EDITORIAL

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Ethics and surgical innovation as moral strangers

Science moves faster than ethics, and consequently the agility of biomedical research and surgical innovation far outstrips the pace of research ethics, even though both fields are increasingly active and productive. When one considers surgery, the improvement in patients' care is even more evident. Characteristic of the history of surgical innovation has been the lack of oversight over the creativity of surgeons to innovate. By contrast with new drugs, which are approved by regulatory agencies only after careful clinical trials, a new surgical technique needs no such approval. As a result of this lack of oversight, surgeons have been given the opportunity to exercise as much creativity as they wish when in the operating room. This situation has led to a series of ethical issues that warrant careful consideration for how future innovation should occur in surgery.

There are several reasons why a reflection on this mismatch is necessary and urgent. First, the soaring costs of research are straining the economy, requiring priorities to be set, value considerations to be analyzed, and some investigations to be curbed. Secondly, both biology and medicine are evolving at a pace that may transform mankind's reality. And thirdly, citizens and communities are faced with alternative technical options where value estimates are of essence (*Nunes et al. 2011; Howe 2019*).

Surgeons deal with the ethical, moral, legal, and compassionate practice of medicine. The principles are not always what we think of as being intuitively correct, and we are further challenged not to impose our own values on those of our patients who may come from moral and ethical value systems very different from our own. In recent decades, although we can technically and scientifically do more for our patients than ever before, our personal, trusting relationships with them have deteriorated to the point where they are sometimes adversarial. We have allowed medicine to become a business, guided in many cases by the financial bottom line rather than by an uncompromising concern for a sick person. Within this now fast-moving corporate system, we see too many patients, do too much surgery, and do not have time to develop a close mentoring relationship with our chosen role models or with our trainees. The cherished patient-physician relationship has been undermined by our own successful advances (*Platz and Hyman 2013*).

As surgeons in this era of exciting scientific and technologic advances that is complicated by the demands of limited financial resources, limited time, and the constraints of managed care and extensive bureaucracy, we are forced to deliver our care and compassion to patients and their families in a manner and timeframe many of us never contemplated when we entered medicine. Surgeons, unlike many members of the health care team, take on a different level of responsibility as they encounter patients. The surgeon and the surgical team take on the continued responsibility of the operative procedure itself, the postoperative care, and usually the long-term results and management of any complications. This intense relationship is often established very quickly and under frequently adverse circumstances. The family and religious beliefs may not be known, and the patient may be unconscious, and certainly will be once the procedure starts (*Angelos 2016*). Despite these difficulties, surgeons cannot abandon the needs of their patients and their families. To help them make informed choices, we must communicate completely and compassionately the requisite information about their disease, treatment options, and long-range plans. To do so, we must learn and apply the ethical principle of truth telling and the doctrine of informed consent for the effective care that has taken us so long to master (*Kottow 2009*).

In recent years, a number of innovative surgical procedures have been proposed that have little if any impact on morbidity and mortality, but instead are primarily focused on changing the cosmetic outcomes for patients. For example, minimally invasive surgery or robotics. In fact, whereas surgeons could traditionally assess the success of a

surgical innovation by objectively measuring certain specified outcome measures, many of the newer techniques are only potentially beneficial to patients if the patients place a significant value on the cosmetic change of the innovation. In this context, we are seeing a significant shift away from surgeon-defined benefit to patient-defined benefit (*Ergina et al. 2009*). As such, given the challenge of even determining whether an innovative approach is beneficial relative to a specific patient's values, in the current era of assessing surgical innovation, we must develop increasingly sensitive assessments of patient's subjective outcomes.

One of the central ethical challenges to the performance of innovative surgical procedures is how informed consent can be effectively obtained from patients (*Angelos 2010*). In order to obtain valid informed consent from a patient prior to surgery, the patient must have the capacity to make a decision regarding his or her best interests. The patient must be offered the opportunity to be informed of the risks, benefits, and alternatives of the procedure so that a decision can be made. As is readily apparent, if a patient is being offered an innovative surgical procedure, the surgeon may not know what the risks actually are. As such, the disclosure of unknown risks is impossible. In this circumstance, the best that can be done is for the surgeon to explain the limits of knowledge about the new procedure and the uncertainty about what the risks of the novel procedure actually are. Although it is possible to explain the lack of knowledge about the risks and for the patient to consent to a procedure with unknown risks, such disclosure of unknown risks is very challenging both for surgeons to explain and for patients to understand (*Bal and Choma 2012*). For example, despite the large numbers of minimally invasive aortic valve replacements performed, individual surgeons failed to acknowledge the increased risks of perivalvular prostheses leaks or massive hemorrhage.

Even if one could get past the uncertainty about the risks of innovative surgical procedures, another central ethical issue is the problem that the learning curve arises. The "learning curve" refers to the increased risks to patients during the time that a surgeon and surgical team need to become comfortable with a new procedure (*Johnson and Rogers 2012*). This means that the surgeon gets better with experience. When surgeons are using new techniques, the problem of the learning curve becomes particularly acute. How can we ensure that patients' safety is maintained while the surgeon gains the necessary experience in the new procedure? Many different approaches have been taken to solving the problem of the learning curve. For example, surgeons often begin by learning new techniques on inanimate models, animal models, and human cadavers before ever using the technique on a patient. In addition, when the first patients are being operated upon with the new technique, an experienced proctor is ideally present to improve the patient's safety (*Good et al. 2015*).

New procedures are often dependent on new technology that is almost always more expensive than what was used with the conventional operation. This additional cost may have implications for the availability of the innovative surgical procedure to the wider population. Depending on the health system, the additional costs might make the new procedure only available to those affluent enough to pay for it or the additional costs may be spread across the entire health system and take resources from other conventional therapies that might have proven benefit. Although what is costly is inherently neither good nor bad, we must clearly assess the cost implications of embarking on innovative procedures (*Howe 2019*).

Whether innovative surgery is dependent on new technology or not, there is another significant cost that must be considered - namely, operative time. The new procedure almost always takes longer than the conventional procedure. Since operating room time is an expensive and limited commodity, there are significant costs when a surgeon decides to offer an innovative procedure that may take twice as long in the operating room. How such increased costs should be weighed against the potential benefits to the individual patient is a complex determination (*Angelos 2013*).

Additionally, whenever discussing surgical innovation, we must not ignore the significant potential for conflicts of interest for the surgical innovators in their relationships with the companies that manufacture the technology that makes the innovation possible. The history of innovation in surgery has numerous examples of how the relationships between surgeons and industry have led to significant patient benefit. Without the input of surgeons, companies often would lack the knowledge of where to focus attention in developing new products. Unfortunately, there are also many examples of surgeons profiting greatly from using certain products. Whenever individual surgeon decision making for a patient is influenced by the potential to make large sums of money, there is the potential for significant abuse (*Parreco et al. 2017*).

At last, learning the ethical aspects of delivering patient care must become an integral part of surgical training programs, and we must be held accountable for mastering the skillful application of bioethical principles. After all, the concept of good clinical medicine and surgery implies the best use of scientific, technical, and ethical considerations. Just as with medicine and science, bioethics and legal underpinnings of bioethical decision-making are evolving all the time.

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