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# Innovation in surgical technology and techniques: Challenges and ethical issues

James D. Geiger, MD[a,*], Ronald B. Hirschl, MD[b]

[a] Michigan Pediatric Device Consortium, University of Michigan, CS Mott Children's Hospital, Ann Arbor, 1540 E Hospital Dr SPC 4211, Michigan 48109
[b] Section of Pediatric Surgery, University of Michigan, CS Mott Children's Hospital, Ann Arbor, Michigan

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ABSTRACT

The pace of medical innovation continues to increase. The deployment of new technologies in surgery creates many ethical challenges including how to determine safety of the technology, what is the timing and process for deployment of a new technology, how are patients informed before undergoing a new technology or technique, how are the outcomes of a new technology evaluated and how are the responsibilities of individual patients and society at large balanced. Ethical considerations relevant to the implementation of ECMO and robotic surgery are explored to further discussion of how we can optimize the delicate balance between innovation and regulation.



## Introduction

Robert E. Gross burst onto the stage of pediatric surgery worldwide when he successfully ligated a patent ductus arteriosis in a 7-year-old girl on August 26, 1938. He was then Chief Resident in Surgery at Children's under William E. Ladd, the Surgeon in Chief. Gross had carefully planned this bold operation by practicing it in the postmortem room and animal laboratory. He did it when Ladd was on summer vacation. Ladd never forgave Gross for that surgical coup. Gross was certain Ladd would not have allowed him to do it if he had been in town. This bold adventure was the opening wedge for surgical correction of congenital cardiac malformations. Gross commented that if she had not done well, he would likely be a farmer somewhere in New England. By the time of his retirement, more than 1400 PDA's had been divided by Gross and his residents.[1]

Today much is the same, innovations in the way surgeries are performed often occur with little or no advance oversight. If supervision is present, it is most likely done by hospital based medical-credentialing or peer review staff, who aim to assure that physicians are sufficiently skilled to perform a particular surgery at that hospital, or by the FDA if there is an investigational device involved, for the FDA tries to assure that surgical devices are safe and effective for their intended use. However, medical staffs do not often ask surgeons to be re-credentialed when they alter a surgery they have privileges to perform. Since completion of the first laparoscopic cholecystectomy[2] in 1985 there is a trend for taking well-established open procedures and performing them laparosocpically. This often involves a steep learning curve for the surgeon, with increased potential risk to the patient. Additionally, the FDA does not regulate the manner in which surgeons use approved surgical devices. This means that, in a practice akin to off-label drug use, surgeons can use approved devices in novel ways without FDA oversight. More than other kinds of medical practice, innovative surgical techniques raise the issue of the variation in skill levels among physicians and the impact that has on deciding whether innovation should be deployed as surgical practice or research. Surgeons can find themselves in the grey area that exists between what is defined as medical practice with little oversight and research which is subject to extensive controls. Surgical innovation raises many ethical dilemmas that affect patients, medical practitioners, the medical profession, and society at large raising the following questions: (1) How is the safety of a new technology or technique guaranteed? (2) What are the principles used by hospitals to responsibly deploy a new technology or technique? (3) How is informed patient consent obtained before undergoing a new technology or technique? (4) How are conflicts of interest that could prejudice the physician's judgment managed? (5) How are surgeons trained and credentialed in a new technology or technique? (6) How are the outcomes of a new technology or technique tracked, evaluated, and reported? (7) How are the responsibilities to individual patients and society at large balanced? To further explore these ethical questions innovations in Extra Corporeal Membrane

* Corresponding author.
*E-mail address:* jgeiger@med.umich.edu (J.D. Geiger).

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**Table 1**
The principles incorporated into the Nuremberg Code and the report from the Belmont Committee regarding ethical and appropriate treatment of human subjects in medical research.

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| Nuremberg Code | |
| 1 | The voluntary consent of the human subject is essential. |
| 2 | The experiment should be necessary and such as to yield fruitful results for the good of society. |
| 3 | The experiment should be so designed and based on the results of animal experimentation and underlying knowledge such that the anticipated results justify the performance of the experiment. |
| 4 | The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury. |
| 5 | No experiment should be conducted where there is a prior reason to believe that death or disabling injury will occur. |
| 6 | The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment. |
| 7 | Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death. |
| 8 | The experiment should be conducted only by scientifically qualified persons and with the highest degree of skill and care. |
| 9 | During the course of the experiment, the human subject should be at liberty to bring the experiment to an end. |
| 10 | During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage if he has probable cause to believe that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject. |
| Belmont Committee | |
| 1 | Respect for persons suggests that individuals should be treated as autonomous agents and persons with diminished autonomy are entitled to protection. |
| 2 | Beneficence notes that persons should be treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. |
| 3 | Justice indicates that the benefits and burdens of research should be "fair in distribution." |

Oxygenation (ECMO) and robotic surgery will be reviewed to illustrate some of the challenges in the deployment of new surgical technology and hopefully further the discussion of how we can optimize the delicate balance between innovation and regulation.

## Surgical and device innovation, the Common Rule, and the FDA

Following the Nuremberg trial of Nazi doctors involved in human experimentation, the 1947 Nuremberg Code defined 10 points outlining legitimate and ethical medical research (Table 1).[3]

The Tuskegee syphilis experiment, in which impoverished, African-American men with syphilis were studied without treatment from 1932 to 1972, led to the Belmont Report in 1978 and the Code of Federal Regulations Title 45, Part 46: Protection of Human Subjects in 1991.[4] (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html) Otherwise known as the Common Rule, 45 CFR part 46 details and implements the concepts of protection of human subjects in research and the development of institutional review boards (IRB). (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html) Thus, human subjects in research are protected by a system which ensures that the doctrines outlined in the Nuremberg Code and Belmont Report are maintained.

Innovation is integral to the care of surgical patients.[5] The surgeon must constantly alter, amend, and combine standard techniques in the care of biologically unique clinical situations. This "surgical practice" adaptation is an accepted aspect of the specialty and one which is necessary to provide excellent patient care.[6] While minor variations are considered standard care, when does an innovation become research and "experimentation"? The Belmont Report defines practice as, "…interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success." (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html) In contrast, research, "…designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective." The Belmont report goes on to say, specifically, that, "When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is 'experimental,' in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective." Thus, at one end of the spectrum of surgical innovation is "practice," while at the other end is "research." In between is a "grey" zone into which major innovations my fall; major innovations which may present significant advances for patients and society, but in which substantial trial and error as well as risk to the individual patient may exist.[6]

The Food and Drug Administration (FDA) regulates devices under the authority first established by Congress in 1938.[7] In 1976, following several amendments to the Act that authorized this empowerment, FDA's authority was extended to regulate and ensure the safety and effectiveness of all medical devices sold in the United States. Subsequently, devices have been classified on the basis of the risk of illness or injury should device failure occur: the greater the risk, the higher the classification and the more stringent the requirements to demonstrate quality, safety, efficacy, and reliability (Table 2). The classifications and requirements are based on the 1976 Amendments to the Food, Drug, and Cosmetics Act and the Safe Medical Devices Act (SMDA) of 1990 followed by the 1997 Food and Drug Administration Modernization Act

**Table 2**
Classes of devices intended for human use based on the regulations from the amended Food, Drug, and Cosmetic Act which describe device classification. The entire FD&C act may be seen at http://www.fda.gov/opacom/laws/fdcact/fdcact5a.htm.

| | |
|---|---|
| A | Class I, general controls—A device for which there is reasonable assurance of safety and effectiveness or which is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and does not present a potential unreasonable risk of illness or injury. |
| B | Class II, special controls—A device which cannot be classified as a class I device. A device that is purported or represented to be for a use in supporting or sustaining human life. |
| C | Class III, premarket approval—A device which cannot be classified as a Class I or II device or is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. |

(FDAMA) (http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/significantamendmentstothefdcact/fdama/default.htm). The goal of the FD&C Act regulations is to oversee manufacturing, marketing, and sales of devices, sometimes via a relatively simple demonstration that a device is "substantially equivalent" to a prior or "predicate" device (510k process) or via a more robust pre-market approval process. The focus of such regulations is not intended to, "limit or interfere with the authority of the healthcare practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within the legitimate healthcare practitioner–patient relationship." It is not illegal, therefore, to use devices in an "off label" manner. It is, however, illegal for a manufacturer to promote an unapproved use of a legally marketed device. Physicians may also obtain devices that are not legally marketed for use in their practice by prescription via the custom device exclusion of the FD&C Act[7]. Thus, while the commercial development of surgical devices is highly controlled, surgeon use of those devices in an unintended, and potentially unexplored, context is not. In addition, surgeons, by prescription, can obtain custom devices from manufacturers without subjecting them to the FDA standard rigors otherwise required of commercially marketed devices.

## Ethics of ECMO innovation

As can be seen from Figure 1, there is, therefore, a gap in the safeguards and protections for and oversight of patients involved in innovative procedures and implementation of medical devices. To take the development of ECMO as an example, the FDA regulates the medical devices used in ECMO, but the devices, for the most part, have been tested for and are approved for only 6 h of use. Thus, in the early days all ECMO devices were being used "off label" for longer than intended periods (many still are). More importantly, the FDA does not review or approve procedures, including ECMO. Since placing newborns on ECMO was a major innovation, but not "research," there was also no oversight under the Common Rule. As a result, the ethics associated with the implementation of ECMO were left to the surgeons developing this novel technique. This leads us to ask what safeguards and protections for patients should be in place in the grey zone of procedure and medical device innovation development where none currently exists. As one publication put it, innovative surgery is "the last frontier" of ethical regulation.[8]

## In the grey zone

Let's continue the theme of innovation in ECMO with a few scenarios. Note that the use of a device is being explored below, but the same concepts would hold for a procedure:

1) A new Avalon venovenous cannula is available at various sizes that has been approved by the FDA based upon 510k clearance since it is similar to prior devices; devices which were cleared for use for cardiopulmonary bypass for 6 h or less (http://www.accessdata.fda.gov/cdrh_docs/pdf8/K081820.pdf; http://www.accessdata.fda.gov/cdrh_docs/pdf11/K113869.pdf). The device has never been used in children and is not "cleared" (FDA clears devices by 510k, but does not "approve" them by this process), but there is no other venovenous cannula appropriate for a 2-year-old child that needs ECMO. You do not want to use venoarterial ECMO because you will need to ligate the carotid artery to do so. Is it appropriate to use the Avalon cannula? Are there unknown risks to the patient? Should the family be informed? Is it important that you are using this new cannula off-label? Is this research, surgical practice, or in the grey zone?
2) The new Avalon cannula has a size that is also available for newborns, but there is already a venovenous cannula that has

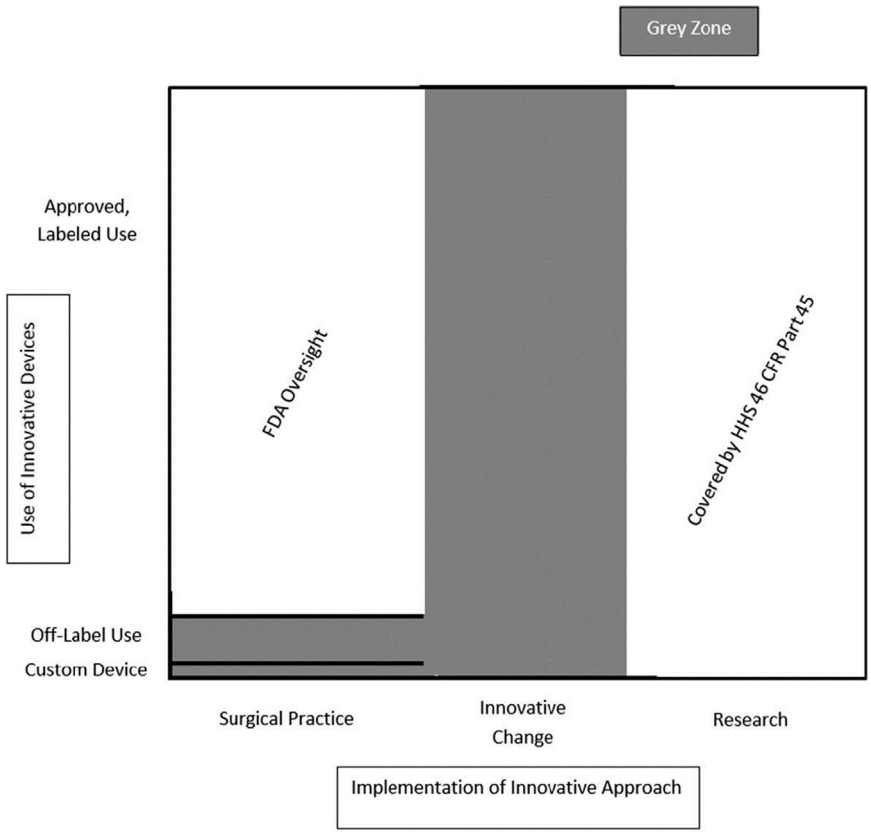


**Fig. 1.** Implementation of innovative approach.

been used off-label for ECMO in this population. The new Avalon cannula might have some advantages. Is it appropriate to explore using this cannula in newborns when an alternative is available? If so, is this surgical practice, research, or in the grey zone?

3) The Avalon device requires wires, dilators, and specialized manipulation to place the cannula percutaneously through the internal jugular vein into the inferior vena cava. Should all of the Pediatric Surgeons in your group perform this procedure or just a select few? Are there competencies that should be demonstrated before performing the procedure?

The Belmont Committee report would suggest that the scenarios above are not related to research: there is no intent to answer a hypothesis and there is no formal protocol (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html). As is common among surgeons, there is simply a desire to benefit the care of this patient and future patients. At the same time, this is clearly more than the surgical practice: the cannula has not been used in this population previously will be used off-label, and there are good, tested alternatives (albeit off-label), especially in example 2. The providers in these examples are in the grey zone using a previously untried device in an off-label manner.

A number of surgeons and ethicists have visited the dilemma presented by the grey zone and, although there is no firm consensus, a following number of concepts consistently emerge:

1) Where appropriate, the procedure or device should be explored in the laboratory to optimize implementation in patients.[9] As is promoted in the Nuremberg Code and the Belmont Report, informed consent is key. Family verbal or written informed consent should be obtained, with patient assent if appropriate, with emphasis on the innovative nature of the device or procedure.[10,11]
2) Outcomes must be reviewed in an ongoing manner in order to ensure ongoing safety and refinement of the procedure/device.[12] This preferably should be via registries as uncommon adverse outcomes may not be recognized in small series.
3) As is suggested by the Belmont Report, conversion of an innovative change to a formal research study should occur as soon as is appropriate and feasible. In fact, the ideal approach to implementation of an innovation is via the following steps: application in those in whom there is no alternative → use in patients who would likely benefit → ongoing analysis of registry data to allow feedback and refinement → clinical trials.[12]
4) The surgeon should ensure that conflict of interest is minimized such that the decision to implement a device or procedure is made in the patient's best interest.[13]
5) The procedure should be performed by those who have the appropriate expertise to optimize outcome in the setting of innovation[9].

Schwartz offered a mnemonic for a similar approach which she entitled the "ETHICAL" model (Table 3).[13] Likewise, other surgeons have recommended permutations on this approach to innovation in the grey zone.[9,12,6,5]

**Table 3**
The ethical model for innovation in the grey zone.

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|---|---|
| E | Expertise in the specific field. |
| T | Technical skills required to perform the innovation. |
| H | Hazards associated with the new procedure or device should be assessed and a risk-benefit assessment made. |
| I | Informed consent from the child's legal guardian. |
| C | Conflict of interest should be minimized. |
| A | Analysis of the outcomes. |
| L | Literature should include the experience and lessons learned. |

## Oversight in the grey zone

In follow up to the scenarios above, the Avalon bicaval double lumen, venovenous cannula was explored as outlined with small, encouraging series reported in the literature.[14,15] However, aggregate data from the Extracorporeal Life Support Organization (ELSO) suggested that the perforation rate was increased in newborns with use of the Avalon cannula.[16] At the University of Michigan our experience revealed that the complications associated with this cannula at the time of placement and during the subsequent ECMO course was high enough in newborns and young children that we no longer use the cannula until design adjustments can be made. The complexity of and potential complications related to percutaneous Avalon cannula placement, as well as the associated competencies required to perform the procedure, have led to a change in practice such that only a few selected surgeons are involved in the procedure at our institution.

Given these outcomes, should there have been more rigorous oversight of implementation of this innovation? Many have suggested enactment of processes to manage innovation in the grey zone from discussion with colleagues to departmental review to federal government oversight.[17,9,12,13]. The tension between oversight that protects the interests of patients and flexibility that allows innovation to develop unimpeded is healthy, but remains unsettled. In fact, there is a concern that formal oversight would stifle the surgical innovation that has resulted in benefits to so many patients. At the same time, there is recognition that in many instances operative intervention has been poorly assessed and, in some cases, proven to be ineffective or even detrimental.[10] There is also a concern that the designation between "surgical practice" and the "grey zone" is ill-defined, making the boundaries for oversight likewise difficult to delineate. While enhanced oversight of innovation in the grey zone is likely to occur in the future, adopting an approach similar to that outlined above for now allows ethically sound implementation of innovative procedures and devices.

## Ethics of robotic surgery innovation

The FDA initially approved the Intuitive Da Vinci system (Intuitive Surgical Inc, Sunnyvale, CA) for robotic-assisted laparoscopic surgery in 2000 for use in general laparoscopic procedures. Since that time, both the number of procedures performed using the Da Vinci system and the number of Da Vinci systems installed in hospitals have expanded exponentially. Between 2007 and 2013, the number of procedures performed with the Da Vinci system increased by more than 500% in the United States to 425,000 procedures (Investor Presentation Q4 2014). Most of the growth of robotic surgery was initially with urologic procedures, but subsequently there has been significant growth in gynecologic procedures with less growth in general surgical, colorectal, cardiothoracic, pediatric, and head and neck procedures. The FDA approvals for the Da Vinci system mirror this expanded market with the two most recent approvals for Transoral otolaryngologic surgical procedures in 2009 and Sing-site laparoscopic cholecystectomy procedures in 2011.

Robot-assisted surgery offers many hypothetical benefits, such as stereoscopic vision, enhanced visual magnification, and more degrees of freedom for surgical instruments, and has facilitated completion of the most complex minimally invasive procedures. Evidence is still lacking for clear benefits to a robotic approach over a laparoscopic approach,[18,19] but the potential of the technology is clear. With competition coming in the market for surgical robotics, it is likely that the cost to value ratio of robotic surgery will improve.

## Problems with deployment

The deployment of the da Vinci robotic system has become increasingly controversial with a gauntlet of litigation, regulatory scrutiny, and professional skepticism about its safety and cost-effectiveness. There are a number of potential reasons for these problems including the credentialing process, lack of monitoring and complication reporting, use by surgeons who were never trained in advanced laparoscopy, and some related to the technology itself, especially the lack of haptic feedback.

Robotic surgery transitioned from an investigational technology to a routine alternative to traditional laparoscopy and open surgery for certain oncologic and benign conditions.[20,21] Robotic surgery is substantial change in surgical technique from laparoscopy and certainly open surgery that requires additional training and a new skillset. There is a significant learning curve, even in the hands of advanced laparoscopic surgeons which almost certainly led to an increased rate of complications. The best studies have been done in urologic surgery and estimate that although 5–20 cases are needed to achieve basic proficiency (as measured by crude operative time),[22,23] 150–250 cases might be required to achieve equal oncologic outcomes compared with open procedures.[24] Given such potentially long learning curves, hospitals and surgeons have an ethical obligation to use safety strategies to minimize preventable harm to patients.

The exact rate of complications and deaths with the da Vinci system has been hard to quantify. When an adverse event or device malfunction occurs, hospitals are required to report these incidents to the manufacturer, who in turn is required to report those incidents to the FDA. The FDA then creates a de-identified report of the incidents in the Manufacturer and User Facility Device Experience (MAUDE) database, a public database. It has been suggested that robotic surgery complications may be more common than represented in FDA adverse event reports. In one study anonymously surveying surgeons, 56.8% reported irrecoverable operative malfunction while using the Da Vinci system.[25] More recently, Copper et al.[26] by comparing a number of databases and media reports identified significant underreporting of robotic complications. There is a clear need for a more robust tracking system for reporting adverse events in robotic surgery. This is not just a problem with robotic surgery as there are major issues in capturing adverse events with other surgical technologies. A more robust, prospective, and open reporting system will allow surgeons and manufactures to learn more quickly that there is a problem and then identify solutions whether a modification in the technology, training or some other issue. Post-market oversight of medical devices must improve and be designed by all the stakeholders including patients, surgeons, hospitals, manufacturers, and the FDA.[27] Such a system could allow for more timely innovation, by shifting the assessment of new technologies more to post-market as opposed to pre-market studies.

There is little disagreement that processes governing the introduction of new technology and procedures should not stifle the adoption of innovative technology and techniques. On the other hand, uncoordinated introduction of new technology and procedures in clinical practice has been demonstrated repeatedly to be associated with an increased incidence of patient complications and poor outcomes. The actual process for implementing new procedures continues to evolve with efforts from multiple stakeholders including the FDA. Any effort to develop a universal set of guidelines for wide application will be very difficult. Progress is being made especially by the professional medical associations that have stepped up and taken a leading role. SAGES in particular has provided thoughtful guidance on what parameters should be assessed prior to the deployment of a new technology or procedure. The guideline states: The effectiveness compared to alternatives, the cost, patient outcomes, and the safety profile of new technology and techniques should always be assessed prior to and after their introduction. Other parameters such as existing and required resources; benefits to patients, surgeons, and hospitals; existing or anticipated volume of use; barriers to adoption; and whether the anticipated benefits prove real after introduction should also be considered, especially for significant changes in devices and procedures, besides minor modifications.[28]

## The need for more robust credentialing and mentoring

Despite the rapid growth of robotic surgery, there is currently no accepted standard for credentialing or post-credentialing mentoring and monitoring. Credentialing is primarily handled at the hospital level and commonly requires a nominal training experience (as no standard training exist) and only a small number of operations (2–10) under the observation of a proctor. There are currently no standards for proctoring or even identifying who is qualified to serve as a proctor or what metrics the proctor should use to determine whether to approve privileges. Given the long learning curve for competency in robotic surgery a healthy program of mentoring and monitoring after a surgeon is credentialed will likely shorten the learning curve and decrease complications. At the University of Michigan, CS Mott Children's Hospital, we have informally adopted a team approach to many of our robotic and complex laparoscopic cases where two sometimes three staff will participate in key portions of the operation to speed the learning process and optimize technique. Although this is a significant investment in time, we have found it highly valuable especially given the low volume of cases completed in pediatric surgery.

In general robotic privileges are not procedure specific and once privileged surgeons could apply robotic technology to other potentially more complex procedures and even procedures that have never been done robotically. From a safety perspective, this is not an ideal process. A process should be in place to handle this situation which could include any of the following (modified from SAGES guidelines[28]): (1) Review of the literature for similar cases, (2) obtain the input of other experts, (3) practice the proposed procedure on simulated or animate models, (4) cadaveric tissue or animals, (5) proctored or team approach to initial cases, and (6) review outcomes. This process should be fully disclosed to the patient. The evaluation of potential conflicts of interest with robotic surgery manufacturers should be disclosed and managed as part of the credentialing process.

An alternative to proctoring would be to record cases and complete video review as was described by Birkmeyer et al.[29] who showed differences in outcomes related to the technical rating of the surgeon based on video reviews. This type of review will require further development to sort out issues of editing, the need to capture intracorporeal and room video. The simulators for robotic surgery and the Fundamentals of Robotic Surgery (FRS) when validation is completed (see next section) should become important components of robotic credentialing and re-credentialing.

## Standardized training and assessment

After FDA approval of robotic surgery in 2000, there was limited training which was initially led with significant input from da Vinci personnel. This training met the criteria of the FDA but in did little to prepare the surgeon for the skills that would be needed to perform robotic surgery safely and effectively. Although there have been a number of attempts to create robotic training

curriculum these have not be standardized, validated and widely adopted.[30,31] Fourteen years since the deployment of this complex technology, we are getting closer to standardized robotic training curriculum. Through the efforts of a number of leading robotic surgeons and 14 surgical societies, Fundamentals of Robotic Surgery (FRS) curriculum has been created and is currently undergoing validation.[32] FRS is similar to Fundamentals of Laparoscopic Surgery (FLS) curriculum which was launched and validated by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). SAGES and the American College of Surgeons (ACS), promoted the FLS as a minimum standard before a surgeon should be allowed to perform laparoscopic procedures independently and in 2009, the American Board of Surgery (ABS) mandated that FLS as a part of board certification. FRS should be a significant improvement in preparing surgeons for robotic surgery especially in our training programs where residents participate in robotic surgery without adequate knowledge of the technology or skills to be successful. Teaching residents in new and complex technology is very challenging especially when the attending surgeon is still on their own learning curve. The lack of control of the trainee when they are at the surgeons console creates additional challenges. The FRS curriculum once validated should be a good step in the right direction.

## Informing patients about the risk and benefits of robotic surgery

The role of the patient in the clinical application of new devices and techniques is paramount, and their welfare and interests must be protected. Patients present with a wide variety of educational and cultural backgrounds, which should be considered during the informed consent discussion. Perhaps due to the aggressive marketing of robotic surgery or patients' desire for the latest technology, patients generally seem enamored with robotic surgery. As negative reports on robotic surgery complications and cost issues are reported in the media and internet, patients opinions may change.

Especially in pediatric surgery, limited data exist on robotic surgery outcomes making the consent discussion more challenging. Additional risk and benefits of using the robotic system should be equally discussed. Conducting these discussions well is an area of great scientific, ethical, and public interest. Surgeons must be as forthright and balanced in the presentation of information as possible. In general, the surgeon is accomplishing the operation in a similar approach and technique than would be done laparoscopically which aids in the discussion. Input from a New Technology Committee (NTC), if present at the institution, may also be helpful by providing an informed consent process or document, developed by the multidisciplinary NTC. This may serve not only to protect patients, but also to protect surgeons and their institutions by moving some of this process to the purview of physician peers and leadership.

The choice of words in "informed consent," is extremely important as eloquently described by Weaver.[33] It has been customary to refer to the process of discussing treatment risks, benefits, and alternatives with patients as the "op consent process," the paper that is signed as the "op permit," and obtaining patient signature on the paper as "getting consent." Using these terms devalues this critical relationship into an adversarial legal context. The discussion between the surgeon and the patient (and family) is a process of listening, understanding, educating, building trust, and advising. Patients should then request the operation or refuse it. Either way, labeling this document as an operative request is more appropriate terminology for medicine, and extricates it from the legal arena.

## Robotic surgery cost and access

The da Vinci robotic system has come under increasing scrutiny due to its significant cost.[18] The most compelling studies have come from gynecology and robotic hysterectomy for benign disease which showed that robotic hysterectomy cost $2200 more per case without any improvement in outcomes.[34] The rapid adoption of robotic surgery has in the study of robotic radical prostatectomy led to racial, geographic and hospital-based variations, with limited access to care for nonwhite patients. Several other studies have demonstrated similar heterogeneity in access to newer technology and therefore limit generalizability of outcomes.[35] With healthcare reform and transformation to value-based healthcare, the value to cost ratio of medical technologies must be optimized. Intuitive surgical will face pressure from payers and new entrants into the market that likely will drive down robotic surgery cost. Additionally, better designed studies and data availability will allow for more informed assessments of the costs and benefits associated with the effective use of innovative medical technologies.

## Conclusion

The pace of medical and surgical innovation will continue to increase. A great challenge for modern healthcare organizations is going to be how to optimize medical technology management to foster the development and timely adoption of new technologies, procedures, and clinical practices that can deliver the best medical care and the highest patient satisfaction at the lowest cost. The lessons learned with the deployment of technologies like ECMO and robotic surgery provide us with lessons that should help us better realize the benefits of surgical innovation in the future.

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