**Surgical Innovation and Ethical dilemmas**

Surgery has made massive advances in the last 50 years. Much of this progress however has not been within the context of transparent, robustly planned, conducted and reported research designs. Many characteristics and complexities inherent in surgical innovation have made it more difficult for surgeons than for pharmaceutical innovators to build their research systematically through to a well-conducted definitive randomised controlled trial. In general, the randomized controlled trial (RCT) is considered the most rigorous form of research and strong regulatory & ethical requirements are necessary for the introduction of new drugs and pharmacological agents. In contrast, everyone talks about evidence-based practice in surgery but procedural and technological innovations as well as medical implants in surgery often take place outside controlled study conditions with relatively little oversight and regulation. However, recently there have been concerns and controversies regarding this. It is now recommended that not only new drugs, but also novel surgical interventions should be properly assessed before these are introduced clinically.

**What is Innovation and Research?**

Commission on the Protection of Human Subjects (Belmont Report) defines **research** as “an activity designed to test a hypothesis, permit conclusions to be drawn and thereby develop or contribute to generalizable knowledge. By contrast **practice/ Innovations** refer to “interventions that are designed solely to enhance the well –being of a patient". These two definitions are not mutually exclusive but they provide a context for differentiating between research and innovative therapy/procedures. **Therefore if a new or modified technique is adopted for treating an individual patient considering** **situation is innovation, while planned study for generalizable message is research.**

**There are 4 main basic issues with surgical Innovation are - Oversight, Informed consent, Learning curve, and Vulnerable patient groups[[1]](#endnote-1). Each of these issues is discussed below.**

1. **Oversight**

If one wants to carry out a surgical innovation, the **IDEAL Collaboration** (**I**dea, **D**evelopment, **E**xploration, **A**ssessment and **L**ong Term Monitoring) developed a framework for surgical innovation, describing 5 phases[[2]](#endnote-2). This includes phase 1-4 of development. In the first phase, innovator should inform the hospital when a new procedure is tried in human, but no research ethics approval would be necessary. In next phase, when the procedure is tested in a small group of patients to assess its efficacy, prior ethical approval must be obtained.

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| **IDEAL Framework** | |
| **Idea** | Every innovation must be recorded whether it was planned, accidental or forced. Surgeon must give rationale and concept behind every innovation. Confidential entry may be permitted for failed innovations to encourage good reporting. Hospital or institution must be informed separately as professional duty. |
| **Development** | This stage includes detailed description of selection criteria, technical details of innovation, clear standardized definition of outcomes and all modifications to be recorded. “Tinkering” (rapid iterative modification of technique and indications, Small experience from one centre Focus on technical details and feasibility) |
| **Exploration** | Technique becomes more stable and is now replicated by others. At this stage it is also important to focus on adverse effects and potential benefits. There is need for evaluating and monitoring learning curves and its variability. This may give idea about complex issues and ways of training. Quality parameters are developed by consensus and defined for new procedures at this stage. |
| **Assessment** | At this stage, technique or innovation gets wider acceptance and is considered as possible replacement for existing treatment as well as best practices. If possible randomized control trials are initiated. Using learning curve data, credentialing criteria are prepared. Quality control as well as outcome measures is defined and finalized. |
| **Long term Monitoring** | This stage looks for late and rare problems as well as changes done after its use. There is need for quality monitoring outcomes as well as indications. |

Hospital can have an “Innovation committee” to manage this kind of innovation or hospital IRB can review the same. Innovation committee may include practitioners, potential patients, payers, and institutional representatives. Innovation Committee should plan, evaluate on going activities, assess endpoints and outcomes, report public and review proposed treatments.[[3]](#endnote-3) This committee should study before the start of the new treatment several aspects, including but not limited to the necessity for introduction of a novel intervention, the performed laboratory studies, criteria for patient selection, and management of surgeons’ learning curves.

Degree of oversight depends on the type of surgical innovation. Usually there are 3 types of innovation in literature

1. **Minor modifications** of a standard procedure – May not require oversight; however must be recorded well for further review
2. **Major modifications** of an established technique or radically new innovations: Some form of formal review is necessary. This formal review could be done by the IRB, senior peers or by an external institution.
3. **Innovations that are new to the institution**, but have been validated elsewhere: Consultation with the Head of Surgery (Institution), Peer review or IRB approval.

Oversight should not be only focus on the potential threats to patients, but also on **identification of potential conflicts of interest and costs that needs consideration.**

**Mechanisms for Oversight:**

These mechanisms highlight the ethical balance of patent safety without disturbing innovation.

1. Surgical exceptionalism: It is characterized by regulation of an innovation by the surgeon performing the procedure without formal oversight[[4]](#endnote-4).Features unique to the surgical profession—difficulty in measuring surgical technique, reproducing surgical procedures, and achieving consistency between operators—make oversight impossible. This approach maintains surgeons’ independence, expedites innovation, and mitigates biases held by the surgical profession. This approach presumes rigorous ethical training, which is presently not met by current medical training or continuing medical education.[[5]](#endnote-5)

2. Departmental & Institutional oversight: Discussion with colleagues through informal conversation, approval by the chair, or case conferences provide departmental forms of regulation. Its benefits include that the surgeon knows patient best, multiple opinions are incorporated, professional dignity and autonomy are maintained, Multidisciplinary opinions can be incorporated and the surgeon protected by legal and ethical expertise.

3. Regional oversight: Its benefits are multidisciplinary opinions are incorporated; there is no inter-operator and intra-hospital variability. Its main drawback is its high cost.

1. **Informed consent**

There is special need for information to patients undergoing innovative procedures and should have special informed consent from such procedures. Many surgeons do not inform about newer procedures ~~but~~, some surgeons have come under scanner for blatantly not doing so. This comes in lime light if there are complications and media publicity of the same. Special Information should be provided to patients that includes: the innovative nature of the procedure, the corollary surgeon's learning curve, referring to his/her experience with the procedure, the risks and benefits of the procedure, possible, unforeseeable or unknown risks, or outcomes , current evidence for the procedure, alternatives to the innovative procedure. In India many fear that if we describe this to patients, patients will run away. However today patients are educated and Mr. Google has all information. If later on patient realizes that physician has not informed him/ her that could disturb patient doctor trust and lead to medico legal case. Third party communicator along with multimedia presentations may be used in case of surgeon is primary researcher to avoid conflict of Interest.

1. **Learning curve,**

Most surgeons agree that some form of training for surgeons performing novel procedures is necessary. Surgeons learning curve must be shortened by hands-on training (in animal models or human cadavers or simulators) or visiting different surgeons who are performing the procedure or and the presence of a mentor/ proctor. It is advisable to have team of experienced surgeons to discuss and then perform procedures in initial stages. As a common sense, group wisdom is better than individual. Initial experience must be shared with peers with transparency. Some new procedures (robotic surgery) surgeons need to be trained, credentialed, and monitored.

1. **Vulnerable patient groups**

While conducting Innovative procedures in vulnerable patients such as unconscious patients, patients in emergency situations, disease refractory patients, and children; alternatives must be found for the informed consent procedure. Some authors[[6]](#endnote-6) have suggested, in emergency situations and unconscious patient’s waivers must be obtained from an IRB before using the innovative procedure if possible or in an emergency situation the family or guardian should consent to the procedure. However in India, IRB procedures are long and hence family or guardian option is more feasible. Vulnerable patients, for example, liver failure patients who might easily consent to any alternative, innovative, procedure in face of the approaching end of life, should be well informed and it is suggested that a second opinion of an independent surgeon is also recorded. In some countries innovative procedures in children require informed consent not only from their parents, but also from the patients themselves if they are above 10 years.

Innovations are responsible for most progresses in the field of medicine and this is also true with surgery. Innovative approaches in surgery have significantly improved patient care delivery and patient satisfaction over years; and have led to improved surgical outcomes. While innovation is motivated by the leader’s expectation that the new approach will be beneficial to patients, not all innovations are successful or result in improved care. The ethical dilemma of surgical innovation lies in the uncertainty of whether a particular innovation will prove to be a "good thing." This uncertainty creates challenges for surgeons, residents, and the hospitals. By its very nature, innovation introduces a potential risk to patient care, a risk that may not be fully known, and it simultaneously fosters an optimism bias. Ideally every surgical innovation involving patients must have patient’s informed consent and permission from authority. Innovative procedures and their associated technology raise issues of cost and resource distribution in the contemporary, financially conscious, healthcare environment. Teachers and institutions must identify and address conflicts of interest created by the development and application of an innovation, always preserving the best interest of the patient above the academic scholarship or conferences or workshops or institutional gains. Potential strategies to address the challenges inherent in surgery; innovation include collecting and reporting objective outcomes data, enhancing the informed consent process, and adhering to the principles of disclosure and professionalism. As leaders, one must encourage creativity and innovation while maintaining ethical awareness and responsibility to patients.

The magnitude and urgency of the challenges to be faced in a developing country such as India and the availability of funds and expertise are usually to be found in inverse proportions. Surgical educators, administrators and academic leaders have to function in a situation fraught with the continuing dilemma of the imperatives of change and development on the one hand, and the severe restraints of tradition and shortage of resources, on the other. In spite of this predicament they are racing against time to compete with better surgical provisions elsewhere in the world. The strain is great: a few individuals and organizations perceive the urgency of finding unconventional ways of conducting different aspects of the surgical procedures, but more often than not they are outnumbered by those keen to hold fast to tradition. In the resulting turmoil, though innovations might arise and take shape swiftly, their careful piloting and systematic diffusion present many difficulties. From this standpoint, the struggle which Indian surgeons have waged since the advent of independence appears to have been fairly rewarding.

Each surgical innovation project has not been based on entirely new ideas, but has often consisted of the pragmatic adaptation of an old idea in the light of the current situation.

Most innovations attempted so far in India highlight greater input of human/ technical effort than of finance with strong administrative leadership. Structural changes abound because new programmes cannot be planned and implemented through outmoded systems. However, one must ensure that while introducing newer techniques of surgery, patients consent must be taken along with institutional review board’s permission and implementations should not hamper the surgical outcomes. If two methods are used, patients should get benefit of best system, even if it means additional effort on part of surgeon and system. Ultimate beneficiary of any innovation should be patients!

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**Conflicts of Interest: None to declare**

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