





SCIENCE OF MELLEILEILE

INTRODUCTION

A woman enters the emergency room with stomach pain. She undergoes a CT scan and is diagnosed with an abdominal aortic aneurysm. The physicians inform her that the only way to fix the problem is surgically, and that the chances of survival are about 50/50. They also inform her that time is of the essence, and that should the aneurysm burst, she would be dead in a few short minutes. The woman is a dancer; she worries that the surgery will leave a scar that will negatively affect her work; therefore, she refuses any surgical treatment. Feeling that the woman is not in her correct state of mind and knowing that time is of the essence, the surgeons decide to perform the procedure without consent. She survives and sues the hospital for millions of dollars.

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The case highlights one of the innumerable ethical issues that the medical fraternity faces. These dilemmas encompass all areas from **distribution of resources to handling the emotionally charged atmosphere** around them. This challenging environment has been **further stretched with outbreak of the pandemic.** The conditions created by the pandemic i.e., limited information about the disease and its cure, chronic shortage of the medical supplies and prevalent misinformation have created several ethical challenges. Also, the theories on origin of the virus have raised some questions on ethics regulating biomedical research.

In a nutshell, the pandemic has shown us that medicine cannot be limited to science. It has to go beyond the scientific principles by incorporating rights, values and needs of patients, collectively encoded in medical ethics. But what exactly is medical ethics? How has it evolved overtime and what are its primary principles? How have these principles shaped the relationships between stakeholders? What are challenges that have arisen in its implementation and what can be done to overcome these challenges and move towards more balanced medical ethics? In this edition, we will try to answer the aforesaid questions.

WHAT DO WE UNDERSTAND BY ETHICS IN MEDICINE AND WHY IS IT IMPORTANT?

Ethics as a subject deals with the right choices of conduct considering all the circumstances. It deals with the distinction between what is considered right or wrong at a given time, in a given situation and in a given culture. Ethics in the realm of healthcare can be divided in two areas:

- Bioethics or biomedical ethics: It refers to the ethical issues that arise from recent progress in biology & biotechnology. Sensitive applications and implications of this progress in life-sciences comes in the area of bioethics.
- For example, dilemmas arising out of research in synthetic embryos will come under the purview of Bioethics.
- Medical ethics: It deals with those ethical principles that govern professional conduct in medicine. It encompasses
 obligations and conduct of all stakeholders i.e., physicians, hospitals, other health professionals, patients and society
 in general.
 - For example, medical ethics dictates the principles that the doctors should follow to ensure that the privacy of patients in not breached.

The profession of medicine is directly connected to the **critical function of preservation of life and relief of suffering**. This function distinguishes medicine from other sciences and puts **special responsibilities on the custodians of the system** i.e., physician and other members of the healthcare fraternity. In this context, importance of medical ethics reflects in following facets:

- **Bringing standardization and consensus to ethical dilemmas:** In situations where physician, patient and other healthcare personnel disagree about what is right way to treat patients, medical ethics can help to **bring consensus** among the stakeholders.
- O Acting as a guide for ethical conduct: The study of ethics prepares medical professionals to recognize different situations and to deal with them in a rational and principled manner. Ethics is important in physician's interactions with society and their colleagues and for the code of the medical research.
- Placing Rights of patients at the center of the medical processes:
 Ethical principles such as respect for persons, informed consent and confidentiality are indispensable to any physician- patient relationship.
 Ethical frameworks help provide adequate emphasis on these rights.
- Aiding creation of a compassionate and just society: Medical ethics helps ensure that the physician's motivations lie in well-being of his patients and society in general. In a nutshell, ethics ensures that a sensitive profession such as medicine **does not fall prey to the sin of** Science without Morality.



Medical ethics has developed over centuries. In the allopathic system of medicine, such developments commenced from the time of Hippocrates and over time several 'codes' have been developed. These include:

○ Hippocratic oath (5th century BC):

Hippocrates is widely regarded as the father of medicine. Under this, the doctors swears by several Greek gods and goddesses like Apollo (physician), Aesculapius (surgeon), etc. It is considered sacred for its religious foundation and sanctity.

○ The Nuremberg Code (1947):

- The Nuremberg Code is a set of research ethics principles for human experimentation created by the USA Vs. Brandt (1946-47) court as one of the results of the Nuremberg trials at the end of the Second World War.
- The code gave emphasis to the rights of the patients and in that sense laid the ground for inclusion of autonomy and justice in medical ethics.

○ Declaration of Geneva (1948):

- This is also called the Physician Oath and is considered to be the modern version of the Hippocratic Oath. This declaration was adopted by the General Assembly of World Medical Association (WMA) in 1948 and has been amended and revised several times in 1968, 1984, 1994, 2005 and 2006.
- It is the declaration of physician's dedication to the humanitarian goals of medicine i.e., care and non-maleficence towards patients.

O Belmont report (1979):

- It was published by National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979.
- The report identifies three basic ethical principles i.e., Respect for persons, Beneficence and Justice which underlie the conduct of research involving human participants.

O Medical council of India (MCI) regulations (2002):

- MCI notifies the rules to Indian Medical Council relating to Professional conduct, Etiquettes and Ethics regulation in 2002 and has been amended several times.
- Recently, Medical Council of India has been replaced by National Medical Commission (NMC) through NMC Act, 2020.

Although, medical ethics varies among cultures, nations and fraternities but the **evolution of medical ethics over centuries has helped achieve a sense of universality in the primary principles** governing it. There are **four universally accepted principles** on which medical ethical frameworks are based-

- Autonomy: It states that the patients have autonomy of thought, intention, and action when making decisions regarding health care procedures. Therefore, the decision-making process must be free of constraints.
- Justice: It requires that procedures uphold the spirit of existing laws and are fair to all players involved. For example, burdens and benefits of new or experimental treatments must be distributed equally among all groups within the society.

| Timeline | |
|-------------------|---|
| 5th century BC | Hippocratic oath |
| 5th century AD | Formula Comitis Archiatrorum: It is considered as the earliest code of medical ethics. |
| 1803 | Thomas Percival's code of medical ethics: It is considered as the first modern code of medical ethics. |
| 1947 | The Nuremberg Code |
| 1948 | Declaration of Geneva |
| 1949 | International Code on Medical Ethics: It codifies the duties of physicians to patients and colleagues. |
| 1964 | Declaration of Helsinki: It is a set of ethical principles regarding human experimentation. |
| 1979 | Belmont Report |
| 2002 | MCI Regulations |





- Beneficence: It states that the patient's well-being is the ultimate goal of care. This principle lies at the heart of medicine, whose mission is precisely to prevent, diagnose and treat illness in order to promote the patient's health.
- O Non-maleficence: It encompasses two key concepts:
 - > The first is that of not causing harm to patients, even before doing them good.
 - The second is the need to properly assess the risks and the benefit/risk balance of a treatment, and hence to refrain from prescribing a treatment that, although effective, could be harmful to the patient.

These principles form the core philosophy of medical ethics. But these principles do not operate in silos. **They operate in a given social, economic and politico-legal context.** These principles and contexts collectively shape the framework of medical ethics for all its stakeholders.

HOW HAVE THESE PRINCIPLES SHAPED THE RELATIONSHIPS AMONG STAKEHOLDERS?

The framework of medical ethics in primarily centered around the **physicians and patients.** But as the framework has developed, **other stakeholders** i.e., **society and healthcare-associated institutions** (these include hospitals, pharmaceutical firms etc.) have come to play a crucial role in this framework.The interactions of these stakeholders can be broadly expressed on following lines-

 Patient-Physician Relationship: The ethics of this relationship has become contingent on patient's trust on the physician. This trust is in turn dependent on adherence of physicians to the aforementioned principles. This translates into following:



- Informed consent and clear communications: The principles of autonomy mandates that the patient should be enabled to make a fully informed decision on every medical process that s/he is going through.
 - Although, this principles has two broad exceptions- one, where patients voluntarily give their decision-making powers to physicians and two, where disclosure of information would cause harm to the patients.
- Maintaining privacy and confidentiality: Patient's autonomy and the principle of non-malfeasance creates an obligation for the physician to protect the private, identifiable information associated with the patient.
 - In keeping with the professional responsibility to safeguard the patient's privacy (physical, decisional etc.), physicians have an ethical obligation to manage medical records appropriately.

Coming back to the introductory case, was the **woman right in suing the hospital?** As we have seen, in accordance with the principle of autonomy- **"competent patients have the right to refuse treatment, even when the refusal will result in disability or death".** According to this framework, **her conduct was not unethical.**

- Society-Physician relationship: This relationship is not based on direct interactions but has a large and lasting impact on the medical system. It is a point of intersection where societal ethics and medical ethics meet to shape the future of medicine in sensitive areas. Facets of this relationship include:-
 - Beginning-of-life and end-of-life issues: Sensitive issues like contraception, assisted reproduction, pre-natal genetic screening, abortion or assisted suicide for terminally ill patients comes under the societal debate, which may vary from culture to culture. This underlying issue in all these areas is balancing autonomy of the society and their collective beneficence. For example, legal status of assisted suicide varies across countries.
 - Several ideas, techniques and processes have been introduced to enable easier and more ethical decision making in these sensitive issues. For example, the 'three-parent-baby' technique has been gaining popularity in several countries. Also, processes such as advance directives are being explored to improve the autonomy of certain class of patients.



"Competent patients have the right

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- Resource allocation and distribution: A society has multiple socio-economic needs. The healthcare system shares the country's resources with all these needs. As a result, it is the society's prerogative on how much resources it wishes to provide to the healthcare system and how it will be distributed. For example, public spending on healthcare in India is close to 1.3% of the GDP.
- Public health Systems: The physicians have a long-recognized responsibility to participate in activities to protect and promote the health of the public. This is driven by the principle of collective beneficence. These include encouraging good hygiene practices, vaccination drives among others.
 - The outbreak of the pandemic has also highlighted how relationship between physicians and society can play a crucial role in protecting public health.

 Relationship of society and patients with healthcare institutions: In the parlance of modern medicine, healthcare institutions such as hospitals, research institutions, pharmaceutical companies etc. are playing a critical role. Their interactions with patients and society can be seen in following areas:

Law and medical ethics

Law in essence is codification of societal ethics. Thus, the relationship between **law and medical ethics** is in **based on the interaction of societal and medical ethics.**

When societal ethics are in consonance with the four primary principles of medical ethics, there is harmony between law and medical ethics. For example, the confidentiality of psychiatric patients in India is protected by the IT Rules 2011 which is in line with the principle of autonomy.

But when societal ethics are at conflict with any of the four primary principles, a conflict between law and medical ethics arises. For instance, under Irish law, abortion used to be illegal, which changed following the outcry over **Death of Savita Halappanavar due to denial of abortion services.** The previous law was against the principles of autonomy as well as beneficence, thus bringing this law in conflict with medical ethics.

- Medical research and innovation: Institutions are the primary source of medical research and innovation. These researches are intended towards benefit of society in general and patients in particular. Therefore, the subjects, methodology and application of medical research are all guided by the four primary principles of medical ethics.
- Enabling the economic cycle of medicine: Healthcare institutions in the form of private hospitals and pharmaceutical companies have been accelerating the economic cycle of 'demand for healthcare-provision of healthcare-availability of medicines'. This has increased access to healthcare especially in the tertiary segment of the system.

WHAT ARE THE ISSUES THAT HAVE ARISEN IN IMPLEMENTATION OF THIS FRAMEWORK?

The issues in medical ethics framework can be broadly divided into patient-centric issues, physician-centric issues and societal-level issues.

• Patient-centric issues:

- Poor communication process: Patients have limited awareness and understanding regarding the medical procedures. On the other hand, physicians have limited time to be able to rectify this informational gap.
 - As a result, a communication gulf gets created between the physician and the patient which results in issues such as unrealistic expectations, anxiety among patient's family and also hinders generation of informed consent.
- Absence of strong data privacy safeguards: There have been several instances where medical data has been illegally accessed and misused. For instance, a report published by Greenbone Sustainable Resilience in 2020, a German cybersecurity firm has revealed that over 120 million Indian patients' medical details have been leaked and made freely available on the Internet.
- Discriminatory access to medical care: The prevalence of discriminatory lines in society i.e., caste, gender, race etc. translates to medical care.

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- For instance, doctors and nurses would refrain from touching a Dalit patient during diagnosis, display indifferent and offensive behavior and interrupt them while speaking. In contrast, non-Dalit patients are treated more cordially and allotted more consultation time.
- Sensitive medical issues are in limbo: Sensitive issues like policy on euthanasia, application of advance directives usage and ethics of In-vitro fertilization (IVF) techniques have not been clearly delineated. For example, the modalities of issuing an advance directive are not yet clear, which limits its usage and its efficacy.
- Medical malpractice: In the recent past, there have been several cases of medical malpractice where the physician actively exploits the patient violating the ethical framework. For instance, prevalence of a physician-pharmacy nexus is widely accepted.
 - This nexus manifests itself in irrational prescriptions of expensive branded drugs and unnecessary prolongment of medical procedures and medicines. This drastically increases the out-of-pocket expenditure for patients.
- Poor affordability and accessibility, especially in a developing country like India: Poor medical infrastructure, shortage of resources and skewed distribution of healthcare institutions hinders access to medical care. This violates the principle of justice i.e., a person's right to medical care. The problem is further compounded by decreased affordability due to rising commercialization of healthcare.

O Physician-centric issues:

- Violence against doctors: Data by Indian Medical Association (IMA) suggests that close to 75% of the doctors have faced some form of violence at the workplace and as a consequence, close to 70% of doctors feel unsafe while treating a patient.
- Poor working conditions of doctors: Physicians are legally forced to work 28-hour shifts and 80-hour work weeks. They suffer extreme sleep deprivation at levels incompatible with life leading to hallucinations, psychosis, seizures and in extreme cases, death.
 - For instance, a study by IMA states that 82.7% of the doctors in India feel stressed out in their profession.
- Health risks to physicians: Physicians are always at a risk for infectious diseases. This gets even more problematic when combined with overwork, poor infrastructure and limited resources. The vulnerabilities of physicians have become glaring as a result of the outbreak of the pandemic.

○ Society-level issues:

- Issues with Medical Education: Medical Education, especially in India is extremely expensive (at both graduation and specialty level). Many times, this drives new entrants towards exploitative and unethical practices such collusion, exploitation of the patient etc.
 - The high cost of medical education also deters physicians from working in non-remunerative areas such as Government hospitals, remote and rural areas, research in areas like public health etc.
- Medical research and innovation issues (refer infographic): In areas such as genetics, neurosciences and organ and tissue transplantation, issues are arising regarding the ethical acceptability of techniques, procedures and treatments. For example, conditions to include a placebo arm in a clinical trial, utility of embryonic stem cells, use of fetal tissue for research purposes and care provided to participants in medical research are not clear.

The forgotten pandemic - Violence against doctors

The pandemic brought the country to a standstill, with doctors assuming the role of frontline warriors. Since the pandemic, doctors have been **working multiple shifts, under the PPE kits** and under the constant threat of the virus.

But the doctors are not only at war with the virus, at times, they have to **protect themselves from patients whom they are trying to protect. The uncertainty, misinformation, anxiety and the pent-up frustration among** patients and their relatives comes out in the form of aggression against doctors.

This **pandemic within a pandemic** needs to be curtailed to protect the medical fraternity and thus the medical system. To protect the medical fraternity, the Government enacted **'The Epidemic Diseases (Amendment) Ordinance, 2020'.** But in the long-term more needs to be done to sensitize patients towards the issues faced by doctors.



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WHAT CAN BE DONE TO OVERCOME THESE ISSUES AND CREATE A MORE BALANCED MEDICAL ETHICS FRAMEWORK?

- Treating ethics as an integral part of medical policy: Inculcating ethics in healthcare policies implies looking at policies not only through the technical system of medicine but also through the values of autonomy, justice, beneficence and non-maleficence. This translates to policy level ideas-
 - Emphasizing on the idea of curative and community medicine: Prioritizing community care and overall well-being would improve the collective care provided to the society.
 - More ethical allocation and distribution of resources in healthcare: The idea of right to equal access to healthcare for all and optimization of health resources could be driving forces for achieving more ethical outcomes.



- Guiding medical research: It is the role of the policy to guide medical research in a direction which is in line with the benefit of humanity in general and the most vulnerable sections in particular.
- Establishing clear communication and consent frameworks: Physicians as well as patients have their limitations in establishing an effective communication channel. To enable the same, following processes and tools can be used-
 - Providing training for a clear communication process: Creation of a process clearly defines the expectations from both sides. One of the most popular communication processes used is 'GATHER' routines.
 - Increasing availability of open information: Increasing transparency and data availability in the healthcare system can help patients make well-informed decisions without engaging the physician.
 - Also, encouraging creation of easy understandable material explaining the medical processes and details can drastically improve patient awareness.

GATHER routine

- **G** Greet the patients
- A Ask about their complaints
- T Tell them about various alternatives available
- H Help the patients in decision making
- E Explain use of intervention
- R Plan patients' return visits
- Creating clear specific consent frameworks: Creating pre-defined consent frameworks for specific processes will deter violation of patient's autonomy on one hand and help physicians navigate through ethical dilemmas on the other.
- Protecting the patients: Various provisions are in place to deter violation of rights of patients. These include sections under the Indian Penal Code, 1860, Health Information Portability and Accountability Act of 1997 (HIPAA) and Guidelines issued by National Medical Commission (NMC). To better enforce these legislations, following steps can be taken-
 - Strengthening the data security framework in healthcare: Clear security checks, especially in the realm of cybersecurity is extremely important for long-term protection of patient's data.
 - Creating strong internal mechanisms to deal with malpractice: Healthcare institutions should be encouraged to create internal mechanisms to monitor and deal with malpractice.
 - Simultaneously, judicial capacities of National Medical Commission can be increased by collaborating with serving/retired Judges. This may help create a well-defined internal judicial process on the lines of 'Vishakha guidelines'.
- Understanding the rights of physicians and duties of patients: The context in which doctors operate has already been highlighted. In the light of this, it becomes important that patients understand their duties and limitations for smooth functioning of the medical system. What should the patients do?



Understanding the medical process and having realistic expectations: Modern medicine is neither cheap nor 100% effective in curing the disease in all cases.Patients need to understand this and act accordingly.

- Civilized resolution of disputes: Disputes between patients and hospitals or doctors cannot to be sorted through violence. Other dispute resolution avenues such as internal dispute redressal mechanism of the institution or judicial process can be pursued.
- Embracing the role of technology, research and innovation: Growth in technologies and research in the form of sophisticated medical devices, using of artificial intelligence for healthcare or data based medical policymaking are drivers of modern medicine. These need to be embraced and regulated rather than opposed. This can be done by-
 - > Encouraging technological penetration in medicine by creating more cross-sectional fields like bioengineering and creating clear and just frameworks for usage of these technologies.
 - > Providing specific research guidelines and creating processes to enforce it: To ensure that participants in the research (including humans and animals) are protected and all proper safeguards are being taken for avoiding any unintended consequences.

Self-regulation

Self-reflection

Transferability O

Continuity

Openness

• Adherence to medical ethics as part of the culture: Generating ethical behavior through rules and regulations has its limitations. To ensure that conduct is always ethical, it has to become a part of the culture of the organization and also the overall medical fraternity. This conduct will translate to all relationships i.e., physician-patient, physician-society and physician-physician.

Inculcation of this culture has to start from educational institutions and has to translate to all healthcare institutions (public as well as private). Creation of such a culture has the potential to transform a physician into a medical expert.



PROFESSIONA

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Transparency

Accountability

Partnership

O Respect

\equiv **CONCLUSION** \equiv

Medical ethics is not a code of conduct or a procedural guide, it is a system based on the interaction of all its stakeholders. Therefore, every stakeholder from physicians to patients to society has to play their role effectively to ensure that the system functions smoothly. This system is subject to changes in technology, techniques, medical procedures and processes. The dynamism of changing medical ethics further demands that the coordination between the stakeholders is robust and continuous. Thus, the energy and efficacy required in the system will have to come from individual commitment to heath in the society.

"Wherever the art of medicine is loved, there is also love for humanity"- Hippocrates.







\equiv TOPIC AT A GLANCE \equiv

Medical Ethics and its importance Medical ethics deals with those ethical principles that govern professional conduct in medicine. Its importance can be seen in following areas-O Bringing standardization and consensus to ethical dilemmas faced by all the stakeholders. It acts as a guide for ethical conduct of physicians based on rationality and medical principles. O It enables placing of Rights of patients at the center of the medical processes. O Indirectly aiding in creation of a compassionate and just society via medical ethics. **Evolution Primary principles** O Hippocratic oath (5th century BC): Doctors swear by Greek gods There are four universally accepted principles of medical and goddesses. ethics-• The Nuremberg Code (1947): Emphasized on rights of patients O Autonomy: Patients have autonomy of thought, intention, through principle of autonomy and justice. and action when making decisions. O Justice: Procedures should uphold the spirit of existing O Declaration of Geneva (1948): Considered as Modern version of laws and be fair to all stakeholders. Hippocratic oath emphasizing on physicians dedication to O Beneficence: It states that the patient's well-being is the humanitarian goals of medicine. ultimate goal of caregiver, whose mission is precisely to O Belmont report (1979): It identifies three basic ethical principles prevent, diagnose and treat illness. i.e., Respect, Beneficence and Justice. O Non-maleficence: It focuses on the idea of not to cause O Medical council of India (MCI) regulations (2002): MCI harm to patients and assess the risk benefit trade-off of any regulations dictates the professional conduct of physicians and treatment. institutions in India. Relationship shaped by these principles Patient-physician Relationship has Society-physician relationship is Society, patient and institution evolved into following frameworkconcerned with following areasrelationship plays its role in following areas-• Respect and equal treatment for all O Beginning-of-life and end-of-life issues patients without discrimination. O Subjects, methodology and which are ethically sensitive in nature. applications of medical research and O Informed consent and clear O Resource allocation and distribution for innovations. communications on every process that the healthcare. patient is going through. • Enabling the economic cycle of O Steps concerning Public Health and medicine by satisfying demand and O Maintaining patient's privacy by protecting Community Health. supply. patient's identifiable information. Issues in implementation of this framework **Patient-centric issues Physician-centric issues** Society-level issues O Poor communication process between patients and • Increasing trends of violence against O Issues in medical education like doctors as highlighted by Indian physicians. high cost, limited importance on ○ Absence of strong data privacy safeguards. Medical Association. medical ethics etc. • Poor working conditions for doctors O Discriminatory access to medical care on the basis of O Medical research and innovation including long shifts, poor caste, gender, race etc. issues concerning ethical infrastructure etc. • Sensitive medical issues such as IVF, application of acceptability of techniques, advance directives are in limbo. • Health risk to physicians which has procedures and treatments.

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 Medical malpractice such as prevalence of physician-pharmacy nexus.
 Poor affordability and accessibility, especially in a developing country like India.
 including long shifts, poor infrastructure etc.
 Health risk to physicians which has been intensified due to the pandemic.
 insues concerning ethical acceptability of techniques, procedures and treatments

Principles to overcome these issues and create a more balanced framework

- **Treating ethics as an integral part of medical policy** by emphasizing on the idea of curative and community medicine, more ethical allocation and distribution of resources in healthcare and breaking the vicious cycle in medical education.
- Establishing clear communication and consent frameworks through training, increasing availability of open information and creating clear consent frameworks.
- Protecting the patients by strengthening enforcement of the relevant regulations and legislations.
- Understanding the rights of physicians and duties of patients through awareness generation and creating zero tolerance for unacceptable or violent behavior.
- Embracing the role of technology, research and innovation in medicine.