The Ethics of Introducing New Surgical Technology Into Clinical Practice
The Importance of the Patient-Surgeon Relationship

Much has been written in recent years about the ethical challenges of surgical innovation. In contrast to the US Food and Drug Administration’s oversight of new drugs and surgical devices, there is no oversight of new surgical techniques. The creativity needed for surgeons to solve their patients’ problems in novel ways is not only allowed but expected in the operating room. However, even though novel technology requires more oversight than does a new technique, there is still a critical role for the surgeon’s judgment in the application of new technology.

In contrast to the unfettered ability of surgeons to innovate and creatively solve their patients’ problems, surgical research requires significant oversight. According to Biffl and colleagues, surgical innovation should be distinguished from both “minor modifications” in surgical technique and “surgical research.” Minor modifications involve decisions such as which suture material to use or whether to perform an anastomosis in a handsewn or stapled fashion. Such minor modifications are within the realm of choice for the surgeon and do not require consent from patients. In contrast, surgical research is designed to contribute to generalizable medical knowledge and requires oversight from institutional review boards.

Surgical innovation falls into the middle range between minor modifications and surgical research. Unplanned innovations that are performed in an attempt to help a specific patient can proceed purely on the basis of the surgeon’s assessment that the patient will benefit. Such unplanned innovations should be disclosed to patients as soon as possible after surgery. In contrast, planned surgical innovation should be explained to patients preoperatively, and specific informed consent for the innovative procedure should be obtained. Innovative surgical techniques are therefore outside of the purview of the institutional review board and depend on the communication between surgeon and patient to ensure that the patient’s welfare is maintained.

How should new surgical technology be applied by surgeons in the operating room? Is, for example, the use of a new stapler or a robot something that should be disclosed to patients prior to surgery? The answer depends on how the new technology impacts the patient. For example, a new laparoscope is unlikely to have an effect on the patient’s outcome and does not rise to the level of concern to require disclosure. However, using a new stapler to perform an anastomosis may have a significant effect on the patient, and, for that reason, it should be disclosed.

Often when discussing innovation in surgery, the paradigm of innovation in business is assumed to be relevant. In business, the visionary leader is one who can “think outside of the box,” take risks on new ventures, and turn them into corporate profits. The new idea may not succeed, but the “courageous” innovator in business is not afraid to take such risks, knowing that there is the possibility for tremendous gain. In surgery, we often also praise the innovator who does not simply continue doing what he or she was taught but thinks creatively about how to solve patients’ problems in a new way. Despite some similarities to innovation in business, the analogy between the business world and medicine falters on closer scrutiny. In business, the innovative executive is risking his or her reputation and the company’s money. In surgery, although the surgical innovator may also risk his or her reputation, the biggest risk is to the patient’s safety. The surgeon is not personally at risk for any of the complications that might occur for the patient if the innovative surgical technique or technology is not successful. Although the surgeon may risk malpractice litigation, the patient faces the risk of morbidity and even mortality.

Unfortunately, too often the business model of innovation is applied in the world of surgery such that the risks to the patient are not given adequate attention. Even though the surgeon rarely owns the new technology (eg, the robot), it is the surgeon who decides whether to offer this new technology to a specific patient. The ethical burden of disclosure to the patient of the risks of a new technology must, therefore, be borne by the surgeon. The device manufacturer should not produce an inferior product or mislead anyone about its potential benefits. Similarly, hospitals must not engage in misleading marketing. However, the interactions between the device manufacturer and the hospital can only be managed in the context of the trusting relationships between patients and their physicians.

Companies do not make recommendations to patients about how to best proceed with an operation. Neither do hospitals carry an ethical responsibility to disclose risks to a patient. It is the surgeon in a patient-physician relationship with a patient who holds the ethical responsibility to critically analyze the available information about a new technology and decide whether it is appropriate to offer to the patient. Although, in a case of planned innovation, the patient may decline a sur-
geon’s recommendation, it is up to the surgeon to decide what to offer the patient. When the unexpected is encountered during surgery, the trust that the patient has placed in the surgeon to act in the patient’s best interest is the basis for proceeding with unplanned surgical innovations.

In the current era of shared responsibility between surgeons and patients for medical decision making, when we emphasize systems over individuals in hospitals, it is often easy to lose sight of the critical role of the professionalism of surgeons in deciding what to offer to patients. Professionalism demands of surgeons self-regulation, ethical standards, and altruism. Surgeons must determine what new technologies to offer to patients not on the basis of increasing volumes or abiding by corporate strategies, but the best interests of the individual patient. It is the expectation that surgeons make decisions in their patients’ interests that patients depend on when they agree to allow a surgeon to proceed with interventions that in any other context would be considered battery.

The recent attention that groups such as the American Association of Gynecologic Laparoscopists have given to providing guidelines for privileging for robotic surgery are laudable attempts to push physicians to obtain adequate training in new technologies before seeking privileges to use them in patient care. However, no amount of required training and oversight of the use of new technology can take the place of a surgeon’s honest assessment of his or her own abilities and whether to use the new technology in the care of a specific patient. Just because there may be ample evidence in the surgical literature that experienced surgeons can safely perform a particular operation does not mean that I, with what may be limited experience and limited skill, should also offer this procedure to my patients. The ethical responsibility continues to rest on the surgeon to make individual recommendations for specific patients based on what is best for the individual patient. I must know my own limitations, and I must clearly communicate my experience with the patient so that he or she can make an informed decision about whether to abide by my recommendation. Regardless of the new technology, the primacy of the individual patient-surgeon relationship must remain in navigating the challenging terrain of applying new technology to patient care.

ARTICLE INFORMATION
Published Online: March 16, 2016.
Conflicts of Interest Disclosures: None reported.

REFERENCES