

Responsible Development and Application of Surgical Innovations: A Position Statement of the Society of University Surgeons

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The field of surgery has a unique culture and rich tradition of innovation.¹ Surgeons are trained to perform continuous situational assessment, decision analysis, and improvisation, in preparation for the challenges and creativity required by nearly every clinical case.¹ Indeed, as Riskin and colleagues¹ point out, “most surgeons innovate on a daily basis, tailoring therapies and operations to the intrinsic uniqueness of every patient and their disease.” In addition, unsolved problems and repetitive failures—or at least sub-optimal outcomes—stimulate surgeons to strive for a better way to address challenging surgical problems. Consequently, the practice of surgery is steeped in innovation.

In the United States, development of new drugs and medical devices is closely monitored by the federal government. The Food and Drug Administration (FDA) regulates biologics, devices, and drugs by reviewing their safety and efficacy for a given indication before granting approval for marketing and distribution. The labeling (package insert) summarizes what the FDA has deemed the safe and effective use of the product, and “off-label” use of a product, although allowed, may be subject to regulatory scrutiny.

Such oversight does not necessarily extend to surgical innovations.^{2–10} The surgical innovator has historically been allowed to “tinker” with procedures, introducing modifications of varying degrees to the point that a procedure could arguably be called new.¹¹ In fact, there are nu-

merous examples of such innovations currently in clinical use, most notably, the myriad variations of minimally invasive procedures. Rapidly advancing technology offers the surgeon a steady stream of opportunities to innovate, and this is encouraged by the incentive to publish or present novel approaches, the need to attract new patient referrals, and the innate desire to improve the quality of care delivered by one’s profession.¹² But there are currently no formal regulations that apply to surgical innovations. Consequently, the gap between regulatory goals and professional reality is widening.⁹ With the importance of ensuring patient safety, it is clear that surgical innovation can no longer enjoy its unmonitored status.¹³

Surgical innovation in itself is not problematic. Indeed, a safer, more effective, or less morbid procedure would have a direct and favorable impact on patients. The absence of any organized oversight or mechanism to protect patients from becoming unwitting research subjects is, however, problematic. Patients may be harmed by innovations that are less effective or more dangerous than expected. More than a decade ago, Roy and colleagues¹⁴ observed, “When large numbers of innovative treatments are being continuously introduced into clinical practice, rigorous testing is mandatory for the protection of individual patients and the just use of limited resources. This holds true with even greater force in light of the evidence that many innovations show no advantage over existing treatments when they are subjected to properly controlled study.” Concerns about inadequate testing of operations have led to increasing calls for vigilance to prevent cavalier innovations and to ensure scientific evaluation of new procedures.^{6,8,15–28}

In general, clinical research with respect to a new treatment, drug, or device is relatively easy to define, particularly when it is sponsored by an entity subject to formal regulatory oversight. Less clear is the point at which a minor modification is substantial enough to require disclosure to the patient and approval and oversight by a third party. As McKneally and Daar¹¹ suggested, it is often diffi-

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Abbreviations and Acronyms

CFR	= Code of Federal Regulations
FDA	= Food and Drug Administration
M & M	= morbidity and mortality conference
SIC	= surgical innovations committee.

cult for surgeons to tell if “what they are doing is an evolutionary variation on a standard procedure, a unique departure from accepted standards, or the first stage of what should become recognized as a formal surgery research project.” A review of 59 publications describing surgical innovations noted that a minority sought earlier Institutional Review Board (IRB) review or mentioned the innovative nature of the procedure to the patient or noted it on the informed consent form.⁷ Although current publication practice generally requires human subjects issues to be addressed, there is a lack of understanding as to what requires formal IRB approval, and a lack of a uniform standard for the responsible implementation and reporting of innovations. As Reitsma and Moreno⁷ indicated, “the current system of definitions, ethical theories, and voluntary professional guidelines may be inadequate to meet the challenge of surgical innovation.”

As outlined in *Ethical Guidelines for Innovative Surgery*,²⁹ part of the problem likely stems from a deficit in education. Some surgeons lack a thorough understanding of federal requirements and the role of IRBs in the conduct of human subjects research.^{7,30} More fundamentally, there is uncertainty and disagreement among surgeons about what constitutes routine variation on a surgical technique to accommodate a specific patient’s unique circumstances and which requires no earlier approval, versus a planned new or innovative technique that warrants specific informed consent, versus an experimental research study that requires formal IRB approval.^{7,31} In the absence of regulations, as McCullough³² argued, professional integrity may not ensure objective decision making. Looking to one’s colleagues for guidance is important, but it risks potential bias and is not a substitute for IRB review when required. Additionally, unless consulted colleagues undertake extensive literature reviews or conduct well-designed studies of their own, they may not be able to offer reliable evaluations of the scientific merit of new proposals. Similarly, departmental morbidity and mortality (M&M) conferences may provide an opportunity for open, critical discussions of difficult patients and might allow innovators to present new techniques and elicit peer commentary, but should not be viewed as a substitute for formal review.³³ Institutional variability in format and facilitation styles for the M&M conference will likely preclude sufficient standardization to

satisfy demands for accountability in the review of innovations. In addition, M&M conferences can be fraught with political overtones and might not withstand accusations of being somewhat superficial. Further, and most important, M&M review would consider innovations only after they have occurred, providing no protection for patients. So although M&M conferences have some characteristics of effective and prudent surgical self-regulation,¹¹ they do not appear to be the ideal forum for prospective review of innovative surgery.

The least favorable option for regulation is retrospective “oversight” in the form of malpractice litigation.^{34,35} A surgical innovator brought to trial by an unhappy patient who claims to have been an unknowing experimental subject lacks legal protections that would have been available to the prudent surgeon innovator who followed a prescribed oversight process. Conversely, ensuring transparency in the implementation of innovations may offer some degree of protection.

In August 2004, the director of the Association of American Medical Colleges (AAMC) Council of Academic Societies Affairs sent a memo to the presidents of five major surgery societies, suggesting that leaders of the surgical community should provide guidance on this issue. The memo urged the leaders to convene a consensus conference or some other process to accomplish this, and it encouraged application for funding of such a venture through the AAMC’s program with the Office of Research Integrity (ORI), the AAMC-ORI Responsible Conduct of Research (RCR) Program for Academic Societies. The Society of University Surgeons chose to pursue this initiative. The objectives of this project were to clarify the distinction between “variations” (minor modifications not requiring specific disclosure), “innovations” (modifications of potential significance to the patient, requiring disclosure), and “research” (systematic investigations designed to develop or contribute to generalizable knowledge); and suggest guidelines to surgeons and hospitals for appropriate implementation and oversight of surgical innovations. The Society of University Surgeons Surgical Innovations Project team was able to draw from earlier work completed by the University of Virginia Center for Biomedical Ethics, led by Angelique M Reitsma, MD and Jonathan D Moreno, PhD, including the proposed criteria used to identify innovations that require formal review (Table 1).^{7,10,29} The ultimate deliberations and recommendations of the Project team were presented and discussed in an open forum at the Second Annual Academic Surgical Congress in Phoenix, AZ in February 2007. Based on discussion and feedback from attendees, these guidelines were subsequently revised, and the final consensus recommendations are presented here.

Table 1. Surgical Innovations Requiring Formal Review

If the innovation is planned*, AND:
The surgeon seeks to confirm a hunch or theory about the innovation;
OR:
The innovation differs significantly from currently accepted local practice;
OR:
Outcomes of the innovation have not been previously described;
OR:
The innovation entails potential risks for complications;
OR:
Specific or additional patient consent appears appropriate,
Then:
a) The described review by a local surgical innovations committee is required, plus
b) submission to the national innovations registry is required, and
c) additional informed consent is required of the patient specific to the nature of the proposed innovation.

*If an innovation occurred unplanned, it should be regarded as performed on an individual as-needed basis for the benefit of that particular patient, unless it meets any of the other five criteria. In such instances, postoperatively, the patient or patient's surrogate should be informed of the innovative nature of the procedure. If it does not meet any of the criteria, the innovation falls under acceptable modifications of surgical technique. (Adapted from: Reitsma AM, Moreno JD.³⁸ Ethics guidelines for innovative surgery: Recommendations for national policy. A position statement from the Committee on the Development of National Policy Recommendations for Innovative Surgery. In: Reitsma AM, Moreno JD, eds. Ethical guidelines for innovative surgery. Hagerstown, MD: University Publishing Group, Inc; 2006, with permission.)

Summary statements and recommendations

Variations

A variation is defined as the minor modification of a surgical procedure that does not have the reasonable expectation of increasing the risk to the patient. Variations should not extend the time of anesthesia. Example: A surgeon decides one day to perform an appendectomy through a periumbilical incision.

The process of informed consent should include a discussion of treatment alternatives, a complete description of the critical elements of the proposed procedure, the expected outcomes(s) and benefit(s) of the procedure, and the foreseeable risks, and should ensure the patient's understanding of same. Specific details, including the minor variation(s), need not be routinely described and are left to the surgeon's discretion.

Research

Research is defined as "a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."³⁶ Human subjects research is defined in the Code of Federal Regulations (CFR) as "research involving a living individual about

whom an investigator obtains data through intervention or interaction with the individual, or identifiable private information." The Federal regulations for conduct of human subject research conducted with federal funding are stipulated in the CFR, specifically, 45 CFR 46. There are also specific FDA research regulations for biologics, drugs, and devices (21 CFR Parts 50, 54, 56, and 312). The IRB functions under the CFR, and IRB policies are fairly standard across institutions. Although these regulations technically apply only to federally funded research, most institutions apply them to all research conducted at the facility. It is recommended that all research involving human subjects or their identifiable data should be reviewed by an IRB using the relevant federal regulations as a standard. The regulations exist to protect human subjects from harm. The investigator is bound by the rules and decisions of the local IRB. It is the ultimate responsibility of the investigator to ensure the protection of research subjects. Example: A surgeon decides to perform appendectomies through periumbilical incisions on odd days and through right lower quadrant incisions on even days, and compare the outcomes.

All surgeons should be familiar with and adhere to principles of human subject research, as described in the manual, "*Protecting Study Volunteers in Research*."³⁶

Certification in human subject research is mandatory before performing human subject research.

Innovations

An innovation is a new or modified surgical procedure that differs from currently accepted local practice, the outcomes of which have not been described, and which may entail risk to the patient. Many innovations are used on an ad-hoc basis as dictated by the clinical situation. Some innovations, however, may be developed in a more systematic fashion and may ultimately meet the criteria for human subjects research, although they do not meet the criteria at the time they are performed. Example: A surgeon decides to perform natural orifice transluminal endoscopic surgery (NOTES), removing an appendix through a patient's vagina.

Innovations that are necessitated by the clinical situation are ethically appropriate. In the interest of full disclosure and trust essential to the physician-patient relationship, it is recommended that the surgeon disclose the innovation to the patient or patient's surrogate. This disclosure should take place before the operation, as part of the informed consent process, if it is a planned innovation, or postoperatively if an unanticipated innovation takes place during the operation.

The informed consent process should include specific discussion of the innovative aspect of the procedure. Any omission of such discussion arguably involves deception and violates patient autonomy-based rights to submit to care, and could create potential liability for surgeons and their institutions.

If the surgeon uses an unapproved drug or device in an emergency, it is expected that the surgeon abide by FDA guidelines for emergency use of unapproved medical devices (<http://www.fda.gov/cdrh/manual/unappr.html>).

If a drug or device is used “off-label,” ie, with a patient population, dose, route of administration, or preparation that is different from the labeling, it is the responsibility of the physician to determine the relative risk and to disclose it to the patient as part of the informed consent process.

When practical, surgeons are encouraged to first perform the innovative procedure in a simulated or animal model, rather than first attempting a new procedure or skill on a patient.

If a procedure is not described in surgical textbooks published in the United States, its novelty should be described to the patient as an integral part of the informed consent process, even if it is a common practice in other parts of the world.

Some innovations may not meet the definition of research, so would be exempt from formal IRB approval, but would require some form of oversight and more-than-routine informed consent by the patient. Such oversight should occur when an innovation is not yet part of a formal investigation; when the surgeon seeks to assess a hunch, hypothesis, or theory (eg, that the innovation is an improvement of technique); when the new approach differs significantly from current practice; when the outcomes of the innovation have not been previously described; or when the innovation entails risks for complications. If the innovation involves a planned activity with essentially unknown outcomes and risks, the innovation requires additional oversight and submission to a national registry, publicly available to surgeons (described below). This additional oversight should come from a local surgical innovations committee (SIC), as described below.

If it is the intent of a surgeon to perform a particular innovation repeatedly, the SIC should review early outcomes—with consideration of a potential proficiency-gain curve—to determine if this is appropriate, and whether a formal research protocol

should be initiated to assess the value of the innovation.³⁷ The surgeon has a professional and ethical obligation to review the outcomes related to the innovation. If the outcomes are notable, either in a positive or a negative sense, the results should be broadly disseminated. This will allow other patients to benefit from useful innovations, and help other surgeons avoid implementing harmful or fruitless innovations. Dissemination of results should conform to the regulations *Standards for Privacy of Individually Identifiable Health Information*, also known as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Regulations found at 45 CFR Sections 160 and 164. Note that both the federal regulations governing research and the HIPAA Privacy Regulations have rules governing the conduct of research and the need for patient or subject confidentiality.

If a surgeon intends to test a formal hypothesis using an investigational plan, and the innovation is expected to produce generalizable knowledge, it is considered formal human subjects research, and the protocol should be reviewed and approved by the relevant IRB before initiation of the investigation.

Recommended guidelines

We propose the following procedure when a surgeon seeks to introduce an innovation (Table 1). Any surgical innovator who has a procedure that meets the criteria outlined in Table 1 would be expected to submit a proposal to the local SIC for review.

The SIC is charged with ensuring appropriate oversight and disclosure of innovations. Like an IRB, the SIC will assess the relative merits and potential adverse consequences of the innovation, and uphold ethical and patient safety standards. Until there is intent to formally evaluate results or disseminate patient outcomes, however, the SIC will not require documentation of data and privacy protections; it will be considered a quality improvement initiative. If and when the SIC believes an innovation should be subjected to more rigorous evaluation or that the outcomes should be publicly reported, or both, the SIC will direct the innovator to an IRB for approval. Research conducted without IRB approval cannot be later approved by an IRB.

The SIC should be appointed by a responsible leader of the institution, such as the chief of staff, and should provide periodic written reports to the institutional leader. The SIC should have no conflicts of interest with the innovator and be comprised of a Department of Surgery representative who is certified by the American Board of Surgery, and a Fellow of the American College of Surgeons; individual(s)

with a vested interest in patient safety, including a designated patient advocate, and other community stakeholders, as deemed necessary and appropriate. The SIC should enlist local or national experts with experience relevant to the proposed innovation, as necessary. The SIC would be responsible for reporting the outcomes related to any approved innovation back to the institutional leadership that convened the committee.

We propose that a national registry of surgical innovations should be established. In fact, such a registry has been developed and is supported by the American College of Surgeons. The registry may be accessed at: <http://web.facs.org/innovations/innovationsdefault.htm>. This registry contains a listing of ongoing and completed surgical innovations and provides contact information for the innovator. This allows surgical innovators to query the registry before embarking on their own innovation, facilitate sharing of information, and minimize duplicative effort on multiple fronts, particularly for innovations that are unsuccessful and are unlikely to be described in the literature. The local SIC would require the innovators to query the national registry before submitting their proposal and to list their innovation with the registry once approved as part of the review process.

Achieving compliance with these guidelines will require cooperation and buy-in from all vested parties: surgical innovators, patients, surgical societies, and journals publishing articles describing surgical innovation. One potential means by which compliance could be achieved would be agreement among editors of surgery journals that review by a local SIC for any procedure meeting the criteria outlined in Table 1 be required before publication. This would substantively help in the widespread implementation of the proposed guidelines and would be similar to the review currently required by journals for review by an institution's animal care and use committee or IRB for animal or human subjects research before publication.

The goals of this undertaking were to define surgical innovations and distinguish them from minor procedural variations, and formal research, and to suggest guidelines for appropriate implementation and oversight of surgical innovations. Innovations differ from variations primarily in that their outcomes are unknown and they may increase risk to the patient, so they require specific disclosure to patients. On the other hand, innovations require some oversight, but not to the degree necessary in a formal research project. The proposed guidelines ensure transparency, but in a less restrictive manner than formal research. In the end, it is anticipated that patient safety will be improved, while at the same time allowing surgical innovation to continue to thrive.

Appendix: The Society of University Surgeons Surgical Innovations Project Team:

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