Review Article

Ethical considerations when implementing new technology into the operating room

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Abstract: The development of new technology is imperative for the advancement of surgery, yet there are multiple ethical considerations that must be made when introducing new technology to the operating room. In this paper, we discuss several specific challenges facing surgeon-innovators, as well as other parties including patients, at every stage of the implementation process. Early in the development of a new technology, one of these ethical dilemmas is a challenge to the informed consent process due to an inherent appeal to novelty for both surgeons and their patients. Early stages of development may be plagued by conflicts of interest between stakeholders as well. Beyond conflicts of interest with hospital systems, industry, and patients, surgeon-innovators must consider potential internal conflicts based on their multiple professional roles as well. Following the initial implementation of a new technology, persistent ethical issues include the ambiguous transition from innovation to accepted practice and the lack of clear responsibility for long-term training and oversight. For these long-term issues, there is a clear need for formalized curricula and oversight bodies to ensure the safe dissemination of new technologies. To promote the safe and timely introduction of new technologies, each of these concerns must be taken into consideration throughout the development process for new surgical technologies.

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Introduction

Technological advances have been central to improvement in surgical outcomes. More so than physicians in other specialties, surgeons are often required or expected to innovate and adjust their technique in order to improve outcomes (1,2). While the development of new techniques and technologies is critical for the broad advancement of surgery as a field, the individuals involved in innovation face multiple ethical challenges.

Innovation in surgery exists on a spectrum, ranging from minor intra-operative adjustments to completely new devices and technologies. The most subtle of these innovations are small adjustments made by individual surgeons in response to intra-operative challenges or emergent scenarios. These minor modifications, as well as more significant changes to procedures that fall short of introducing new technologies, are often not subject to strict scrutiny or a standardized review process. Multiple frameworks have been developed for the assessment of innovations in surgery, including the IDEAL framework, but these are only used sparingly (3,4). Considering that there is no broad consensus for what constitutes an innovation, it is not surprising that these minor changes in surgical techniques have been difficult to

regulate (5).

Truly novel technologies are more easily recognizable and are required to go through a more rigorous process for approval. As discussed in guidelines from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), the term "new technology" generally indicates the introduction of new devices or instruments rather than new procedures (6). To ensure patient safety, these new devices are subject to approval by the Food and Drug Administration (FDA) before they can be widely implemented. Even this process has limitations, however, and several ethical considerations must be regularly considered throughout development and implementation. In this paper we will outline four ethical concerns central to the development of new technologies: challenges to informed consent due to the appeal to novelty, conflicts of interest, the transition from innovation to accepted practice, and the challenge of long-term oversight.

Informed consent and the appeal to novelty

The appeal to novelty (*argumentum ad novitatem*) is a well-known fallacy, stating that something new must be better or improved from the status quo. This logical pitfall can affect any industry, but may be particularly prevalent with the introduction of new medical treatments (7). Both surgeons and patients are susceptible to this fallacy, and it can have significant implications for the informed consent process.

Most surgical advances build upon prior accepted standards of care. Given that a reasonable or proven approach already exists in most cases of innovation, the development of new technology must be rooted in the belief that it can improve outcomes. This belief by the surgeon is natural yet it may lead to an overconfidence in the new technology that is not yet supported by data. Rogers and Johnson discussed this tendency in a 2013 paper on countering bias in informed consent, commenting that the surgeon's optimism regarding a new treatment can lead to a "bias blind spot" (8). This blind spot, borne out of the appeal to novelty, may affect how a surgeon presents information when obtaining consent. Beyond potentially overestimating the benefits of a new technology, surgeons presenting an innovative treatment risk discounting more evidence-based standards of care. Any biased delivery of information on the part of the surgeon, conscious or not, comes into direct conflict with the principle of patient autonomy. This is even more problematic as patients will likely assume a surgeon is experienced in the use of any intra-operative technology unless they are explicitly told otherwise (1). To obtain truly informed consent, surgeons must consciously combat the appeal to novelty and their inherent biases when delivering information about new technologies.

In addition to their own potential biases, surgeons must consider how the appeal to novelty can influence patient decision-making in the consent process. Patients are in a vulnerable position before surgery, and this may make them even more susceptible to the appeal to novelty. Even if surgeons provide the appropriate information about an innovative technology there is a risk that patients will overvalue new approaches. This is particularly concerning with the newest technologies since the risks cannot be accurately known or discussed for something that is truly novel. In the absence of known risks, patients may specifically seek novel procedures and even pressure surgeons to perform them (5). Acknowledging this tendency and taking measures to reduce its impact are essential steps in upholding the integrity of the informed consent process.

Conflicts of interest

The introduction of a new technology into the operating room involves multiple stakeholders including the patient, the surgeon, the broader healthcare system, and medical industry. Implicitly, all parties share the same primary goal to improve outcomes either on an individual or population level. For the patient this is personal, but each other party is primarily motivated at least abstractly by the principle of beneficence. Without the central objective of improving patient care, there would be no impetus for innovation.

Conflicts can arise between stakeholders as secondary goals develop and clash with the primary interest of patient care (8). Occasionally, conflicts can occur internally for specific parties. These conflicts are most acute for the surgeon-innovator who must balance the roles of physician and researcher. The role of innovator comes with multiple secondary objectives related to both career advancement and financial benefit. Pioneering surgeons, if successful, are well-regarded and may assume an elevated social status among other surgeons. This type of prestige is enjoyed by innovators in other industries as well, but for surgeons this temptation can conflict with the foremost goal of patient care. Surgeons who introduce new technologies may also stand to gain financially from their work, either directly through industry relationships or indirectly through career promotion. These rewards for guiding successful innovation

can be substantial and may bias a surgeon towards the new technology. This potential bias must be consciously addressed during both the informed consent process and the long-term evaluation of the new technology.

The broader healthcare system supporting the use of new technologies faces a separate set of potential conflicts that are largely oriented around fair resource allocation. Hospitals and other healthcare organizations have finite resources that must be employed strategically to provide the most benefit to the largest number of patients. With respect to new innovations, this presents several challenges. Healthcare systems have an interest in limiting the financial costs of innovation, particularly early in development when a new technology has not yet proven to be beneficial. While this is prudent, it can create an obstacle to early innovation. Funding from device companies in early research can ease this financial pressure, but this support introduces further potential conflict due to the companies' profit motive. If technologies do succeed then these roles evolve; industry representatives develop an interest in recouping the costs of development and rewarding shareholders by maximizing profits, while hospitals conversely seek sustainable and equitable use of the new technology. This relationship remains complex at every stage. Above all, however, the hospital or healthcare system must maintain the primary goal of beneficence (i.e., benefiting the patient) throughout this process. Commitment to this fiduciary responsibility to patients ensures safety and helps to build trust with the surrounding community.

Transition to accepted practice

For every new technology there is a latent period between its introduction to the operating room and the point when its use becomes accepted practice. The appropriate timing of this transition is both difficult to determine and variable based on the individual surgeon and practice setting. In a broad sense, there are ethical risks to both early and late adoption of a new technology (9). If the technology grows in popularity before there are adequate data to support its ubiquitous use, then patients may be burdened with undue risk. Conversely, if the widespread adoption of a new technology is delayed, many patients may lose access to treatments that would benefit them. While the FDA is responsible for device approval, it lacks clear guidelines on how to safely but efficiently implement new technologies after approval (10).

To illustrate the difficulty in timing the implementation of new technologies, consider laparoscopic gastric banding in bariatric surgery. Adjustable gastric banding was first described in 1993 and, following clinical trials by trained surgeons, the LAP-BAND Adjustable Gastric Banding System was first approved by the FDA in 2001 (11). By 2008, laparoscopic adjustable gastric banding had become the most common weight-loss operation performed in the world, representing 42.3% of all weight-loss procedures globally and a similar proportion in the United States (12). While this gap of almost 20 years between the first description of the gastric banding and the peak of its use does not seem rushed, there were multiple risks that only became apparent after it had dramatically risen in popularity. Band erosion, slippage with gastric prolapse, port site infections, and device malfunctions were all major complications that were found to occur at unacceptably high rates. Patients undergoing adjustable banding experienced major morbidities and re-operation at significantly higher rates than comparable procedures such as Roux-en-Y gastric bypass or laparoscopic sleeve gastrectomy; compounding this increased risk, patients undergoing banding also experienced relatively less weight loss (13,14). In response to these findings, adjustable gastric banding has steadily decreased in volume; by 2020 it counted for less than 2% of all bariatric procedures in the United States (15).

Given the risks of adjustable banding and its limited efficacy relative to other options, it is no longer a standard operation at most medical centers. Due to its rapid implementation in the 2000's however, gastric banding has been slow to regress completely. Many surgeons learned in their training that this was an accepted practice, and a certain number continue to perform gastric banding. In a 2016 survey on innovation in bariatric surgery, 8% of surgeons stated that they would still consider adjustable banding to be a standard of care to examine new technologies against (16). This is certainly a lower percentage than it would have been a decade earlier, but the fact that 8% of the surveyed surgeons continue to consider banding a gold standard clearly demonstrates how firmly ingrained a technology can become even when outcomes do not justify its broad use. Once surgeons have been taught that a new technology is a standard treatment, it is difficult to unlearn that training.

Based on the principle of non-maleficence, surgeons have an obligation to avoid such technologies that definitively increase risk for patients. Determining when exactly the evidence against a technology is definitive, however, remains unclear. It is well-known that there is a learning curve for

the use of new technologies in the operating room for surgeons at all levels of training. As such, some skepticism is warranted when analyzing early results from a new technology. Surgical innovations and procedures develop in response to these initial experiences, and one may expect an improvement in outcomes as pioneering surgeons gain experience (5). Performing clinical trials too early for a new technology risks overemphasizing these cases on the learning curve, yet performing them too late risks costly delays in access. The correct time to formally study a new technology remains ambiguous.

When a new technology ultimately does demonstrate benefit and transition to accepted practice, there is a duty to also acknowledge degrees of novelty. The use of a technology can be completely novel, novel for an institution, or simply novel to the surgeon. The latter two scenarios present an ethical obstacle; if a new technology can be used safely at a high-volume center by a surgeon who has progressed beyond the initial learning curve, why should patients have to seek higher-risk care from inexperienced surgeons? This is an unavoidable dilemma as every high-volume surgeon begins, at some point, as a low-volume surgeon. To combat this challenge, surgeons must make every effort to mitigate risk. Effective strategies may include use of cadaver labs to practice techniques, observation of experienced teams at other centers, or in-person mentoring for a surgeon's initial cases (17). If these reasonable measures are taken and the surgeon's experience is disclosed to the patient, then the use of novel technologies at new centers can remain ethically sound.

Long-term oversight

New technologies undergo a period of regulatory scrutiny during the FDA approval process, but several ethical concerns exist regarding the long-term monitoring of use and outcomes. The FDA approval process requires an average of 3–7 years before a new device is approved, with three classes of medical devices defining the likely regulatory pathway. New devices are, by default, class III devices subject to the most extensive approval process (18). Following approval of a device, hospitals and physicians are required to submit post-marketing reports for adverse events or potential harm; while this system can help identify the most harmful devices, these sporadic reports do not shed light on more nuanced outcomes. Even devices that receive pre-market approval or humanitarian exception approval contingent on the future completion of clinical trials often do not report patient-specific outcomes outside of these adverse event reports. In one recent study, only 13% of these expedited devices had reported outcomes by 3–5 years post-approval (19). There is a clear ethical duty to patients to continue evaluation of new technologies as they spread to new centers, and more ambitious processes are likely required to meet this goal.

The principal issue with standardizing post-approval device monitoring is the lack of a defined oversight body. The task of collecting and analyzing specific long-term outcomes with new technologies is labor-intensive and, as of yet, not clearly within the domain of any specific oversight group. There is similarly a lack of broad, consistent standards for introducing approved technologies to new centers or training surgeons to use new technologies. Several survey studies demonstrate that surgeons recognize the need for improved implementation processes, yet solutions to this issue remain elusive (6,16,20).

Multiple proposals have been made by different surgical societies to add structure to the implementation process, though few have been realized. A leading example would be the technology and value assessment committee (TAVAC) created by SAGES that has created formal assessments of new technologies since 2013 (6). This positive step is not reflected in many other subs-specialties, however, and broader solutions are required. In a position paper from the Society of University Surgeons (SUS), Biffl *et al.* proposed the creation of a standardized review process for surgical innovations, overseen by institutional or local Surgical Innovation Committees (21). These bodies would be similar to Institutional Review Boards with a specific focus on innovation and new technologies. Similar "innovation committees" have been proposed elsewhere as well, though there are discrepancies about the potential roles of these bodies (17). The SUS group also proposed a national registry of surgical innovations to aid dissemination and potential avoid redundant, parallel innovations. These ideas are achievable and would place an emphasis on self-governance by surgeons and professional societies as opposed to increased governmental oversight.

If these measures were implemented, there would still be the challenge of standardizing training for new technologies. In the above section we discuss potential ideas for training new surgeons including cadaveric labs and mentored initial cases, however these place the onus on individual surgeons to ensure their own training is adequate. Ideally, there would be standardized training protocols in which surgeons could demonstrate proficiency

to both patients and colleagues. SAGES is again at the forefront with this issue as shown by the Fundamental of Laparoscopic Surgery curriculum that most residents are now required to complete (10). Similar programs for new technologies would add needed structure as surgeons become familiar with new devices. These courses may be particularly valuable as ongoing education for surgeons who are several years removed from residency and do not have built-in access to the newest technologies.

Lastly, any potential oversight body should consider formalizing review processes for novel uses of previously approved technologies. Once a technology is approved, surgeons are given wide latitude to use it how they see fit in the operating room. Minor modifications and adjustments that do not clearly harm patients are likely not studied. Even significant changes to procedures may be undertaken without formal approval. Take, for example, laparoscopic inguinal hernia surgery. Once the laparoscope was an accepted and standard surgical instrument, it became critical in the development of multiple new innovative procedures including the transabdominal peritoneal patch plasty (TAPP), total extraperitoneal patch plasty (TEP) and intraperitoneal onlay mesh (IPOM) repairs. Each of these is a distinct approach to inguinal hernia repair, yet unlike the individual devices used such as the laparoscope or mesh, the procedures themselves would not have required a formal approval process. Similar innovations can be seen in the rise of robotic surgery as the volume of robotic procedures has risen exponentially since the DaVinci system was first approved in 2000 (22). As before, new applications of an available technology receive significantly less oversight than the initial approval process. Institutional bodies such as the surgical innovation committees mentioned above could provide value by formally monitoring these modifications to existing technologies and procedures.

Conclusions

The ethical considerations discussed in this paper present significant obstacles to surgical innovation. Conscious and deliberate efforts to mitigate their impact are needed by all parties involved in surgical care. Multiple potential solutions have been suggested in previous literature, as noted in a recent review by Broekman *et al.* (17). The challenges to informed consent and the influence of conflicts of interest may be addressed through improved transparency in the informed consent process; this may be achieved through patient advocate consultations, inclusion of neutral third parties for consent when the surgeon is an active researcher, and standardized multimedia presentations to consistently describe risks. Each of these measures is feasible if surgeons and individual institutions have the collective will to implement them. Ethical challenges in the transition to accepted practice and long-term monitoring will likely require solutions at a more macroscopic level. Training may be improved with formalized curricula, potentially including simulation courses, cadaveric or animal labs, observation at experienced centers, and in-person mentoring for initial cases. Lastly, oversight of new technologies would benefit from organized innovation committees or nationally organized data collection.

Ultimately, it will be necessary to define who is responsible for long-term oversight and monitoring to widely implement any of these measures. Addressing these concerns at every stage of innovation will help ensure safety and ultimately build trust between patients and the surgical community. Innovation will continue to be an essential part of surgery, and as new technologies supplant old ones there is an ethical expectation that surgeons will incorporate them into their practice. By considering the ethics of innovation, surgeons can pursue the use of new technologies in a safe and responsible manner.

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