# ENSURING MEDICAL CODE OF ETHICS-THE LEGAL APPROACH

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**BACKGROUND:**

Contrary to popular belief around rising number of medical negligence cases against doctors and hospitals every year, it was found that there is a decrease in filed medical negligence cases in India. In the year 2018, a total of 3241 cases of medical negligence cases had been filed in India while in the year 2019 only 2638 cases of medical negligence cases, which is 18.61% decrease. A government panel formed to investigate into medical negligence cases has found that only 15% of the complaints received in Gurugram, from 112 cases filed between June 2017 and January 2019 were actual cases of medical negligence. The responsibility to regulate the medical profession lies with the Medical Council of India (MCI): a statutory regulator. A total of 69 cases of medical negligence in 2017 were awarded punishment by the MCI, which constituted 44% of the cases referred to MCI by the state medical councils. In 2018, 28% or 40 cases referred to MCI by state medical councils awarded punishments to doctors and in until June 2019, 46% or 28 doctors were punished by MCI for medical negligence.

From the above data, it appears that the overall number of cases of medical negligence (Negligence of Omission and Commission) being referred to MCI by the state councils is going down, but the percentage of cases receiving punishment is increasing. Is the falling number of cases, because of growing ethical practice or is it because of non-reporting of actual cases of negligence? Where does one count medication error related negligence? A Harvard study, in 2018 reported 5 million cases of medication errors in India annually. Probably, cases, which fall under the category of '*Res Ipsa Loquitur*', a Latin phrase that means the thing speaks for itself, are the only ones which get booked as negligence. For example, the 26 years old Rajkumar losing his 24 year old wife Priya to sepsis caused by an allegedly leftover cotton swab inside the abdomen during a C-section surgery on December 27, 2019 at Vridhachalam in Tamil Nadu.

Usually, in India the medical negligence cases are received by the State Medical Councils (SCI), or filed with the police. The SCI conduct inquiries and investigate the case with the help of a panel of expert doctors. The order of SCI can be appealed in the MCI by the patient or the doctors. The punishment awarded by the MCI ranges from warning the doctor who is found guilty to removing the name of the doctor from the Indian Medical Register/ State Medical Register for a specified period. The MCI order can also be appealed in a court of law by the aggrieved party.

The non-acknowledgment of medical negligence cases in India can be because of: (i) lack of an independent expert group to hold doctors accountable; (ii) doctors being lenient while judging their professional colleagues; (ii) conflict of interest of being judged by another professional colleague, not an independent expert; (iii) doctors safeguarding group interest and maintain respect for the profession in the eyes of the society; (iv) influence of doctors in the society; (v) medical negligence cases registered in wrong sections of Indian Penal Code (IPC) as 'unnatural death' (IPC Section 174 of CrPC), instead of 'death by negligence' (IPC section 304A), as in case of aforementioned case of Priya. This is because, whatever doctors do is considered as their job and not a criminal offence, and therefore, even the police before registering a medical negligence case under IPC Section 304A think twice.

The MCI's moralistic approach- “Code of Conduct”, instead of legal approach to regulation of the profession may be the cause for issues of medical

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malpractice/ negligence in India. And rightly so, a profession of the stature of a 'doctor' should operate at a moral high ground, because of its tenant to safeguard life! While there are several studies that have explored quantum of medical negligence, reasons for the same, the Consumer Protection Act and its ramification on medical practice, or how to avoid negligence; there are far and few studies that have scrutinized the legal dimension of moral. Therefore, this paper makes an effort to understand the legal enforceability of ethical codes of medical practitioners.

While the Medical Code of Ethics, 2016 purports 60 points of morality/ ethical practice illustrated in 7 sections expected out of a medical professional. The section 8 talks about the disciplinary proceedings as regards non-compliance to the MCI Code of Ethics. We have picked up only 3 tenants from the MCI Code of Ethics and weighed them against the scale of morality and legality, within which the MCI swings like a pendulum on each occasion that it is put to test. The effort is to explore the need for doctors' to self-regulate one's own-self as clinician to uphold the spirit of the profession, is there a need/ space for enforcement of a legal system.

## MORALS V. LAWS

To understand the difference between 'Morals and Law', there's a need to drill deeper to demystify the understanding around these words in practice. Regulation is a legal system as opposed to a moral system which is largely persuasive. A legal system differs from morality in three important ways:

## SPECIFICITY

Moral standards are usually generic, and rarely provide clear direction in individual situations. In contrast, legal standards strive to be specific and is cognizant of the exceptions to the rule. For example, a moral standard may be a generic statement like: '*Thou shalt not kill*'. Law, on the other hand, recognizes that killing is justified in many conditions like, defending oneself from a murderous attack, soldiers killing the enemy, executioner killing the condemned, and so on. All of these are codified in various laws justifying killing of another human being in specific circumstances. These have been thought through and developed through legislation and jurisprudence.

## CONSEQUENCES

Morals statements may prohibit some actions, but rarely provide a consequence for violating them. In contrast, laws, may not even prohibit actions, but always provide the consequence for violating them. For example, morals may be drafted as: ``though shalt not kill''. The Indian Penal Code, on the other hand, has no statement prohibiting people from committing murder. It simply states: *Whoever commits murder shall be punished with death, or imprisonment for life...*

## ENFORCEMENT MECHANISM

Morals usually do not have a state system to enforce them. In contrast, laws have a vast and complicated machinery enforcing them. For example, there is no enforcement mechanism for people lying. For legal offences, on the other hand, we have the entire state machinery to enforce against violations. This includes police, judiciary, and other supporting laws like law governing trials (Cr.P.C.), evidence, etc.

## MEDICAL CODE OF ETHICS

The MCI made The Medical Code of Ethics, 2002 (the Code), amended in 2016 to govern medical practitioners. While it uses the word "ethics", it is a legal system and not a mere moral system. It has been made under an Act of Parliament, (the MCI Act) by the authority granted by Parliament and therefore, forms part of the legal system. An analysis of a few provisions of the Code shows that while the MCI is pro-active in setting standards, when it comes implementing them it acts more like a moral authority with little will or no systems to actually enforce any standards. In this article we use the difference between laws and moral to review three parts of the Code pertaining to: medical records, generic drugs and commissions.

## MEDICAL RECORDS

### 1.1. Section 1.3.1: of the code states:

***"Every physician shall maintain the medical records pertaining to his/ her indoor patients for a period of 3 years..... in a standard proforma... attached as Appendix 3."***

Appendix 3 expects the doctor to mention: Name of the patient, age, sex, address, occupation, date of 1st visit, clinical note (summary) of the case provisional diagnosis, investigations advised, observations, signature in full, and name of treating physician, etc. The record-keeping obligation on physicians is limited to ``indoor patients'' only. Indoor patients refer to patients in medical establishments (hospitals, nursing homes etc.) for 24 hours or more.

This provision suffers from three defects:

## INCOMPLETE COVERAGE

This provision covers a very small proportion of patients that a doctor sees. It completely excludes the vast majority of interactions (such as, chronic case management and procedures) between doctors and patients: outpatient visits. There is no obligation to keep records or even record prescriptions in any standard manner.

## DUPLICATES WORK

Medical establishments (hospital, nursing homes, etc.) are already required to keep records. It makes no sense for individual doctors to duplicate the effort. Doctors admit patients in different hospitals and offer consultations, take clinical rounds in hospitals seeing scores of patients. Maintaining records for each patient/ prescription in person with the doctor (not the medical establishment) is irrational.

## EXCEEDS JURISDICTION

Record keeping is a function of medical establishments which are regulated by state government under various clinical establishments laws. It is not clear how the Medical Council which has no jurisdiction over medical establishments can make regulations about record keeping.

The code doesn't specify how MCI can identify non-completion. Will it receive complaints from patients or hospitals? What are the penalties for non-completion?

### 1.2. Section 1.3.4 of the code reads:

***``Efforts shall be made to computerize medical records for quick retrieval''***

This provision looks more like a moral statement than a legal obligation. It does not put any clear obligation on any party. Who has to computerize medical records? What constitutes ``efforts''? Even if there was an enforcement system, this provision of the code is unenforceable, as it is *impossible* to violate this provision. A doctor could just claim that he enquired about computerizing records and that could constitute efforts.

## GENERIC NAMES OF DRUGS

This provision is designed to prevent doctors from prescribing *brands* in return of kickbacks from pharma companies. The problem is so endemic that the government proposes to bring a new law to tackle this. The Code already has a provision governing this, which is clearly not adequate. Section 1.5 of the Code reads:

***"Every physician should prescribe drugs with generic names legibly and preferably in capital letters, and he/she shall ensure that there is a rational prescription and use of drugs."***

This obligation does not have any consequent penalty for violation. The code expects that there should be a rational prescription without any form to verify it. Since there are no standards for how prescriptions have to be written for patients, it is impossible to verify this obligation. Since a doctor is not required under the code to write down the diagnosis; it is impossible to verify if the prescription was rational or not. There are medical texts and standards in training which specify how a prescription is written. However, the code makes no obligation on doctors to follow them.

## COMMISSIONS

Kickbacks from pharma companies to doctors have become a major problem in India. In February 2016, the MCI amended the Code to insert a new provision governing payments received by doctors from pharma and medical technology firms: clause 6.8.1 of the MCI code. This provision is very different from the other provisions in the Code. It clearly leans towards a more legal system rather than a moral system:

- Instead of a general prohibition, commissions have been divided into eight headings: Gifts, travel facilities, hospitality, cash or monetary grants, medical research, maintaining professional autonomy, affiliation, and endorsement.
- Each heading has a definition of what constitutes violation.
- Each heading has a definition of what constitutes violation. An example of this is the heading: *cash or monetary benefits*. While this prohibits receiving money from pharma companies, research grants have been exempted. To qualify as a research grant, such *cash or monetary benefits* must be channeled through approved research organizations, as per their rules, and disclosed.
- For each type of violation there is a specific penalty. For some, it has been graded depending on the magnitude of the violation. For example, if a doctor receives cash more than Rs.1000 and up to Rs.5000 he is liable for a *censure*. However, for receiving cash more than Rs.50,000 but up to a lakh, the penalty is removal of name from the medical register (barring practice) for one year.

This is a small step towards making professional regulation *legal* in India. However, it misses the third ingredient of a legal system: enforcement machinery. The MCI has no system of tracking such gratification or the administrative machinery required to investigate and penalize violators.

## SUMMARY

From the review of literature, it is clear that there's lot to be done to improve the medical practice, especially to reduce medical negligence of omission or commission, which is to avoid sentinel events. However, as 'to err is human'! irrespective of profession they are in; achieving the extent of compliance desired is not always practical in practice; without a strong deterrent or nudging that serves as reminder to enhance human alertness.

Further, from the three sections that have been exemplified, it is evident that an effective regulatory system should not depend on moral codes alone. The provisions under the section on '*commissions' as amended in 2016* shows that the MCI is able to write a more legalistic obligation, when it chooses to. Also, the Section 8 of the MCI Code, already has described the possible disciplinary proceedings for non-compliance thereof, which the national and state councils can fall back on, for errors that result in morbidity and mortality of patients.

However, spelling out the codes clearly with clear legal obligations itself serves as significant deterrent to repeat defaulters at large. Therefore, for every 'code of ethics' that one expects people to follow, two changes to the approach should be followed to make it legally binding:

## CREATE LEGAL OBLIGATIONS

Instead of writing moral standards, MCI should move towards more legal standards. This is to cover major areas of practice of doctors (including outpatient records, and not just for inpatient medical records), clearly state outcomes or behavioural standards expected, and provide clear penalties for violation of standards.

## CREATE ENFORCEMENT MECHANISMS

The MCI does not seem to have any enforcement mechanism for the legal- requirement it places. For example,

- It could carry out sample surveys to check if prescriptions meet the requirement under the Code and look for mechanisms to make doctors

accountable to what they prescribe.

- Making online self-declaration, with evidence mandatory on each point of ethics every 5years as a practice to renew registration.
- Such declarations can then be sample surveyed for validation and non-compliance noted from such sample surveys can treated appropriately de-novo in legal terms, to bring in seriousness amongst the practitioners.

Such measures, have the potential to significantly impact the quality of care rendered to the masses and prevent harm to the people from the very system that seeks to improve health of people.

**REFERENCES**


1. https://www.researchgate.net/project/Study-of-medical-negligence-cases-decided-by-Consumer-Court-NCDRC-SCDRC-DCDRC-in-India
2. https://timesofindia.indiatimes.com/city/gurgaon/only-15-medical-negligence-cases-genuine/articleshow/ 67579198.cms
3. https://www.thenewsminute.com/article/justice-denied-why-medical-negligence-goes-unpunished-india-what-can-be-done-115783
4. https://www.business-standard.com/article/current-affairs/india-s-medical-error-deaths-nearly-5-mn-a-year-can-be-cut-by-50-expert-118102800193_1.html
5. https://www.newindianexpress.com/states/tamil-nadu/2020/jan/03/woman-in-tamil-nadu-dies-as-surgical-sponge-left-inside-stomach-2084252.htm
6. http://www.karnatakamedicalcouncil.com/userfiles/file/NewsLetters/N202010161408289141603584737.pdf
7. https://dhindia.org/2020/05/15/regulations-to-amend-the-indian-medical-council-professional-conduct-etiquette-and-ethics-regulations-2002-consultation-by-telemedicine/#:~:text=1.,accorded%20approval%20to%20these%20Regulations.
8. https://egazette.nic.in/WriteReadData/2020/219374.pdf