Challenges of Surgical Innovations in India

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Abstract: Newer surgical interventions have been planned and conducted over last few decades, but many of these novel surgical interventions have not been properly assessed before they were introduced clinically. Indian Council for Medical Research, Ethical Guidelines 2017, have specifically mentioned regarding surgical interventions and have emphasized proper ethics committee review, need for animal/modelling data, monitoring during surgical interventional trial as well as provision of compensatory mechanism. Basic issues with surgical innovations (as developed by IDEAL Collaboration framework) such as Oversight, Informed Consent and Vulnerable group of patients have been now well emphasized by Indian Guidelines. Some form of training (Simulations/Animal/ Cadaveric) is necessary for surgeons performing novel procedures. Surgeon's learning curve must be shortened by hands on training on simulated models preferably in presence of a mentor. Medical devices rules 2017 also necessitate use of new medical device only after ethical committee review and other statutory permissions. Surgical innovations must be performed keeping in mind recent guidelines and ethical principles for safety and benefit of patients.[Agrawal P. Natl J Integr Res Med, 2020; 11(1):89-95]

Key Words: Surgical Innovations, New surgical procedures, Ethical guidelines

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Surgery has made significant advances in the last two to three decades. Much of this surgical innovations and progress however has not been within the context of transparent, robustly planned, conducted and reported research designs[1]. 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 (RCT).

In general, the 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[2]. However, recently there have been concerns and controversies regarding this[3]. It is now recommended that not only new drugs, but also novel surgical interventions should be properly assessed before these are introduced clinically.

There is lot to learn from history of surgery, that not all new ideas are good ideas. Internal mammary artery ligation for the treatment of angina[4] and gastric freezing for the treatment of ulcer disease[5] were both innovative approaches that were originally thought to be good for patients. The presumed benefits were purported to be the reduction in subjective symptoms of patients. Unfortunately, many things can influence a patient's subjective assessment of symptoms and overtime, it became clear that internal mammary artery ligation and gastric freezing are not actually effective in reducing these subjective symptoms. Rigorous study to carefully assess these outcomes it was possible to show that these widely accepted surgical procedures were not effective and therefore did not constitute surgical progress.

What is Innovation and Research? Commission on the Protection of Human Subjects (Belmont Report[6]) 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.

ICMR ethical guidelines 2017[7] have given the following guidelines for surgical intervention**:**

1.References must be provided and most likely complications must be included in the protocol to be assessed by Ethics committee (EC) and also a benefit risk assessment should be provided.
2. In trials where a modification of the established surgical intervention is to be tested, the protocol and Informed Consent Document (ICD) must specify the need for this modification and the expected complications, if any. It is preferable that a comparative study be conducted where the conventional method is compared to the test surgical intervention.
3. In trials where an entirely new surgical intervention is being tested, the EC may insist on some animal data/modelling data which establishes the efficacy and safety of the technique or case reports/case series that indicate benefits and describe risks.
4. Provision of free treatment and compensation for any study-related injury must be ensured for the trial participant. The EC must determine the compensation amount after the investigator has described the relatedness.

There are four main basic issues with surgical Innovation - Oversight, Informed consent, Learning curve, and Vulnerable patient groups[8] Each of these issues is discussed below.

Oversight: In the present context oversight[9] implies that if someone has oversight (supervises) of a process or system, they are responsible for making sure that it works efficiently and correctly. If one wants to carry out a surgical innovation, the **IDEAL Collaboration[10,11,12]** (**I**dea, **D**evelopment, **E**xploration, **A**ssessment and **L**ong Term Monitoring), (See Table 1) developed a framework for surgical innovation, describing 5 phases[13]. This includes phase 1-4 of development. In the first phase, innovator should inform the hospital when a new procedure is tried in human with approval of Institutional Review Board (IRB) or EC. In next phase, when the procedure is tested in a small group of patients to assess its efficacy, prior ethical approval must be obtained.

Table 1: IDEAL Framework for Surgical Innovations

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 or EC 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[14]. 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[8].

Minor modifications of a standard procedure – May not require oversight; however must be recorded well for further review

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.

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[15].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[16].

2. Departmental& Institutional oversight: Discussion with colleagues through informal conversation, approval by the chair, or case conferences provides 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.

Indian perspective: India is not new to innovations economic concerns draw much more attention in surgical innovations in India and low cost indigenous products are often used for innovations[17]. However while using such products, although the cost is reduced, some of the ethical issues may be overlooked. Surgical innovations have been used and have benefitted patients but without an ethical approval have faced media attention and penalisation[18].]The Jaipur Foot developed at the SMS Medical College Hospital, Jaipur, in 1968, by a group of eminent orthopaedic surgeons Dr PK Sethi, Dr SC Kasliwal; Dr MP Udawat and a highly innovative craftsman Ram Chandra permits mobility in all planes despite being non-articulated, the dorsiflexion at the ankle, a special feature of the foot, not only addresses the cultural and lifestyle needs of Oriental people but also positively influences the performance of amputees even in Western societies. A biomechanical comparison of the Jaipur Foot with the SACH and Seattle Foot, Jaipur Foot is more natural and closer to the movements of the normal human foot. Owing to its performance, it is the most widely used prosthetic foot in the world.

Chitra Heart Valve Prosthesis[19], based on the tilting disc concept, was conceived in early 1978 as a viable alternative to expensive imported heart valves. Prof. MS Valiathan‟s vision and will, integrated with the dauntless pivotal efforts of a team of technologists, clinicians and scientists for 12 years and four modifications in material to suit and amalgamate the patient's need with available technology, yielded a unique biomedical device of low cost, comprising durable biomaterials. The first valve implantation was carried out on December 6, 1990 at the Institute. In the first mono-centric clinical trial phase, spanning from December 1990 to November 1991 period, 40 valves were implanted in the Institute. Based on the encouraging results from the first phase clinical trials, a multi-centric clinical trial was conducted including five additional centres spread over the country. Based on these data, the Monitoring Committee cleared the valve for commercial production and sale in

February 1995.The recent ICMR guidelines 2017[7], emphasizes ethical review and monitoring of novel surgical interventions as a positive step towards patient safety.

Informed consent[20]: There is special need for information for patients undergoing innovative procedures and there should be a special informed consent process for such procedures. There have been incidences where, surgeons have not informed about newer procedures and have come under scanner for blatantly not doing so[15]. 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 had not informed him/ her, 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.

The ICMR ethical guidelines 2017[7], mention that an informed consent document should explain to the patient, the benefits of the research to the participant and the community. It also mentions that the document should include freedom of the individual to participate or withdraw from research at any time without penalty or loss of benefits to which the participant may be entitled.

In India, the problem is more pertinent as patients are illiterate & poor as well as have blind faith in doctors. At times, this makes the informed consent process suboptimal, weak and its concept can be abused[21].

Learning curve[22]: Some form of training Simulations[23] or Animals[24] or Cadaver[25] is necessary for surgeons performing novel procedures. 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. In India, over last two decades, animal laws have been enforced to ensure the anti-cruelty provisions and promote the cause of animal welfare[26, 27].It is advisable to have team of experienced surgeons to discuss and then perform procedures in initial stages. Asa 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[28].

Vulnerable patient groups: Indian Council of Medical Research Guidelines[7] define “vulnerable population for research” as individuals who are Socially, economically or politically disadvantaged incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently(For e.g.unconscious individuals) able to give consent but whose voluntary abilities are temporarily compromised unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

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[19].Others[29] 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. In India, Indian Council for Medical Research (ICMR) has published guidelines for ethical research and mention obtaining valid informed consent in human emergencies. ICMR Guidelines state “Obtaining valid informed consent in humanitarian emergencies is a challenge as the decisional capacity of the participants would be so low that they may not be able to differentiate between reliefs offered and research components. This should be very clearly distinguished during the informed consent process.”

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 from parents, and assent from the patient themselves if they are above 10 years[30]. Indian ICMR guidelines[7] now clearly define need for consent and assent. There is no need to document assent for children below 7 years of age. For children between 7 and12 years, verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded. For children between 12 and 18 years, written assent must be obtained. This assent form also has to be signed by the parents/LAR.

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. ICMR guidelines[7] also mention that any participant should not be charged for any new device or trial. This is necessary in resource poor country like ours where there could be conflict of interest.

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 program scan not 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. In addition, in India, Ministry of Health and Family Welfare has recently published Medical Devices Rules, 2017[31] that have stated rules for grouping, accreditation and using various medical devices and has also developed national accreditation body. The Medical Devices Act of 2017 by Ministry of Health and Family Welfare defines "active therapeutic medical device" as any active medical device used, whether alone or in combination with any other medical device, to support, modify, replace or

restore biological functions or structures, with a view to the treatment or alleviation of any illness, injury or handicap". It also states medical device shall be initiated only after approval has been obtained from the Ethics Committee(s), registered under rule 122DD of Drugs and Cosmetics Rules, 1945, and permission granted by Central Licensing Authority. (Stated from Medical Device rules 2017[31]. This will definitely standardize use of medical devices and ensure safe use of new devices. If two methods are available for treatment or two devices are available, patients should get benefit of best system, even if it means additional effort on part of surgeon and system. Innovative solution to contemporary problems in surgery is the way ahead. Though these innovations will be greatest challenge to professional ethics of surgeon they ought to be guided by standard guidelines as ultimate beneficiary of any innovation should be patients!

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