the Indian Medical Association (IMA), publications like the *Indian Journal of Medical Ethics* and conferences like the NBC will take the knowledge to all the stakeholders and create an environment in which criminal enforcement can be avoided and disputes can be settled in a matter supportive of ethical research, ethical medical practice and public good.

The problem before us is not so much the articulation of ethical codes of behaviour in different sectors of biomedical research and practice, even though that itself requires a lot

of balancing of competing interests. The real difficulty is its interpretation and enforcement among different stakeholders, all of whom may not be available to the jurisdiction of the same professional board or authorised body of experts. If records are not properly and uniformly maintained, evidence-based investigation becomes difficult. Corruption in the system can provide impunity to the violators, leaving ethics a matter for individual conscience. And when violations happen systematically under corporate cover, people will lose faith in the system and fall back on police and courts. In the process, the entire system gets projected as unethical and corrupt. This is what happened in the organ transplantation field and the sex determination regulation. It is this apprehension that brought the medical profession and healthcare personnel under the consumer protection law. And the same attitude has brought in police and penal action in some cases of extreme behaviour that has invited adverse media publicity and an unhealthy relationship between healthcare personnel and patients. We are aware of the occasional violence in hospitals in which doctors and nurses are attacked by the relatives of deceased patients, alleging medical culpability. We are also aware of cases where increasing numbers of prosecutions for murder, culpable homicide and cheating are registered against medical practitioners in different cities in the country. There is a virtual breakdown of communication between healthcare professionals and patients in situations where ethics are disregarded, and the relationship assumed to be one of commerce and trade. With trade in services becoming an acceptable mode of delivery of health services and competition growing internationally, the status of enforcement of ethics becomes a critical issue in the future of medicine and healthcare.

The various sessions of the conference largely tried to identify ethical issues in many frontier areas of medical discovery and healthcare services. In some cases the discussion moved to the next step of articulating best practices towards evolving codes of ethical practice to be mandated by professional bodies. Very little work was done to evolve effective strategies on how best to enforce these codes of practice, given the demands of human rights standards, the advent of commercialisation of the healthcare industry, and the inevitable cost, delay and distrust arising out of existing dispute settlement procedures. This is where the government and the profession should sit together and come out with mechanisms that are quick, fair, transparent and effective.

What is available currently are the professional bodies with their in-house mechanisms of peer group justice, which, as they work today, are not always fair, transparent and effective. A lot of preventive strategies, including constitution of advisory boards, medical ombudsmen and monitoring oversight bodies, are in place, but they are seldom effective because of ignorance, indifference, lack of supervision or absence of effective sanctions. Failure of in-house mechanisms leads to demands of ombudsman-type institutions that for a large country with its numerous health centres pose difficulties in management. Only when scandals erupt or violence breaks

out is the inadequacy of institutional mechanisms noticed and other options sought. Thus, come the consumer courts and the criminal justice system in the domain of management of healthcare systems and institutions.

Obviously, what prevails today in the area of enforcement of ethical standards is not a happy situation. By the time we hold the third National Bioethics Conference I hope we will be able to place on the table the institutional arrangements that are both acceptable and effective to control violations of ethical codes in different sectors of biomedical research and technological applications in healthcare systems. I wish voluntary organisations like those which sponsored this conference set up standing committees of professionals of great integrity and community leaders to propose alternative systems of enforcement for the consideration of the government and policy planners. Elected bodies like the medical councils have their limitations. Even the ICMR can play only a catalytic role. If public-spirited people do not act on the basis of evidence and in the best interest of all, the government will necessarily step in with measures that may not always be to the advantage of research and development of professionalism and ethics.

A word about judicial interventions in balancing of rights in healthcare services and delivery systems. In a case of criminal prosecution of doctors under Section 304A (Negligent Homicide) of the Indian Penal code, a three-judge bench of the Supreme Court highlighted the consequences of treating medical personnel like ordinary criminals, and wanted the government of India to make suitable statutory rules or issue necessary instructions to incorporate certain guidelines so that medical personnel in rendering their services are not unduly harassed by police and the public (1). Till a law is framed, the court itself issued the following guidelines to be observed by police as law enforcing agencies:

A private complaint may not be entertained unless the complainant has produced *prima facie* evidence before the court in the form of a credible opinion given by another competent doctor to support the charge of negligence or rashness on the part of accused doctor. The investigating officer must, before proceeding against the doctor, obtain an independent and competent medical opinion, preferably from a doctor in government service qualified in that branch of medical practice. A doctor accused of rashness or negligence may not be arrested in a routine manner unless his arrest is necessary for furthering the investigation, or for collecting evidence, or unless the investigating officer feels satisfied that the doctor may not make himself available to face the prosecution unless arrest is effected.

These court-prescribed guidelines provide a window of opportunity to the medical world to evolve strategies and procedures, statutory or otherwise, not only to avoid harassment and humiliation of innocent practitioners but also to isolate and expose shady characters amongst them who bring the entire profession into disrepute. Such strategies, *mutatis mutandis*, can be extended to the world of biomedical

research involving human beings. No one can deny the abuse and exploitation now prevailing in several sectors of research, clinical trials and treatment. The ignorance of rights by people and their inability to access remedies are giving relative impunity to unscrupulous researchers and research organisations. This shall not be allowed even if they are isolated incidents today. Health is a fundamental right of every individual, and the legal and judicial system has to necessarily intervene to protect these rights when violated or threatened. This jurisdiction is bound to expand and receive greater attention in the days ahead. However, there is no reason that it should inhibit progress in medical research or in the practice of new technologies helpful to healthcare. This would only require development of standards and guidelines, establishment

of institutions for fair enforcement of such standards, and participation of all stakeholders in the regulatory regime put in place. The Supreme Court guidelines, in dealing with medical negligence in homicide cases, can provide the logic and support for a specialised scheme of regulation and enforcement in high-tech medical research and healthcare management systems. This is the need of the hour to balance basic human rights with developments in scientific research and experimental technologies involving humans.

Reference

1. Jacob Mathew vs State of Punjab, decided on 2004 Aug 4.

Valedictory address at the Second National Bioethics Conference, Bangalore, December 8, 2007.

IJME ANTHOLOGIES

Technology in health care: current controversies

Editors: Sandhya Srinivasan, George Thomas **Published by:** Forum for Medical Ethics Society and Centre for Studies in Ethics and Rights, Mumbai. December 2007. 288 pages. Rs 200

This collection of essays covers important discussions related to medical technology that have been carried in the *Indian Journal of Medical Ethics*. Each of the nine sections is preceded by a commentary by an expert in the field. The nine chapters cover placebo controls in research; intellectual property rights; family planning and population control; the HIV/AIDS programme and research; electro convulsive therapy without anaesthesia; liver transplant technologies; end-of-life care; medical professionals and law enforcement, and technology in public health programmes.

Indian Journal of Medical Ethics: selected readings 1993-2003

Editorial collective: Neha Madhiwalla, Bashir Mamdani, Meenal Mamdani, Sanjay A Pai, Nobhojit Roy, Sandhya Srinivasan **Published by:** the Forum for Medical Ethics Society and the Centre for Studies in Ethics and Rights, Mumbai. November 2005. 248 pages. Rs 150.

This selection of essays previously published in the *Indian Journal of Medical Ethics* can serve as a short education on healthcare ethics in the Indian context. The articles are divided into five sections: personal integrity, communication, technology and social justice, research ethics, and law, policy and public health. **The preface** provides an overview on the emergence of medical ethics as a topic of interest in India. **Introductions** to each section and article give the reader a background to the discussions and their relevance today.

The topics covered include: the Hippocratic oath; ancient and modern medical ethics in India; problems in medical education; the relationship between physicians; the role of the pharmaceutical industry; informed consent; debates on medical technology; ethics committees; whistle blowing; how to interact with patients intending to try another system of medicine; AIDS vaccine trials; sexuality research; authorship, and violence and the ethical responsibilities of the medical profession.

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