Potential Barriers to the Diffusion of Surgical Innovation

Although many modern concepts and principles of innovation have been defined according to the business perspective, the field of surgery, built on a unique culture of continuous innovation, represents an area where creativity and initiative have been central to progress. Surgical innovation can be thought of as the introduction of new concepts and ideas or, more specifically, as the practical use of a new technology, technique, or some combination of both. Given that there are no accepted definitions for surgical innovation, it is important to delineate between surgical research and innovation. Surgical curiosity may lead to the initiation of a research project whereby new technologies and concepts are tested using cell lines and animals in research laboratories or with large data sets using epidemiological or statistical methods. In contrast, innovations typically represent the practical application or intended use of these concepts and ideas in humans. Although this bench-to-bedside pathway has received considerable attention over the past 2 decades, there is increasing awareness that the transition from theoretical ideas to use in humans occurs infrequently. While many surgical innovations presuppose some form of research, not all research leads to innovation. Barriers to crossing this translation gap can be related to 3 general clusters of influence: the role of market forces and economic limitations, ethical considerations of innovative surgery, and the potential conflicts of interest associated with the use of surgical innovations.

Market Forces and Economic Considerations

In an era of economic reform focused on greater accountability and reducing health care costs, it is critical that innovations be cost-effective and justifiable from an economic point of view. As such, a variety of market-based terms have been used to describe the commercial effect of innovation. For example, a disruptive technological innovation is defined as an innovation that decreases the market share of leaders or large corporations that determine technological promotion. Traditionally, disruptive innovations cater to emerging markets and focus on a new set of product attributes that may have been otherwise ignored by industry leaders. Perhaps the best example of such a disruptive innovation in surgery has been percutaneous transluminal balloon angioplasty. Initially thought to be dangerous and inferior to more traditional open approaches, percutaneous transluminal balloon angioplasty has since proved to be “disruptive” within the field of cardiothoracic surgery, becoming the gold standard for certain pathologies and therefore shifting market shares toward interventional cardiology. In contrast, it is unclear whether similar minimally invasive technologies can be adopted for other procedures. For example, although robotic surgery represents a surgical innovation that allows surgeons greater access to confined spaces by filtering out undesired movements and tremors, the high level of expertise and costs associated with robotic surgery have limited its widespread use. Additionally, given the dearth of data demonstrating improved clinical outcomes with the use of robotic-assisted approaches, payers and policymakers have been reluctant to adopt this technology and have questioned its cost-effectiveness. Further, it is likely that such advancements will be completely unfeasible in several parts of the world, highlighting the importance of considering opportunity costs associated with surgical innovations as well as ethically limiting the use of resources to safe and effective procedures.

Ethical Considerations

Ethical considerations for innovators are related to avoiding patient harm and providing patients with information so they can make an informed decision about whether they want standard of care or novel treatments. Compared with existing standard procedures and treatments, surgical innovations have the potential to cause increased mortality and morbidity and therefore direct patient harm. This is apparent from the early adoption of harmful treatments, including various oncological procedures, and from the rapid uptake of certain laparoscopic approaches. Perhaps the most striking example of this can be found in gynecological surgery, specifically, the treatment of uterine leiomyomas. Although initially popularized, studies have demonstrated significant long-term risks associated with the use of power morcellators in laparoscopic hysterectomy, implicating their use with a higher risk of disseminated disease and subsequent peritoneal carcinomatosis. To this end, the US Food and Drug Administration issued a safety communication discouraging the use of power morcellators for leiomyoma extraction. Collectively, these data reiterate the need for surgical innovations to be strictly regulated and rigorously tested before their use in humans.

Additionally, patients can also be harmed if surgical innovations are safe but ineffective because patients undergoing such procedures are still at risk for complications given the invasive nature of surgery and anesthesia. When using an innovative approach, surgeons need to make patients aware that they will be exposed to new procedures or techniques. Furthermore, the risks and benefits of any innovative technique need to be explained and any misconceptions relating to the effectiveness of these new and innovative surgical procedures need to be discussed and clarified. Surgeons must ensure the preservation of patient autonomy via...
appropriate informed consent for innovative surgical procedures.\textsuperscript{6} However, obtaining appropriate informed consent remains particularly challenging given the lack of established guidelines and the frequent lack of clear evidence regarding the potential risks and benefits at the early stages of innovation.\textsuperscript{6}

\textbf{Conflicts of Interest}

Another barrier to surgical innovation are potential conflicts of interest affecting both surgeons and health care institutions. Conflicts of interest may pertain to economic gains associated with the desire to attract referrals and receive academic credit for the development of new devices.\textsuperscript{5} These conflicts of interest can directly and intentionally prejudice decision making and can result in surgeons pursuing innovations despite risks to patients in the absence of substantial evidence supporting their use. Information relating to the sources of funding and the roles of surgeons must therefore be adequately disclosed. Additionally, robust data relating to patient outcomes must be collected and appropriate methods used to successfully assess the safety and efficacy of new surgical treatments. Furthermore, the successes and failures of such endeavors must be shared with patients and surgeons and be documented in a transparent manner to empower patients with adequate information promoting patient autonomy.

The translation from research to innovation in surgery is highly variable, yet surgical innovations are responsible for much of the progress in the field of surgery and, in turn, improved safety of patients. Moving forward, surgeons must continue to pursue creative thinking, technological advances, and improved training while remaining cognizant of the economic and ethical issues central to the proper implementation of innovation in the surgical setting. Furthermore, surgeons must ensure that all potential conflicts of interest are appropriately declared and that patients are equipped with all necessary information to make informed decisions pertaining to their treatment.

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\textbf{REFERENCES}