Chapter 10
Ethical Challenges in High-Risk Innovative Surgery

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Abstract The fields of surgery and anesthesia have storied histories with advances in care fueled by innovation by creative individuals striving to improve the care of their patients. Ethical dilemmas arise when contemplating how to allow innovation to continue for the benefit of future patients while mitigating harm to current patients. In this chapter, we explore ethical issues in high-risk innovative surgery from the perspectives of the key stakeholders: the surgeon, the patient, the anesthesiologist, the medical device industry, and other members of the healthcare team.

Keywords Innovation • Informed Consent • Medical Devices • High-Risk Surgery • Surgical Ethics

Case Presentation
After taking courses and workshops to learn an innovative surgical technique, a surgeon spends some time working at an outside institution with the innovator of this new surgical technique that is claimed to improve clinical outcomes for patients. The surgeon believes it to be better than the conventional

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technique although the risks are possibly slightly higher. The new procedure requires the anesthesiologist to insert a central line and infuse a new medication that may have severe complications. In addition, potential complications for the procedure require both ICU management and emergency intervention by interventional radiology. When the surgeon returns to his institution, he sees that the institution has advertised that this new surgical technique is now available and will be performed by him. One week later, he sees a patient in his clinic. The patient is requesting that the surgeon perform the innovative surgical technique to address the patient's problem. The patient asks the following: What are the risks and benefits of the procedure compared to the traditional technique? What is your experience with this technique? How many patients have you operated on using this innovative technique? While the surgeon looks forward to performing the innovative technique he just learned, what should he tell the patient? Additionally, how important is it for the surgeon to involve the anesthesiologist and other healthcare team members in the early discussions with the patient of this potentially risky and innovative approach?

Introduction

The fields of surgery and anesthesia have storied histories with advances in care fueled by innovation by creative individuals striving to take better care of their patients. Advances in surgical technique have led to surgeries considered commonplace today that would have been deemed impossible in the past. For instance, in the nineteenth and early twentieth century, it was considered taboo to even consider operating on the heart, and those that dared to do so were often met with disapproval, and often justifiably so. Of 10 reported cases of surgery attempted for mitral stenosis between 1923 and 1928, eight patients died. Of the two surviving patients, only one benefitted from the surgery [1]. Over two decades later, in 1948, Charles Bailey, having experimented with mitral valve operations on dogs, attempted mitral valve surgery on patients at different hospitals in Philadelphia [2]. His first success came on his fifth patient, after four mortalities, for which he received the nickname the "butcher of Hahnemann Hospital." Bailey's first success came while operating on a patient in the afternoon following the death of his fourth patient in the morning at a different hospital. Recounting those events, Bailey noted, "We…promptly drove to Episcopal Hospital to commence the other operation before the morning's news could be effective in possibly having the Episcopal Hospital administration forbid us from doing the procedure" [3]. This is one of many stories of surgical innovation that provokes numerous ethical questions.

Thousands of patients annually now benefit from mitral valve surgery pioneered in part by surgeons like Dr. Bailey. Regardless, this achievement does not justify the loss of life of the patients Dr. Bailey treated before his surgical technique was

successful. While informed consent, as we currently use the term, was not commonplace at that time, it would be interesting to know what information was shared with the patients and their families prior to their surgery. Were these procedures approved by the hospitals? Were the procedures and their implications discussed with the other physicians and healthcare providers involved in the care of these patients? Many of these issues have been addressed to different degrees since the time of Dr. Bailey's first operations for mitral valve stenosis.

In the United States, patients must now give informed consent before undergoing any procedure, for instance. Yet, other questions remain largely unanswered with ongoing ethical challenges. The care of patients undergoing innovative surgical procedures requires more than the skills of the surgeon alone. Anesthesiologists must provide safe anesthesia for the surgical procedure and care for the patient in the postoperative setting, including sometimes in an intensive care setting. Nurses and other healthcare providers also care for the patient throughout this process. There are no set rules or any guidance on how a surgeon might engage these other crucial members of the surgical (and medical) team in carrying out an innovative surgical procedure. Furthermore, unlike pharmaceutical drugs or medical devices, which are regulated by the Food and Drug Administration, the introduction of new surgical techniques requires no formal oversight. Surgeons must self-regulate the introduction of new surgical techniques. In some instances, surgeons may develop a new procedure as part of a protocol overseen by an Institutional Review Board, but not always [4]. The ethical dilemma lies in determining how to allow surgical innovation to continue for the benefit of future patients while mitigating harm to patients and engaging all parties involved in the process of surgical innovation. This complex undertaking may be approached by considering ethical issues from the perspectives of the key stakeholders in the process of surgical innovation: the surgeon, the patient and the public, the anesthesiologist, the medical device industry, and other members of the healthcare team.

The Surgeon

To a great extent, the history of surgery is a story of iterative improvement of established procedures punctuated by the introduction of radical departures from past techniques. A surgeon has significant creative leeway in the operating room in developing innovative procedures. In fact, although surgical techniques are described in textbooks and journal articles, there is no single mandatory method of completing any particular surgery. Moreover, unlike innovation in the development of new pharmaceuticals, there is no governing body that regulates the creation of new surgical techniques [5]. Surgeons have the right, and perhaps even a duty, to alter surgical techniques or develop new surgical techniques for the benefit of their patients. However, in developing innovations, surgeons face ethical challenges as new techniques will create new complications and alter the incidence of known complications. Hence, how can a surgeon disclose the risks of an operation when they are

unknown? Without external oversight, the patient must depend on the surgeon's self-regulation to assess the effectiveness of the technique and to protect patients from harm. Other ethical concerns of innovative surgical procedures include the appropriateness of healthcare resource utilization to implement the new surgical technique, and also the identification and disclosure of potential conflicts of interest that may arise as surgeons are often the creators and promoters of new surgical techniques.

Any new technique in surgery has the potential to either help or harm a patient. One of the key ethical tenets of patient care is "nonmaleficence", which is based on the maxim Primum non nocere: "Above all [or first] do no harm" [6]. New techniques developed by surgeons have the potential to cause significant patient harm as illustrated by a number of historical cases. Consider, for example, the idea of ligation of the internal mammary artery for the treatment of angina. Angina was thought to be caused by decreased blood flow to the coronary arteries that perfuse the heart muscle itself. The new innovative approach to treating this problem was based on the idea that ligation of the internal mammary artery could potentially increase perfusion to the coronary artery. Surgeons, many at large academic centers, started offering this surgery to large numbers of patients. Thousands of patients underwent this invasive surgical procedure and developed complications from the surgery, including infection and postoperative arrhythmias. Unfortunately, these risks were not associated with any benefit. Cobb and colleagues ultimately showed that internal mammary artery ligation was not an effective way to treat angina [7].

Evaluating risk and disclosing it to the patient in reference to an innovative surgical procedure creates a complex informed consent process. The paradox of informed consent in innovative surgery lies in the fact that many risks of a new surgical technique cannot be known at the outset. Risks of new procedures can only be estimated. Such risks are much more difficult to disclose to the patient. Furthermore, even when a procedure is well documented in the literature, a surgeon may not know what the exact risks of the procedure will be in his or her hands. The period of time during which a surgeon adopts a new surgical technique is sometimes referred to as the "learning curve." During this variable time period, as multiple studies have shown, complication rates generally improve as surgeons gain more experience with the procedure [8, 9]. It is the surgeon's duty, then, to disclose his or her own experience to patients undergoing a new procedure and technique. It is equally important that the surgeon discloses to the patient the lack of long-term outcome data for an innovative procedure. This lack of outcome data makes the balancing of risks and benefits particularly challenging to the patient. Only by disclosing what is known along with the uncertainties of the new procedure can the surgeon respect the autonomy of the patient to the fullest extent possible in these challenging situations.

Another ethical implication of innovative surgical procedures includes the disclosure of potential conflicts of interest. There is a natural conflict of interest that arises when surgeons develop new innovative surgical techniques. As the innovator, the surgeon may have an emotional investment as well as a significant investment of time in the success of the procedure. The surgeon might also benefit from the

procedure economically and by gaining prestige. For these reasons, the surgeon may also feel pressure from his or her institution to have the procedure succeed. This conflict of interest can potentially bias results tracked for the procedure by the surgeon or the hospital. These concerns suggest the importance of an objective third party oversight of innovative procedures, which can be obtained by an institutional review board (IRB). The IRB must approve the protocol and the consent form, and oversee any adverse events associated with a research protocol. Although IRB oversight can be helpful in protecting research subjects and in reducing bias in evaluating an innovative procedure, this type of oversight is only present when innovative techniques are evaluated in formal research protocols. Frequently, the assessment of the new innovation remains the responsibility of the surgeon.

Innovation takes many forms. Sometimes it involves coming up with a truly novel procedure, whereas other times it involves doing a procedure that is novel to a hospital or region. In the latter situation, it is particularly important that surgeons keep track of patient outcomes and compare them with outcomes in areas where there is an established history of completing the procedure to assure there are no significant increases in the rate of complications. It is important to note that obtaining and evaluating outcome data in routine clinical practice is far more difficult than generally appreciated. For example, at the Bristol Royal Infirmary, between 1988 and 1995, pediatric cardiac surgeons continued to perform heart surgery on children despite a mortality rate of 55%, which was much higher than the national average at that time [10]. Interestingly, these patients were not undergoing innovative procedures. Although ultimately this problem was recognized and managed, it serves as an example of how challenging outcome data evaluation for innovative surgery might be.

Although the costs of health care in the American healthcare system were previously largely ignored, in recent decades increasing attention has been directed towards the value of healthcare resource expenditures and utilization. Accordingly, surgeons must now consider the costs associated with innovative surgical procedures. Surgeons have the obligation to balance the costs associated with new techniques against the healthcare resources that could otherwise benefit patients in some other manner. However, the cost to the healthcare system should be considered in the context of the potential benefit of the procedure in the long-term and not just short-term increased health resource utilization, which tends to occur early in the adoption of innovative surgical techniques. For example, after laparoscopic cholecystectomy was introduced in the 1980s, it quickly became one of the most popular operations performed in the United States. Although laparoscopic cholecystectomy eventually led to improved postoperative recovery and reduced pain, early studies revealed increased complication rates including longer operative times and higher rates of common bile duct injuries. Had the assessment of the procedure been completed early in the experience of many surgeons, the increased healthcare expenditures and increased risks in the short term may have led to abandonment of the technique [5, 11]. Had such an early assessment been undertaken, we would likely not have developed the wide range of laparoscopic techniques now benefiting thousands of patients every year.

Surgeons must contemplate and navigate through a wide variety of ethical challenges in developing and implementing innovative surgical procedures. Whether the innovative procedure is novel or novel to the surgeon or region, surgeons have an obligation to address key ethical issues to adequately inform and protect their patient, minimize their own bias, and optimize utilization of limited healthcare resources.

The Patient

Prior to the Belmont report, physicians were free to perform experiments on patients without their explicit informed consent. Additionally, there was no consensus about what constituted an acceptable explanation of a proposed treatment for a patient. For many decades, paternalism ruled, and patients surrendered themselves to the care of their physicians with little knowledge of the risks of the treatments. In this context, iterative improvements in treatment were not considered innovation, and new procedures that, in principle, had significant therapeutic promise were not regarded as experimental but rather as straightforward improvements. The distinction between these is not a bright line, but a gray area. Exactly how much innovation constitutes experimentation remains undefined, with the opinions of practitioners and ethicists varying enormously. Regardless, optimism about the benefits of innovative procedures has shaped the consent conversations of patients since obtaining consent became an expectation.

Arguably the most important stakeholder in surgical innovation is the patient and the public on which the new innovation will be used. A number of external and internal forces must be considered in addressing the ethical issues of surgical innovation from a patient's perspective. Although patients look to physicians for counsel and guidance in making medical decisions, medical marketing also plays an important role in shaping patient desires. A phenomenon exists in American medicine in which what is 'new' is also considered 'improved' by patients, often regardless of the evidence that exists to support such a claim. Patients are also frequently enticed by hospitals with the latest technology. What may be potentially misleading to patients is that while progress in the field of medicine is often aggressively marketed, different aspects of medical innovation have different methods of regulation and approval that may not be clearly evident to the patient or public. For example, the Food and Drug Administration (FDA) has significant oversight over the development and approval of new drugs, a completely separate and different process than for the approval of new medical devices, and no formal regulation of new surgical procedures [12]. It is plausible that patients may think that the stringent criteria applied to the approval of new drugs also apply to medical devices or surgical techniques. Take for example the rapid adoption of robotic-assisted surgery throughout the United States. Despite a relative paucity in evidence in support of improved outcomes using robot-assisted surgery, it has been heavily marketed by a number of hospitals nationwide. A recent study by Dixon and colleagues showed that patients

were more likely to choose a robot-assisted procedure when it was described as "state-of-the-art" or "innovative" instead of a procedure with uncertain evidence in the current literature [13]. In the modern era of "direct-to-consumer marketing", such treatment seeking by patients is evidence of the success of such marketing and of benefit to those who engage in it.

The process of informed consent requires the surgeon to explain the proposed procedure, including its risks, benefits, and alternatives to the patient or the patient's surrogate decision maker. This process is already difficult when surgeons are trying to explain complex but well-established procedures. However, when informed consent is sought for an innovative procedure, patients are forced to weigh the known risks of the established procedure (with more thorough evidence supporting its use) against the uncertain risks and benefits of the innovative procedure. A major challenge the patient faces in the informed consent process is attempting to understand the disease process they have and the procedure that is being done to address it. Studies about informed consent for surgical procedures often reveal that patients do not adequately understand the information provided about the procedure or the risks associated with their surgery [14]. The consent process for an innovative procedure adds an additional layer of complexity, as it requires the surgeon to explain both the proposed procedure and its alternative, and to elucidate the uncertain risks and benefits of each.

The main source of information about an innovative surgical procedure beyond medical marketing the patients are exposed to is the surgeon who will be operating on the patient. As previously discussed, surgeons have an inherent conflict of interest in this relationship with their patient. In fact, the surgeon will potentially benefit from the risk the patient may undertake. Therefore, there is an incentive for the surgeon to undersell the risk during the informed consent process. In describing the informed consent process for high-risk surgeries, Schwarze and colleagues described the concept of surgical 'buy-in', a process in which patients enter a contractual relationship when they consent for surgery and are expected by their surgeon to also commit to the necessary postoperative care, which can involve significant complications [15]. Similarly, when patients are involved in innovative surgical procedures, they may be expected by their surgeon to commit to postoperative care and potential complications, even when postoperative complications may not be well-known. Patients may additionally feel that they are an important part of the process of surgical innovation and, as such, patients may mistakenly feel a duty to help advance the field for surgery for the general public. Conversely, in choosing the conventional approach instead of the innovative procedure, patients might mistakenly believe that they are not doing their part to advance medicine and may feel that they are disappointing their surgeon. Ultimately, patients trust that their surgeons will do everything within their power to produce the best possible outcome.

In the process of surgical innovation, the patient and public have the burden of trying to understand and make decisions about complex procedures that they may not fully understand, and that may or may not benefit them. At the same time, patients may not appreciate that the incentive for surgeons may be to promote the innovative procedure rather than give priority to patient understanding and

outcomes. Surgeons have a great deal of influence on medical decisions made by patients. It is the ethical duty of the surgeons to inform patients of the risks and benefits of an innovative procedure to the best of their ability while minimizing the surgeons' own bias towards the procedure, even when this practice might not be the most beneficial to the surgeons.

The Healthcare Team

A surgeon performing an innovative procedure may require the cooperation of other members of the healthcare team to change their practice in important ways that may not have been disclosed to the patient. Such perturbations may be minor, such as requiring an operating room technician to learn how to operate new equipment and change their workflow. Yet, both of these actions of the technician have their own learning curve and may impact patient outcomes and safety. In other instances, a surgeon might involve another practitioner, such as the anesthesiologist, to participate in procedures involving patient care and outcomes that the anesthesiologist might find troubling. Moreover, cases involving bad outcomes or demonstrating significant gaps between the procedure as explained to the patient and the procedure as performed by the surgeon can compel other healthcare providers to take extreme measures. These healthcare team members might call the attention of leadership or authorities, which can in turn provoke years of tension and strife. For example, many years ago, pediatric anesthesiologists in Winnipeg, Manitoba reported to their clinical and hospital leadership a series of bad outcomes from a new surgeon [16]. The result was an inquiry of findings, significant institutional conflict, and compromised careers [16].

With innovative surgery, these tensions exist in a context in which the risks are ill-defined, and some of the complications have not been anticipated. In general, surgeons who participate in innovation should preemptively engage everyone on their care team to understand the implications of the proposed innovation, and ensure that all team members are comfortable with the responsibilities and actions that may fall upon them.

The Medical Device Industry

Throughout surgical history, innovation has been closely linked with the use of novel surgical instruments and devices in addition to novel surgical techniques.

Medical devices such as cardiac defibrillators can be enormously beneficial and even lifesaving for patients. However, they can also cause harm. Unlike surgical techniques, medical devices must undergo an FDA approval process to be cleared for use in patients. However, the process by which medical devices are approved in the United States is very different from the standard set for pharmaceuticals. While

clinical trials are required for drugs, medical devices have different approval paths based on the risk to the patient and this varies from a tongue depressor (FDA Class I) or surgical mesh (FDA Class II), to cardiac defibrillators (FDA Class III). A Class III device is "one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury" [17]. It has recently been suggested that due to its purpose as addressing physician error resulting in significant morbidity and mortality, electronic medical records and health information technology should be considered a Class III device [18]. Class II devices must meet the less stringent criteria of being "significantly equivalent" to an already existing product that has been approved by the FDA through an application process called the 510(k) [17]. The process is purposely permissive to encourage innovation, although it can also leave patients vulnerable to potential harm. One cautionary tale comes from the use of surgical mesh, a FDA Class II device, in the treatment of pelvic organ prolapse. The FDA cleared the ProteGen Sling from Boston Scientific, as "substantially equivalent" to other similar devices on the market without human testing via the 510(k) process. Adopted by numerous gynecologists nationwide, the sling was used in thousands of patients. The ProteGen Sling was soon found to cause significant complications such as erosions, bleeding ulcers, and infections. However, the product was not removed from the market until reports of the complications surfaced in peer-reviewed medical journals that raised concerns about safety. The product was eventually removed from the market after 2 years of use with hundreds of complications surfacing after the product was recalled [19].

This episode illustrates the enormous challenge of recognizing problematic outcomes with established medical devices, especially when complications are rare or not anticipated. In most instances, medical devices provide significant benefits to patients. Regulation that hinders innovation through overly strict standards may ultimately do more harm than good. Medical devices have been and will be an important component of surgical innovation. Regulation of medical devices should ideally find that balance that promotes innovation and improved outcomes in a responsible manner while maintaining patient safety as its highest priority.

Discussion

The many stakeholders involved in the development and implementation of new innovations in surgery interact with each other in a complex network that may involve a variety of ethical challenges. At the center of this interaction are the patient and the public who can benefit from, or be harmed by, the new surgical innovation. The surgeon plays a critical role in both the process of developing the surgical innovation to advance the field of surgery and in that of self-regulation. At the same time, the surgeon must properly inform the patient of the risks, benefits, and alternatives of the procedure and prevent harm to the patient. Anesthesiologists and other members of the healthcare team play an important role in the process of surgical

innovation. The details of any new innovation should be fully disclosed preemptively to team members so they are informed about and approve of their role in the process. Medical devices also play an important role in advancing surgical innovation and a balance must be struck between promotion and regulation of these devices to maximize patient benefit while minimizing potential harm. Policies and regulation in surgical innovation should incentivize the different stakeholders to focus foremost on the well-being of the patient.

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