

**JUSTICE V. R. KRISHNA IYER CHAIR ON HUMAN RIGHTS**  
SCHOOL OF LEGAL STUDIES,  
COCHIN UNIVERSITY OF SCIENCE & TECHNOLOGY, KOCHI-22

**National Conference on**  
**Health Care System in India and Human Rights Concerns**

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***A Conceptual Note on the Conference***

In modern day world, humans are infected with innumerable diseases. New diseases are discovered each day with the result that the frequency of human interaction with the health care system has considerably increased. In the course of this interaction, the possibility of many human right violations is writ large, ranging from infringement of the right to life to invasion of the right to privacy. Alongside, there are other human rights concerns like right to autonomy, dignity etc. The need of the hour is a human rights based approach to health which would provide strategies and solutions to address the many facets of human rights violations and unjust power relations which are the main reasons for inequitable health outcomes. The goal of a human rights based approach is that all health policies, strategies and programmes need to be designed with the objective of progressively improving a meaningful enjoyment of people's right to health. This objective can only be achieved by adhering to rigorous principles and standards viz. Acceptability- all the health facilities, goods and services must be respectful of medical ethics, Accessibility- health facilities and goods and services should be accessible to everyone in terms of equality, physical accessibility, economic accessibility and information accessibility, Availability, Accountability, quality, etc. Thus, it is the obligation of the state to take care of these rights of citizens by appropriate regulation of the health care sector. It is also important to assess the credibility of the laws made by the state in this context.

Health regulation in India encompasses a variety of factors and issues which include promulgation of legislation for health facilities and services, disease control and medical care, human power (Education, Licencing & professional Responsibility), Ethics & Patients Rights, Pharmaceuticals & medical devices, Radiation Protection, Occupational health & accident prevention, Family, Women & Child Health, Mental health etc. The supervision and

regulation of the quality of services provided by the Health Care Delivery system to the people both public and private has always remained a contentious and unresolved issue. In India, despite there being a specific enactment regulating clinical establishments, many States are reluctant to adopt such regulatory framework. The regulatory laws need to be more stringent especially in the background of the mushroom growth of private healthcare entities. Similarly, there are many regulatory bodies which regulate the health care system like DCGI, ICMR, Indian Medical Council, Indian Pharmacy Council etc. Functioning of these institutions along with Medical education needs proper control from the part of the State. There is always a shadow of doubt cast on the private sector health care delivery system which remains largely unregulated and uncontrolled with problems ranging from inadequate and uncontrolled treatment, excessive use of higher technologies, increasing costs of medical care, Diagnostics, medicines, medical devices, overcharging, sub standard care, Medical care commodification, increasing capital investment in medical care for profits, increase in costly high tech capital intensive medical care in the name of high standards to serious problems of medical malpractice and medical negligence and lack of an effective Grievance system.

The nature of doctor-patient relationship existing in India needs to be revisited. Conventionally, the doctor-patient relationship in India is addressed as contractual or fiduciary in nature. In India, the socio-cultural and economic climate being totally adverse, this concept needs to be thoroughly revised. This approach is equally required in the case of the doctrine of informed consent. Providing adequate information to the patients and educating them about the realities and obtaining informed consent before subjecting a patient to any test/procedure/ surgery is very essential. This concept of informed consent arises from the ethical principle of patient autonomy and basic human rights because a patient has the freedom to decide what has to be done or not done with his/her body and to gather information before the test or surgery. In this respect the doctor merely acts as a facilitator in the patient's decision making. Informed consent connotes providing adequate information to enable the patient to take a rational decision in respect of his health. A deliberation in this area will help to understand the liability of medical professionals in therapeutic care. The Indian law on the liability of medical professional is to be discussed in the context of judicial responses.

Cause of Human Rights violations in the Health Care system is equally concerned with Patients' rights. Patients' rights include information disclosure- to receive accurate information about health, treatment, health plan and health care facilities, choice of providers

and plans so as to make informed health care decisions, access to emergency services- in case of injury or sudden illness, to get emergency services whenever and wherever required without additional charges, participation in treatment decisions- to know of all the treatment options so as to make one's own decision, respect and non-discrimination- to be entitled to considerate and respectful care and dignity and not to be discriminated by the Doctors and other health care providers, Confidentiality of health information- to have the health care information protected. These rights need to be protected by the state. These patient rights can be appreciated in the background of the Indian legal system by an analysis of the policy documents and judicial pronouncements. In this context a comparative analysis will be much relevant.

Medical Research and Ethics is another vital area for discussion. Ethics in clinical research is mainly concerned with identifying and implementing the acceptable conditions for exposure of the research participants to the risks and burdens for the benefit of the society at large. Ethical guidelines for clinical research were formulated after disturbing stories of inhuman behaviour with participants during research experiments were revealed to the outside world. Thereafter, the International community woke up to laying down ethical principles for clinical research like the Nuremberg Code, 1947, the Helsinki Declaration, 1964, the Belmont Report of the United States etc. The Indian Council of Medical Research has also laid down 'Ethical Guidelines for Biomedical Research on Human Subjects' in 2006 which were revised in 2006. Concepts of vulnerable population, therapeutic misconception and post trial access hold special importance in ethical conduct of research especially in a developing country like India where most of the research participants are uneducated and economically backward. So far as India is concerned, the fact that these ethical guidelines are mere recommendations explains the cause of its lethargic implementation. Moreover, the Clinical Trials Registry of India (CTRI) has been instituted by the ICMRI with the object of encouraging all clinical trials conducted in India to be prospectively registered i.e. before enrolment of the first participant. In *Swasthya Adhikar Manch Case*, the Honourable Supreme Court had an occasion to deal with the problem of unethical clinical trials wherein issues like denial of compensation to participants with adverse effects, the participation of members of ethics committee in clinical trials and inactive role played by the Ethics Committee, were brought to the notice of the court. Thus, it is necessary to review the Indian law regulating the clinical trials and other human life based research works conducted in India.

There are many other areas in health care system which involve many ethical and legal debates like organ transplantation, surrogacy and other treatment techniques like abortion, artificial reproductive technologies, embryonic stem cell research and euthanasia. In a rapidly globalising world, the growth of reproductive tourism and the business centred around Organ Transplantation is a fairly recent phenomenon. There is a need for regulation of the commercial interests involved in these activities. Surrogacy business tends to exploit poor women especially in India. Without a foolproof legal framework regulating surrogacy, the patients will invariably be misled and the surrogates exploited. Stem cell research offers the potential to make treatments more affordable and aid in economic development. The scientific and economic promise of new health technologies has propelled the politicization of stem cell science across the international, regional and national policy domains. The potential use of stem cells for generating human tissues and organs raises ethical, legal, religious and policy questions and the legal & ethical issues centred around euthanasia is also a subject of ongoing public debate. All those legal and ethical questions are to be addressed by the state and the state is cast with the responsibility of evolving a well balanced formula accommodating the interest of many pressure groups in this context.

Another main area associated with the right to privacy in the health care system relates to access to Medical records and access to health care. Medical records being the only document to prove the therapeutic measures adopted in the course of medical treatment, the patient's right to access the same and the extent of access is always a question of great concern. The state policy in this context is always crucial in determining the patients' right in any health care system. In India various aspects of the health care lie on a blurred line between the interest of the public and the sole right of the individual seeking treatment. The impact of electronic medical records makes the issue further significant for discussion in the course of the Conference. The patients are not made aware of the laws which govern disclosure of information in government and private hospitals and diagnostic laboratories. The scheme of health care system in a state determines the people's accessibility to health care. For example, In India, the Primary Health Care centres and their functioning assumes greater importance as it is instrumental in addressing the health issues of the economically backward populations. This has to be critically reviewed in the light of the Alma-Ata Declaration of 1978.

Drug discovery, patent regime and access to essential drugs is another vital area which warrants discussion. The interrelation between drug discovery, access to drugs and intellectual property jurisprudence has assumed international significance. Pharmaceutical companies face

serious financial challenges in relation to drug discovery and development and are faced with aggressive competition from generic drug companies. In India, the drug regulatory system is poor and neglected on account of poor enforcement mechanisms and multiple interpretations of the Drugs and Cosmetics Act, 1940. This poses a serious threat to the patient's right to essential and life saving drugs. Here the role played by the state in addressing the right to access drugs at affordable price is to be determined. Apart from this, the scheme of regulating drugs and cosmetics under the Drugs & Cosmetics Act, 1940 and allied laws is to be analysed to detect major flaws.

The conference also seeks to highlight the importance of the Indian System of Medicine. Traditional medical practices have played a key role in safeguarding the health of the indigenous communities for generations. The contributions made by traditional medicine to modern system of medicine is worth noting. Traditional medicine is the first level of contact for rural people when they require medical care. Therefore, the government needs to take steps to introduce the use of traditional medicine to support the Primary Health Centres. The traditional medical knowledge needs to be utilised, preserved and developed by due research activities and the law and policy should favour the same. Inventory and Documentation of various medicinal plants and herbs which are used to treat common diseases needs to be developed. At the same time there is a need for regulation of misbranded drugs in this system by the state.

Above all, the Health care system has a pivotal role in the criminal justice system of the country. It aids in criminal investigation and criminal trial. Forensic medicine has made significant contributions in detection, reporting and prevention of human rights violation. However, due to heavy misuse and lack of knowledge of the courts regarding scientific evidence, the courts are hesitant in applying these techniques. The pros and cons of the use of the medical science as a forensic tool is also subject of deliberation.