Ethical Implications of Advanced Technologies in Surgical Care

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Alberto R. Ferreres

"That any sane nation, having observed that you could provide for the supply of bread by giving bakers a pecuniary interest in baking for you, should go on to give a surgeon a pecuniary interest in cutting off your leg, is enough to make one despair of political humanity … It is simply unscientific to allege or believe that doctors do not under existing circumstances perform unnecessary operations and manufacture and prolong lucrative illnesses."

GB Shaw
The Doctor's Dilemma: The Preface on Doctors
1911

Introduction and Framing the Issue

Without the contribution of innovative surgery to Medicine, there would not be organ transplantation, stapled gastrointestinal anastomosis, hip replacement, or substitute heart valves. Minimal invasive (laparoscopic, NOTES, single site and its variants) and robotic surgery belongs to this category and has revolutionized the treatment and approach of surgical conditions since the 1990s. Nonetheless surgical innovation also generates substantial ethical concerns with respect to surgeon's training, patient harm, patient autonomy and decision making, fair distribution of health resources, and conflicts of interest [1]. In that sense, the rate of biliary duct injuries was fairly increased after the wide adoption of standard 4-port laparoscopic cholecystectomy and similar data has been reported with single incision laparoscopic cholecystectomy [2, 3].

What is the meaning of advanced and novel technologies?

The Oxford Dictionary defines novel as "interestingly new or unusual," and innovation is a broad term defined as "the act of introducing something new or the use of a new idea or method." Surgical innovation includes a wide array of the necessary variations for usual practice and surgical research and development of new surgical procedures or improvement of existing ones. All definitions of innovation involve both ideas and an act of use or practice. New and innovative techniques have one thing in common: they are intended to lead to the renewal, refinement or betterment of the surgical technique offered for the treatment of human diseases.

Innovation in the surgical field tends to be more a process than an event, for example laparoscopic cholecystectomy, which was a huge innovation from 1990 on, should now be considered a standard procedure due to its rate of adoption. Other procedures cannot be termed exactly in the same way, and due to that fact, remain as innovative for longer periods and may never acquire the status of standard procedures.

A.R. Ferreres, MD, PhD, JD, MPH, FACS (Hon.) (✉)
Department of Surgery, Hospital Dr. Carlos A. Bocalandro, University of Buenos Aires, Vicente Lopez 1831 PB, Buenos Aires 1128, Argentina
e-mail: albertoferreres@gmail.com

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Ideally all surgical interventions should be controlled. When real hazard is involved in a new and unproven procedure, it may be urgent to determine the value of such intervention [4].

Due to its development and lack of wide acceptance, NOTES surgery may still be considered an innovation, though this approach may generate some discussion. Many times an early precursor does not gain wide acceptance and a couple of years later the same procedure presented by another physician gains widespread attention. For example Ortega proposed endoscopic myotomy for achalasia [5], which was very soon abandoned for the risks and 30 years later Inoue, amid the fashion of NOTES procedures, achieved POEM (Per Oral Endoscopic Myotomy) with worldwide impact [6].

The history of natural orifice surgery can be traced to three early developers such as N. Senn [7], Dimitri Oskarovich Von Ott [8], and Raoul Palmer [9].

Gynecologists were proficient in the culdoscopic approach and that may be the reason why Daniel Tsin performed the first transvaginal cholecystectomy and reported the case in 2003 [10], 4 years earlier than Zorron [11], Bessler [12], Marescaux [13], and Ramos [14].

The same can be said of single incision laparoscopic surgery, having reported Pelosi, the first single incision appendectomy years ago [15], and Navarra and Wg, the first single incision laparoscopic cholecystectomy [16, 17].

These procedures were not widely accepted. But after the first NOTES cases were reported and made clear the difficulties and necessary skills requested by this approach (flexible endoscopy, gynecologic approach, gastric closure), a bridge was inclined from NOTES to SILS, with the support of the industry.

Robotic surgery represents another field of innovation: this technology enables a surgeon to perform a procedure using laparoscopic instruments attached to robotic arms, which he or she manipulates from a console while viewing the cavity in three dimensions, very similar as if it were open surgery. First approved by the FDA in 2000, this approach was used in about 292,000 cases in 2011 and in about 367,000 the following year. The procedures performed with robotic technology include predominantly gynecologic, urologic and abdominal operations. Though this sounds like a wonderful addition to the surgeons' armamentarium, recent reports have raised concern regarding issues of safety, cost-effectiveness, and advertising by physicians and institutions [18]. Wu mentions "…The results show how direct-to-consumer marketing can lead to the explosion of an expensive new treatment—even when little evidence exists to support the therapy's superiority over standard care" [19]. More recently, a group from Johns Hopkins Institutions reported 245 adverse events due to the use of robotic surgery [20].

Nonetheless, in order to judge accordingly and to increase patients' knowledge and awareness, good science is mandatory for good ethics and may be considered a prerequisite. Which is the correct and adequate knowledge? From an epistemological point of view, three concepts must be considered: belief, truth, and justification. Belief is an individual faith and conviction regarding the truth of a proposition; truth is considered to be the reality and includes the meaning of veracity, and justification explains the basis or motives for believing [21].

Background

The Surgical Procedure and the Surgeon–Patient Relationship

Surgery has five unique characteristics that set it apart from any other kind of medical specialty:

1. Surgery harms before it heals.
2. It penetrates the patient's body and thus is highly invasive. According to the judgment of Judge Benjamin Cardozo in "Schloendorff v. Society of New York Hospitals" (1914): "A surgeon who performs an operation without patient's consent commits an assault."
3. It is fallible, which means that surgery is predisposed to human error. Increased awareness on this topic has developed since the Institute of Medicine's "To Err is Human" was published.

4. Surgeon's decision-making is performed under circumstances of uncertainty.
5. It is prone to risks and complications.

On the other hand, the surgeon–patient relationship is built around trust, so it is preferable to speak about fiduciarism and not about a contract. As John Gregory stated in the eighteenth century, the physician:

- Must be in a position to know reliably the patient's interest
- Should be concerned primarily with protecting and promoting the interests of the patient
- Should be concerned only secondarily with protecting and promoting his own interests

The concept of acting as a moral fiduciary of the patient is central to the core of surgical ethics. Being a fiduciary is legally understood to be "a person holding the character of a trustee, in respect of the trust and confidence involved in it and scrupulous good faith and candor which it requires" and also to be a "person having duty, created by his undertaking, to act primarily for another's benefit in matters connected with such undertaking."

The surgeon–patient relationship is attained and perfected throughout the process of the surgical informed process which includes the following elements:

1. Preconditions: competence and voluntariness of the patient
2. Information: disclosure and recommendations by the surgeon, and understanding by the patient
3. Consent: decision-making (acceptance or refusal), communication, registration, and authorization to proceed from the patient

Ethical Principles and Considerations

The principles of biomedical ethics as collated by Beauchamp and Childress and addressed by the Belmont Report (April 1979) have become one of the most widely used frameworks for considering bioethical issues. They are: respect for patient autonomy, beneficence, non-maleficence, and justice [22].

No concept overrides the other; there is no preeminence among them and all stand alike. Besides the four classical ethical principles, truthfulness, fairness, integrity, dignity and respect to people's rights, and honesty virtue should be added.

Respect for Patient Autonomy

The concept of autonomy examines individuals' decision-making in health care and research, as patients and as subjects in the surgical care process. In a properly structured theory, respect for autonomy is not excessively individualistic (thereby neglecting the social nature of individuals and the impact of individual choices and actions on others), not excessively focused on reason (thereby neglecting the emotions), and not unduly legalistic (thereby highlighting human rights and downplaying social practices and responsibilities).

The word autonomy is derived from the Greek "autos" (self) and "nomos" (rule, governance, law) and originally refers to the self-rule or self-governance of independent city states in Greece.

There are two conditions essential for autonomy: freedom (independence from external controlling influences) and agency (capacity for intentional action). Autonomous choice has to be obtained from the patient. The moral requirements of respect for autonomy include autonomous action in terms of normal choosers who act intentionally, with understanding and without controlling influences that determine their action.

The theories of two philosophers have powerfully influenced contemporary interpretations of respect for autonomy: Immanuel Kant and John Stuart Mill. Kant argued that respect for autonomy flows from the recognition that all persons have unconditional worth, each having the capacity to determine his or her own moral destiny. Mill concerned himself primarily with the individuality of autonomous agents, arguing that society should permit individuals to develop according to their own convictions, as long as they do not interfere with a like expression of freedom by others or unjustifiably harm others.

Kant's position entails a moral imperative of respectful treatment of persons as an end of itself.

The basic paradigm of autonomy in health care is represented by the informed consent process and entails a competent judgment. The conditions of a competent judgment must satisfy the standards for its determination in order to be valid.

Beneficence

Beneficence stands for acts of mercy, kindness, and charity and refers to the character trait or virtue of being disposed to act for the benefit of other persons. As opposed to utility, positive beneficence requires agents to provide benefit to others and is more an ideal than an obligation; according to the Good Samaritan's parable we cannot demand acts to exceed ordinary morality.

The principle of positive beneficence supports an array of moral rules of duty or obligations:

1. Protect and defend the rights of others
2. Prevent harm from occurring to others
3. Remove conditions that will cause harm to others
4. Help persons with disabilities
5. Rescue persons in danger

The rules of beneficence, in contrast to those of non-maleficence, include:

1. Positive requirements of action.
2. Need not always be followed impartially ("impartial adherence"). We are morally prohibited from causing harm to anyone. However, we are morally permitted to help or benefit those with whom we have special relationships, and we often are not required to help or benefit those with whom we have no such special relationships.
3. Generally do not provide reasons for legal punishment when agents fail to abide by them.

Physician obligations to patients represent philanthropic service, whereas obligations to their teachers represent debts incurred in the course of becoming physicians. However, today many physicians and health care professionals owe a large debt to society (for education and privileges) and to their patients, past and present (for research and practice). Because of this indebtedness the medical profession role of beneficent care of patients is misconstrued if modeled primarily on philanthropy, altruism, and personal commitment. This care is rooted in the reciprocity of giving after having received.

Non-maleficence

This principle imposes an obligation not to inflict harm on others. It is closely related to the aphorism "Primum non nocere." Often considered the fundamental principle in the Hippocratic tradition of medical ethics, it does not appear in the Hippocratic Corpus exception made of the translation of a single passage: "at least do no harm." Nonetheless the Hippocratic Oath expresses obligations of non-maleficence and of beneficence: "I will use treatment to help the sick according to my ability and judgment, but I will never use it to injure or wrong them."

The most important rule of this principle consists in not to inflict evil or harm; that means that this principle requires only intentionally refraining from actions that cause harm. When we refer to harm, we focus on physical harm, especially pain, suffering, disability, death, or loss of chance (survival) as well as mental harm. We can summarize as intending, causing, or permitting death or the risk of death.

The rules of non-maleficence are:

1. Negative prohibitions of actions
2. Must be followed impartially
3. Provide moral background for legal prohibitions of certain forms of conduct

The obligation of non-maleficence includes not only the duty not to inflict harm but also the duty not to impose risks of harm. In cases of risk imposition, both Law and Moral recognize a standard of due care that determines whether the agent who is causally responsible for the risk is legally or morally liable as well. This standard is a specification of the principle of non-maleficence.

On the other hand, negligence is the absence of due care, it involves a departure from the

professional standards that determine due care in given circumstances. The term negligence covers two types of situations:

– Intentionally imposing unreasonable risks of harm (advertent negligence or recklessness)
– Unintentionally but carelessly imposing risks of harm (inadvertent negligence)

Justice

The concept of justice dates back to Aristotle, who conceptualized justice as "the rendering to each individual of what is due to him or her." Justice is interpreted as the fair, equitable and appropriate treatment of what is due or owed to persons. More recent influences in biomedical ethics originate from John Rawls' "A theory of justice," in which he argues that a social arrangement forming a political state is a communal effort to advance the good of all in society. Representing an egalitarian point of view, Rawls attempts to solve the problem of distributive justice (the socially just distribution of goods in a society) by using a variation of the familiar device of the "social contract." The resultant theory is known as "justice as fairness", from which the author derives his two principles of justice: the liberty principle and the difference principle.

In health care, justice primarily refers to the distribution of scarce resources in a fair way from a communitarian point of view, but includes the obligation to respect the patients' rights and morally acceptable laws from the patient's individual point of view. Hume considered that justice was a social virtue while benevolence was a principle of human nature.

The four ethical principles embrace more specific rules applicable to surgical care and innovative practice, providing a framework to consider systematically the ethics of surgical practice. In that sense the principles typology of surgical ethical issues includes the following:

- Respect for autonomy: surgical informed consent, truth telling, confidentiality, communication skills.
- Beneficence: surgical competence, sound judgment, continuing medical education, accountability, communication skills.
- Non Maleficence: surgical competence, sound judgment, recognizing one's limitations, disclosure and discussion of complications and surgical errors.
- Justice: allocation of scarce resources, legal issues, human rights.

Nonetheless, Sir David Ross (1877–1971) was the first one to achieve the prima facie ethical duties, originally in the number of five: fidelity, reparation, gratitude, promotion of a maximum of aggregate good and non maleficence [23]. Not all these duties bear the same importance. In his argumentation, the duty of non-maleficence overcomes the one to promote a maximum of aggregate good and the duties of fidelity, reparation, and gratitude are more preeminent than the one to promote the good. The four elements that are basically good include: virtue, knowledge, pleasure, and justice. He taught that moral decision-making sometimes requires us to think about the past and act according a sense of duty rather than focusing on the projected outcome, following the Kantian "moral imperative." His Duties-based (deontological) Ethics served as a foundation for the work of Beauchamp and Childress.

Ethical Considerations

The advancing technology and knowledge provide greater opportunities to save lives and relieve pain and suffering.

Many of the operations that are currently in use have never been formally tested by any rigorous scientific trial. They have been introduced into clinical practice as so many other procedures before them: as innovative therapies. As such, they were simply implemented without safeguards to protect patients. This has been, and largely still is, accepted, everyday surgical practice. Less high profile innovative surgeries, however, escape added scrutiny and eventually find their way into standard clinical care.

Some authors consider three minimal requirements that make a surgical innovation ethical: laboratory background, field strength and institutional stability, others include a fourth requirement,

institutional review board (IRB) evaluation [24, 25]. Surgical innovation is an important driver of improvements in technique and technology, which ultimately translates into improvements in patients' outcomes. Nevertheless, patients may face new risks of morbidity and mortality when surgical innovation is used, and well-intentioned surgical "experimentation" on patients must be regulated and monitored. Besides, surgical innovation is not always a synonym of surgical evolution; patient safety must be the overriding ethical consideration.

Surgeons' responsibilities to individuals and to the society to which they belong cannot be disregarded in any sense. J.E. Dunphy stated them very clearly in his 1963 American College of Surgeons Presidential Address about "Responsibility and authority in American Surgery": "Surgeons have a collective responsibility to seek the benefit of humanity … the autonomy of the individual surgeon is only possible because society is in agreement with surgeons that they will act to benefit humanity and surgeons must have some form of central authority to ensure that certain standards of professionalism are met."

Some of the questions that need to be answered concerning the ethics of these new techniques include the following:

- Is this an experimental procedure?
- Is this frontline surgery?
- Who can perform this surgery?
- Requirements and training.

Probably we can consider NOTES as a combination of different approaches into a new one; more than a new surgical procedure of experimental nature, in the transvaginal approach we can find old historical landmarks of culdoscopic surgery, mostly in hands of gynecologists. Single site laparoscopy represents, on the other hand, a closer placement of the entry sites more than a radical new approach. Robotic surgery raises similar concerns, particularly regarding high cost, making it unavailable to many patients worldwide, cost/effectiveness, and the achievement of real benefits for the patient.

These procedures are not for every surgeon, not for every patient and not to be performed anywhere, but some talented surgeons should provide these approaches, under rigorous scrutiny and supervision and with a huge concern for patient safety.

Whenever a new technique is introduced, ideally a group of experts should encourage the critical evaluation giving answer to these crucial questions:

- Feasibility of the new procedure or technique, regarding its widespread acceptance, rate of adoption and efficacy for the condition to treat.
- Safety of the procedure, analyzing how easily this technique can be learned by the average surgeon, if there is an increased risk of complications and the requirements for training and education in this field.
- Clinical advantages, defining the real (and not the potential) benefits either to the patient or the health care system.

The four ethical challenges generated by innovative surgery can be grouped in the following categories:

1. Harm or disability to patients: Surgical innovative procedures have the ability to generate increased morbimortality in comparison to standard and/or conventional procedures. This is true and specially evident in the early stages of development, since the learning curve or curve of expertise needs a minimum number of cases to be attained. So the question posed is the following: How can the most obvious source of patient harm be minimized?
2. Compromise and threats to the surgical informed consent process: This addresses the concern regarding patient autonomy and the risk that patient freedom to decide may be compromised in different ways: Information may not be fully disclosed regarding the nature and type of the procedure, data about risks and dangers may be withhold to prevent patient's refusal to the procedure. An interesting point in informed consent for new proce-

dures is the general tendency among the public to equate newness with increased benefit or better quality. The role of IRB in supporting this process, as well as that of colleagues and faculty would sort any inconvenient in this sense.

3. Distribution of health-care resources: Innovative surgery presents—many times and particularly in developing countries—a challenge to the fair distribution of health-care resources. Common sense indicates limiting expenditure to interventions with proven safety and efficacy rather than "wasting" money on ineffective and/or unsafe and/or dangerous procedures. A fair distribution of resources revolves around notions of: liberty, associated with autonomy and the authority of individuals and institutions; equality, considered as the equity of surgical care and fraternity, targeted as the solidarity of the surgical profession within society.
4. Conflicts of interest: The last challenge is represented by the conflicts of interest, which may affect the individual surgeon, a faculty group, and sometimes their institutions. The most obvious is the economic one, usually associate with the willingness to attract more patients, to be considered a pioneer and its inherent prestige and with the development and use of new devices, provided by the manufacturing biomedical companies. This and other conflicts of interests can directly impact sound and appropriate decision making.

Some suggestions to aid in solving the abovementioned issues include:

- Regulation by government agencies, in a similar way as in the pharmaceutical industry
- Control by scientific societies, which usually turns to be late and outdated
- Self-regulation by chairs, faculty, and colleagues
- Participation of the IRB or institutional Ethics Committee
- Mandatory collection in databases which allow a precise and prompt understanding of the innovation, facts and figures about outcomes, safety, and efficacy
- The implementation of randomized clinical trials, more challenging to run in surgery but not impossible

The Balliol Collaboration's IDEAL (innovation, development, exploration, assessment, and long-term study) model addresses some of the discussed topics and provides tools for the "surgical innovation ethics paradigm" [26]. It attempts to identify and describe stages of surgical innovation providing a basis for recommendations about regulation and assessment. They firmly propose the development of databases, which will provide the necessary collection of evidence:

- Innovation: the primary aims of this stage include safety and proof of the pursued concept. In this stage, the surgeons should inform hospitals and IRBs of their intention to perform innovative procedures.
- Development: regulation and evidence from well designed studies should be a requisite. Steps to be complied before patient recruitment include: mandatory monitoring, reporting of patient selection, detailed description of the procedure and modifications and outcomes of all cases.
- Early dispersion and exploration: with increasing adoption of the procedure, mentoring and learning assessment are pillars as is the collection of data for every patient.
- Assessment: the effectiveness of the innovation should be tested against current standards, including efficiency (economic assessment).
- Long term study: a registry should be established to monitor outcomes that are rare and those that only become apparent over time.

Conclusions

In conclusion, strict adherence to the following principles of the American College of Surgeons (The American College of Surgeons Statement of Principles, revised September 21, 2006) will provide a safe frame for innovation in surgical practice:

- *Performance of surgical procedures by those who are not properly trained to perform them should not be a frequent or continuing practice.*
- *Fellows are strongly encouraged to be actively involved as leaders of quality assessment and improvement activities in their own hospital.*
- *Acquisition of skills in new procedures should be fostered by attendance at courses with both didactic and hands-on sessions. The fellow should seek appropriate proctoring of cases as new procedures are added to his or her surgical portfolio. Continuous self- appraisal of surgical outcomes is strongly encouraged with the goal of improving patient outcomes.*

Besides, the Committee on Emerging Surgical Technologies of the American College of Surgeons published the following statement [27], which summarizes all the abovementioned issues:

"New surgical technologies are the combined product of basic and applied surgical research. The introduction and application of any new technology should proceed through a series of steps intended to ensure its safety, appropriateness, and cost-effectiveness.

1. The development of a new technology must be accompanied by a scientific assessment of safety, efficacy and need.
2. Diffusion into clinical practice requires appropriate education of surgeons and evaluation of their use of new technology. An in-depth knowledge of the relevant disease process and its management, gained through formal training and clinical experience, is a prerequisite. Acquisition of new technical skills and the development of appropriate support facilities must follow, and must be subject to initial assessment and periodic monitoring of outcomes.
3. Widespread application of new technologies must be continuously assessed and compared with alternative therapies to ensure appropriateness and cost-effectiveness through outcome studies."

Summary

This chapter surveys the foundations of the surgeon–patient relationship and the ethical principles of surgical care, providing a frame for those interested in achieving changes and/or innovations in surgical procedure. An analysis of the issues related to surgical innovation is also included as well as problem solving tools.

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