

Medical Ethics - the Evolving Paradigms in India

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ABSTRACT

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Though India has a strong and enviable legacy of ethics related to patient care, the discipline of Bioethics is still in its infancy in the country. Bioethics, an integral part of modern medical practice and research, is gradually percolating to the fields of medical education, research and practice, though not at a commendable pace. The Medical Council Regulation Act that guides the medical practice in the country and the Guidelines on biomedical research involving human participants are yet to gain widespread popularity among the practitioners as well as researchers. The Medical Council Regulation Act, drafted almost two decades back, with modifications instituted several times, still remains to be modified or even rewritten to suit the current situation. The medical profession during this period has undergone a sea of changes and the demarcation line between 'profession' and 'healthcare industry' is fast thinning out due to various reasons including the growth of 'profit oriented' non-government and corporate sectors in healthcare. Added to this is the growing menace of attacks on hospitals and healthcare providers. Medical Council Regulations, drafted with 'single doctor- single patient' and their one-to-one relations in mind is fast losing its relevance and needs to be revisited. Similarly, institutional mechanisms for overseeing research involving human participants needs to be strengthened. Ethics education needs to take a centre-stage in Medical Education and Ethics Committees, both clinical as well as research need to have more professionals trained in Bioethics. The Medical Councils at the Centre as well as at the regional levels need to have more ethics professionals and the existing situation demands for paradigm shifts in ethics related to medical practice and research in India.

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Ethics and Professions

"Ethics" is a 'generic term' for various ways of understanding and examining moral life. It has close links with "Morality" which constitutes the norms about right and wrong human conduct that are so widely shared that they form a stable social consensus. The term 'Common Morality' refers to the set of norms that all morally serious persons share. Thus, it becomes imperative that any morally serious person is bound by certain principles of societal living that makes the coherence and the societal binding possible. Professions, due to their peculiar character, have developed their own ethical standards to safeguard the integrity, sanctity and high moral standards.

Medical Ethics in India

Discourses related to the ethics in medical practice in India date back to as early as 400 BC. 'Charaka Samhita' of ancient times describes in detail about the prerequisites to become a physician and ethics in medical practice.¹ But, the modern era of ethics

related to medical practice, especially the Western System of Medicine evolved only later and is known as Bioethics or ethics related to ethical issues emerging from advances in Biology and in Medicine. Medical ethics tends to be understood narrowly as an applied professional ethics, whereas bioethics has a more expansive application, touching upon the philosophy of science and issues of biotechnology.

Bioethics and Medical Council Regulations in India

Bioethics² tends to revolve around four cardinal principles viz. principle of autonomy, beneficence, non-maleficence and distributive justice and various applications of these cardinal principles in issues emerging in the day to day medical practice as well as research involving human participants in medicine. Thus the concepts like "Informed Consent", "Informed Refusal", "Confidentiality" and "Conflict of interest", among many such others, evolved from these principles and constitutes the day to day guiding principles for medical practice

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and research world over. Along with the advent of Modern Medicine or Western Medicine in India, the western medical ethics or Bioethics also got its advances in the country. Ethical Guidelines overseeing medical practice were formulated and a step ahead, unlike in many countries in the west where they remain as guidelines, such guidelines were enacted into law in India.³ It could also be found that the Indian Guidelines are more stringent and directive than many of its counterparts from various parts of the world. But, it is a common complaint about Indian laws that “the rule of law that exists on paper does not always exist in practice”.⁴ The code of medical ethics in India that came in to force from 2002 and amended up to 2016 needs to be examined in such a context.

As was stated earlier, in India both the Code of Medical Ethics as well as the directive is very stringent. It imbibes various principles of bioethics and aims at ensuring foolproof adherence to the highest standards of ethics by the practicing physicians. But, it has also to be borne in mind that the healthcare scenario is fast changing in India and medical profession is fast evolving into a ‘healthcare industry’. It is worthwhile examining the medical council regulation act through the lens of such changes.

Evolving Healthcare scenario in India

Over the past few decades a sea of changes has occurred in the healthcare scenario in India. Earlier the non-governmental sector in healthcare was constituted mainly by charity missionaries or non-profit organizations to a very large extent and the Government played a major role in the healthcare provision. Pure private sector, the so called “profit oriented private sector” had minuscule role in healthcare provision. Gradually the picture changed and currently the ‘profit oriented private sector’ plays the major role in the country.⁵ Health is a “State subject” and the contribution from the Central Government comes in the form of grants and National Health Programmes. Over the past few decades the Governments’ contribution- both the Central as well as States had gradually been coming down year by year. A corresponding increase in the growth of private sector as well as increase in the out-of-pocket expenditure in healthcare had also been reported. One-doctor clinics, small and medium sized hospitals run by groups of doctors, cooperatives, missionaries and non-profit non-governmental organizations that constituted the

backbone of healthcare scenario in the country has started disappearing fast and in came the corporate sector in health care which is fast transforming “healthcare” into a ‘healthcare industry. It is in this context that the Medical Council Regulation Act, that stipulates guidelines to individual doctors need to be examined in detail for its relevance and appropriateness in the current context.

Medical Council Regulations Act- Square peg in round hole?

Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 aims at providing ethical guidelines to practitioners of Modern Medicine in India. Naturally, the guidelines are aimed at individual doctors. At the very outset, it goes on describing the expected character of the doctor and his ethical responsibilities. Then it proceeds to describe as to whom all can practice Modern Medicine in the country.

Clause 1.1.3 of the act states that “no person other than a doctor having qualification recognized by Medical Council of India and registered with Medical Council of India/State Medical Council(s) is allowed to practice Modern system of Medicine or Surgery. A person obtaining qualification in any other system of Medicine is not allowed to practice Modern system of Medicine in any form. But, currently, the Government themselves have come out with suggestions to provide license to many categories like Nurses, practitioners of other systems of medicine etc to prescribe modern medicines, though they lack any qualification prescribed by the Medical Council. Several States have gone ahead with creating such cadres of practitioners. Thus, we find a situation where the authority itself is violating the guidelines.

The clause on degrees and credentials of medical practitioner, that could be exhibited with name, is often misunderstood and misquoted than any other clauses in the guidelines. This clause, viz. 1.4.2 clearly states that “physicians shall display as suffix to their names only recognized medical degrees or such certificates/diplomas and memberships/honours which confer professional knowledge or recognizes any exemplary qualification/achievements. It never mentions about ‘only degrees or diplomas approved by the Medical Council or in their list’. But, often even the regional councils come out with instructions that only those qualifications recognized and listed in the Medical Council appendix should be

displayed which is a clear violation of this clause. It is worthwhile to remember in this context that many postgraduate and super specialty degrees offered by some of the reputed medical colleges in Kerala fail to find their place in the medical council list, often due to technical or beaurocratic reasons, leave alone the case of fellowships, memberships, short term diplomas and degrees offered by reputed universities and boards in India and abroad.

Clause 1.5 had been modified with effect from 08.10.2016 as “every physician should prescribe drugs with generic names legibly andpreferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs”. Here again, In India enforcement mechanisms for assuring quality of drugs is dubious⁶ and such a clause without ensuring the availability of quality generic products is difficult to implement. Moreover, the pharma industry in India is poorly regulated with rampant “fixed drug combinations” and myriads of brand products with trade names that flood the market. The prescribing physicians often go by their experience with individual products in terms of their usefulness and efficacy. Insisting for ‘generic’ prescriptions in such a scenario is counterproductive and could a doctor be held ‘unethical’ for prescribing a drug that one has experience and belief over decades over a ‘generic’ that one does not have any experience on?

Clause 1.8 deals with payment of professional services. Here again, it is assumed that the there exists a one to one relation between the doctor and the patient which might have been true when doctors practiced alone or in small clinics where the doctors themselves decide the fee. Now, the situation is far more complex and in large and corporate hospitals, treating physicians seldom have any role in deciding the fee which is often merged with several items starting from room rent to cleaning charges. Moreover, after the advent of ‘Clinical Establishment Act’, many States have started enacting different laws related to licensing and regulation of clinical establishments which often include clauses on doctors’ fee as well as for medical interventions. These duplications in law make the situations more complex.

These clauses are cited as representatives that show the complexities and inappropriateness of them in the present context. It’s worthwhile examining more basic principles of medical practice in the sub-continent. For example, take the case of informed

consent. Though, the concept is discussed in length and breadth, the actual scenario of its implementation is again murky. In Government institutions, where the sheer number of patients is unmanageable, it’s often complained that even the ‘human rights’ of patients are being violated very often. Even the Medical Council Regulation Act is alleged to be ignoring the human rights of patients.⁷ But, the fact is that there remains a lot of grey areas related to informed consent in India which could only be addressed by proactive interventions from the medical profession.⁸ The ‘Clinical Ethics Committees’ mandated for accreditation under NABH often remains in paper than in real practice. It would be evident if one looks at the number of cases such committees have dealt with in one or two years and compare that with their western counterparts. These committees are constituted as ‘inevitable evils’ for the process of accreditation and remain in paper once the accreditation process is over. Added to this is the dearth of professionals formally trained in Bioethics or Clinical Ethics to be part of such committees.

Clause 6.1.1 of the Act deals with advertising. It could easily be seen that the clause is more often violated than being complied with. The clause is framed without any knowledge on the evolving healthcare scenario in India. The healthcare, as stated earlier, is emerging more as an ‘industry’ than as a ‘profession’. Industry has its own sets of rules on entrepreneurship and resorts to its own ways to boost the same. The emerging citadels of healthcare in the corporate sector rely more on advertising and ‘client canvassing’ and doctors working in such hospitals do not have much say in the strategies resorted to by the management in such matters. In the current context, the clause requires serious reconsideration and rewriting.

Similarly, drawing a line between the rights of the individual doctors and their associations is also very difficult as shown with regard to endorsement of products and apparatus. Similarly Clause 6.4 which deals with rebates and commissions is also very difficult to implement in the current scenario as shown in any number of such complaints arising related to medical practice. Gone are the days of ‘one doctor treating one patient’ and in the current scenario of medical practice in India, several doctors simultaneously are involved in the care of a patient. Referrals and cross-referrals are the rule rather than an exception and prescribing investigations is part

of daily routines. Once again, mushrooming of laboratories and investigation facilities make the competition cut-throat and such establishments resort to all sorts of adjustments in their daily struggle for existence. They function as commercial establishments, purely 'profit oriented', rather than as 'professional establishments'. What set of rules are applicable to them is still doubtful and the methods they resort to in 'promoting their business' need not always comply with the ethical guidelines of medical profession. It is argued that "in the absence of a clear, logical, bold and community oriented health care policy on the part of the government and a lobby of strong, honest, clear thinkers representing the medical profession in the corridors of power, the present situation is unlikely to change in the near future".⁹

Conflict of interest, considered to be unethical, seems to be not even well understood. Conflict of interest is considered to be a 'precursor to corruption' and it is alleged that the Government is yet to come out with measures to address this issue.¹⁰ Medical Council Regulations proceed to direct medical professionals to avoid unnecessary consultations, consultations only for the patients' benefit, totally dispensing with rebates and commissions, abstaining from receiving gifts, travel facilities, hospitality or cash and monetary incentives from pharma companies etc. These are again elaborated with the 'single doctor' in mind. Currently, such issues assume greater dimensions where the management of the hospitals, often non-medical, receives huge grants, cuts, commissions and incentives etc from pharma companies including those in the trade of devices and equipment. The ultimate sufferers in these cases are the 'end use' beneficiaries viz. the patients, and the doctors have no role in preventing them. The current regulations are incapable of preventing such 'atrocities'.

Attack on Hospitals and Healthcare providers

Attack on hospitals, vandalizing and assault on healthcare providers is a growing menace assuming epidemic potentials all over the country.¹³ It shows the failure of the system and medical practice is becoming more and more unsafe for the providers. Among the multifarious reasons cited for such an exigency includes failure of the existing system to address the grievances arising in day to day practice, lack of proper communications and the failure of the system to meet the expectations of the society and lack of proper communication between the

providers and recipients. The internal mechanisms for redressal of grievances including the role played by the medical councils seem to be inadequate in the present scenario.

Biomedical Research involving human participants

Medical Research involving human participants is a vast area with multitudes of ravaging problems. Though governed by 'strong' legislations like the "Ethical Guidelines on research involving human participants" by the Indian Council of Medical Research (ICMR)¹⁴ with several agencies including the Drugs Controller General of India and the ICMR itself on the implementation side, totally ethical research still remains an elusive goal. Institutional mechanisms to oversee ethical research viz. the Institute Ethics Committees (IECs) still remain weak and vulnerable¹¹ and need to be strengthened in their structure and function.¹² Newer techniques of 'recruiting participants through primary care physicians, taking away the bulk of research from medical colleges and teaching institutions to the periphery through the contract research organizations, employing 'ghost authors' along with the advent of 'Independent Ethics Committees' are all areas that need urgent attention in this regard.

Way ahead...

In short, Bioethics is still in its infancy in India. Ethics education, though given a high priority in the medical curriculum, remains neglected due to various reasons. Paucity of duly qualified and trained faculty, who could impart ethics education, is one deterrent factor. Added to this is the fact that neither the knowledge, nor their skill to tackle ethical issues arising in medical practice are tested during the medical education. Ethics committees at various levels, both clinical and research ethics committees, grossly lack trained manpower. Even the medical councils at the regional levels often lack duly qualified professionals in Bioethics and unfortunately, as in every other fields, appointment or nomination to such posts often remain political, with their inherent issues. A closer in-depth look in to the current scenario definitely calls for training of more and more professionals in bioethics, their utilization in teaching as well as in ethics committees and empowering both the clinical and research ethics committees to deal with ethical issues in medical practice as well as research looks imperative. Revisiting the Medical Council Regulations

and rewriting them to suit the current healthcare scenario is the need of the hour. Academia and researchers need to be sensitized more on ethics and human rights and Institute Ethics Committees are to emerge more robust in their structure and function. Examining ethical issues arising in the day to day clinical practice needs to become routine and cadre of 'practicing clinical ethicists' needs to become a reality. This calls for paradigm changes in the current scenario.

END NOTE

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