Ethics in Surgical Practice and Research

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There are two ethical vantage points for surgeons; one during surgical procedures and another while conducting surgical research. Both have various commonalities and a few differences.

Surgeons should display competence and diligence in their academic and technical activities. They should be trustworthy from a moral and ethical standpoint and skilled in the science and art of surgery. Surgeons must act as ethical models for society, for those surgeons in training, and for their colleagues in the place he/she works. A person can determine what is right or wrong based on the ethical principles that serve as their compass. Surgery requires a unique ethical approach because of its many unique aspects. Surgery involves penetrating the patient's body, which is invasive and unpleasant before recovering. Surgery-related decisions are frequently made in the shadow of ambiguity. Given how quickly the field of surgery, particularly robotic surgery, and other cutting-edge techniques, is developing, the surgeon is being presented with more and more difficult ethical dilemmas.

When treating patients, doctors' primary duty is to prioritise their healthcare needs over all other considerations, both personal and professional. Respect for a person's autonomy, often known as patient autonomy, is one of the cornerstones of the medical ethics. It recognises a person's right to decide what will happen to their own body and to act accordingly. The manifestation of this principle in medical practice is informed consent, which consists of three crucial components: The prerequisites for decision-making (capacity to make decisions and voluntariness), the disclosure of information (relevant facts and recommendations), and the consent (which includes both the patient's actual decision and permission for others to carry out that decision).

There are many ways that one's ability to make decisions can be impaired or diminished. A patient may become handicapped as a result of a physical condition (such as a stroke, dementia, or traumatic brain damage), being young (such as a newborn or preadolescent), or having a severe mental disability.

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When a patient lacks the mental capacity, the decisions are typically made on his behalf by a surrogate decision-maker (someone who is legally permitted to make decisions) or proxy decision-maker (someone who has previously been given the patient's consent to make decisions). The decision of the patient (or other designated individual) may accept or reject the doctor's advice. Refusal has the same significance and weight as consent.[1]

In medical research, ethical issues have been discussed and debated very extensively, however, when it comes to surgical domains and surgeon researchers these are rarely explored. Very little and reliable data is available both nationally and internationally. The important areas for surgeon researchers and scientists are data integrity, conflict of interest, training of junior surgeons, manuscript authorship, and most importantly, use of human bio-specimens including stem cells.[2] Therefore, a very strong and robust ethical review process is required at the institute level which will help the researcher to address ethical issues at the start of the study through its progression and final result evaluation.[3] The ethical review board should draft standard protocols in the form of validated checklists to be submitted along with the initial application. Informed consent is the most important cornerstone before performing any surgical procedure or clinical trial. It should be taken by the primary operating surgeon / researcher but is rarely practised in our setup.

Ethical issues in surgical practice and research in our local context are rarely addressed as per the guidelines. Some areas to be highlighted are the adoption of new procedures and using new instruments without sufficient data in patients with surgical issues. The most worrying concern is the industry-driven adoption of new procedures crafted without much background evidence.[4] The same applies to research in surgical fields where again ethical issues are not addressed formally during various steps of research, particularly data collection and analysis (methodology).

There are four fundamental principles of ethics accepted and practised widely. Respect for autonomy requires that the participant should be given an independent right to self-determination and decision-making. No maleficence requires avoiding any further harm (*primum non nocere*). Beneficence means acting in a way that it is beneficial to the patient with minimal potential risks and harms. Justice mandates that equality is maintained while treating patients/participants and there should be fair distribution of risks and costs.[5] In surgical research, the emphasis is on voluntary participation with informed consent, keeping anonymity and confidentiality.

Miles Little categorises surgical ethics into five principles: Rescue, proximity, ordeal, aftermath, and presence.[6] As a surgeon, deep and close involvement is required in all five areas, and it starts with the first clinical encounter (where a diagnosis is made) to the final outcome of the procedure. A safe and successful result is the goal however, in a situation where complications occur, close proximity and presence should be maintained.

Surgical research should have a social or scientific value, validity, fair participation selection, favourable risk-benefit ratio, independent review, informed consent, and respect for the enrolled participants. All these are some important and critical ethical principles in surgical research.[7] A research proposal should get the approval of an ethical review board with a clear declaration of conflict of interest.[8] Ethical review boards should have independent members who make unbiased decisions without any external influences.

During the actual conduct of study, data falsification and fabrication is an important area to be avoided, plagiarism needs to be clearly checked and rectified. Formal scrutiny and backup records should be available for presentation at different forums. Use of artificial intelligence (AI) should be declared. In all phases, from the conception of an idea, data collection, and analysis to reporting, the utmost responsibility is that of the principal investigator. Timelines should be agreed upon at the very outset of the research proposal implementation.[9]

The qualities of a competent surgeon include reliable clinical skills, appropriate and correct surgical judgement, knowledge of and expertise in the performance of operations, practice of humanism, ethics, and solid moral values. He also understands the value of when not to operate and when to stop.[10] Primary objective is to save a life and achieve a cure.

A recent article from India highlights a very burning issue in this part of the world that is; conflict of interests between the government and medical institutions, between medical institutions and medical personnel, and between physicians and patients.[11] The situation is getting worse and more serious and complex, with courts and media playing their roles. The patient's advocate groups and societies are also intervening and playing their role which sometimes is negative.

In our country, the areas of surgical ethics both in research and practice are unaddressed, but it is encouraging to note that the need to improve and formalise the training of surgeons and physicians in Pakistan with regard to medical and surgical ethics is growing.[12] PMDC (Pakistan Medical and Dental Council) is changing the undergraduate curriculum (MBBS, BDS) and has introduced a complete module of ethics with summative assessment.[13] HEC (Higher Education Commission) and various medical universities have introduced ethical review boards (ERBs) and institutional review boards (IRBs) and mandatory workshops on the said subject as well.[14] CPSP (College of Physicians and Surgeons Pakistan) has included ethical principles as an integral component in its various membership and fellowship programmes.

The context-specific understanding of surgical ethics is imperative for an equitable surgical healthcare system in Pakistan, and such a system can only succeed if all institutes work together with advanced technical competence and implementation. This requires investing time and resources into the teaching of ethics, and the adequate implementation and monitoring of ethical standards and practices are necessary. Who should monitor, is a big question.

Health regulatory authorities that are in place across the country should collaborate with the other regulatory bodies and develop a plan for both ethical surgical practice and research. There should be uniformity with mandatory, essential and quality standards. As international collaboration in research has taken a new shape during and after COVID-19 pandemic, our regulatory bodies should also incorporate international ethical practices in surgical procedures and research.

Kotzee *et al*. very rightly narrated that 'ethics lies at the core of professionalism'. A well-trained and qualified surgeon should not only be competent enough to perform surgery safely as traditionally understood, but also be ethically and morally reliable.[15] The supervisors' role is very crucial in this regard, not only in teaching surgical skills but also in inculcating ethical principles, both in surgical practice and research.

The College of Physicians and Surgeons Pakistan is shifting to writing a research article mandatory to appear in the final fellowship examination. The new change will encourage the administrators and supervisors to develop high-standard fully-equipped research departments with clinical trial units (CTUs) and strong unbiased ERBs in their institutes. JAMA has released 2024 guidelines for surgical research covering all aspects and emphasising the importance of addressing ethical issues related to surgical practice and research is a comprehensive reference document.[16]

COMPETING INTEREST:

The author declared no conflict of interest.

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