Surgical Innovation: Too Risky to Remain Unregulated?
Haavi Morreim, Michael J. Mack and Robert M. Sade
DOI: 10.1016/j.athoracsur.2006.07.003

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://ats.ctsnetjournals.org/cgi/content/full/82/6/1957
Surgical Innovation: Too Risky to Remain Unregulated?

Haavi Morreim, PhD, Michael J. Mack, MD, and Robert M. Sade, MD

University of Tennessee, Memphis, Tennessee; Medical City Dallas Hospital, Cardiopulmonary Research Science and Technology Institute (CRSTI), Dallas, Texas; Department of Surgery and the Institute of Human Values in Health Care, Medical University of South Carolina, Charleston, South Carolina

Introduction

Robert M. Sade, MD

A recent investigation of cardiothoracic surgical studies involving human subjects (Annals of Thoracic Surgery and the Journal of Thoracic and Cardiovascular Surgery) showed that only 10% of such studies are randomized clinical trials, the gold standard for human research. This should not be surprising, because surgical studies are qualitatively different from medical investigations, for example, drug trials, in a number of ways. Surgical trial protocols that use placebo controls or controls with no treatment are often not ethical or not desirable, or both. Target populations for many surgical procedures are often quite small, so series large enough for accurate statistical evaluation may be difficult to develop. Double-blind studies are usually not possible because the surgeon-investigator must always know what he is doing. Most importantly, surgical procedures are characterized by a learning curve that leads to progressively improving skill in performing the procedure, and small incremental changes in the procedure itself lead to progressive improvement in results.

Most progress in surgery comes from innovation that does not fit into the category of surgical research. A commonly accepted definition of research is that contained in federal regulations regarding human subject research: “Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge.” Innovative surgery is often not systematic but is designed to benefit individual patients; there is often no intent to publish the surgical series at a later time, or such intent is secondary. Thus, most surgical innovation is outside the scope of “research” and not subject to oversight by institutional review boards (IRB).

A surgeon’s decision-making is generally motivated by pursuit of the patient’s best interests, yet other motivations lurk in the shadows; for example, pursuit of the surgeon’s interests, such as increasing personal income. Most surgeons recognize the importance of placing the patient’s interests above their own and reject even the intimation of any temptation to recommend unjustified operations for personal gain.

Surgeons who wish to be innovative, however, may have additional interests of their own to pursue ahead of those of their patients: the intangible reward of emotional excitement from breaking new ground and making new discoveries, the possibility of enhanced reputation and of academic advancement through discovery of new information and its publication; the possibility of obtaining grants, awards, or contracts to create a formal clinical trial if an innovation is successful, and perhaps the satisfaction of very strong personal dedication to advancing the science of medicine.

The following case illustrates surgical innovation that is clearly not research, is outside the domain of the IRB, but perhaps requires some kind of oversight.

Case

At general surgery grand rounds, Dr Outinfrunt, a cardiothoracic surgeon at Far South University Health Sciences Center, learns of FlexTexPatch, a new tightly woven polymeric fabric that is used as a covering for abdominal wall defects and as a vascular patch. It has been available for several years in Europe and recently became available in the United States. A few reports in European journals regarding its use as a vascular patch indicate that the material does not calcify as other patch materials do and seems particularly resistant to thrombosis. Dr Outinfrunt looks up the material’s technical specifications and finds that it is resistant to tearing, supple, easy to suture, dimensionally stable, and highly durable, as well as resistant to calcification and thrombosis.

The surgeon is well aware that pericardium, the most frequently used material for reconstruction of left-sided cardiac valves, is subject to structural deterioration after 10 to 15 years due to calcification in 50% of patients in which bovine pericardium is used, and due to tears and infection in 40% of patients in which autogenous pericardium is used. He obtains samples of several different thicknesses of the material and brings them to the
autopsy room where he uses them to augment human mitral and aortic valve tissue. He is very pleased with the handling of the material and its strength in holding sutures. This experience, combined with what he learned about FlexTexPatch’s technical specifications and its performance as a vascular patch, leads him to believe that this will be an excellent material to use for valve reconstruction.

The following week, Dr Outinfrunt has a patient with severe aortic insufficiency who has been scheduled for valvuloplasty. Preoperatively, he conducts his usual discussion with the patient about the benefits and risks of the operation. He also explains in some detail that he intends to use a new material, FlexTexPatch, rather than the pericardium that he has used in the past, because he believes it may be superior in the long run. The patient understands and agrees to the plan, and signs an operative consent form.

Dr Outinfrunt completes the operation and is satisfied with the result. He decides to use this material for such operations in the future. If it works out as satisfactorily as he believes it will, he may even be able to publish his results.

A month later, the patient is readmitted to the hospital with progressive fatigue and dyspnea and echocardiographic findings of severe aortic incompetence. The patch is intact, but the adjacent thin aortic leaflet has torn, due in part to its fixation to a stiffer artificial material and the stresses of frequent opening and closing of the valve. Dr Outinfrunt reoperates, performing an aortic valve replacement.

Surgical innovation has been extraordinarily productive in improving survival and quality of life for many diseases and injuries. Yet, a surgeon’s impulse to innovate may be particularly sensitive to external controls on the surgeon’s judgment. Do potential incentives for innovative surgeons to serve their own interests before that of their patients justify creating some form of third-party supervision of innovative surgery? Is adoption and expansion of oversight systems by governmental bureaucracies inevitable? Can any oversight system avoid creating barriers to surgical innovation? Do the potential benefits from oversight of at least some kinds of innovation outweigh its costs in terms of lost opportunities to advance surgical science?

Dr Outinfrunt’s approach to surgical innovation in this case is repeated daily in different forms by cardiothoracic surgeons throughout the United States. Should there be some form of oversight for surgical innovation?

---

Pro

Haavi Morreim, PhD

Surgery isn’t medicine. On this we can agree, and much more. As Dr Sade points out in his introduction, advances in surgery often do not lend themselves to evaluation by way of the gold standard of clinical trials: double-blind, randomized, (placebo-)controlled. As he also points out, the real work of surgical advancement often comes through incremental innovations, not the decisive sweeps of change that may more obviously require—and permit—a clinical trial.

We can also agree that Dr Outinfrunt’s off-label use of an approved device does not require the approval of any government agency, nor even of an IRB. This is innovation, not research. Unlike a research protocol, his intervention focuses on helping this specific patient, even if done in hopes that others may also benefit from whatever is learned. Research is a protocologized study whose goal is to gain knowledge. Any help to the particular individuals who enroll is by good fortune, not by design [1–3].

Just as importantly, we can agree that this surgeon is highly conscientious and serious about undertaking this innovation in an ethically sound way. He has identified a clear problem with the current standard of care, namely, the significant inadequacies of using pericardium for valve reconstruction. He has done his homework, from evaluating the new FlexTexPatch’s technical specifications and its performance in Europe, to hands-on work in the cadaver lab. And he has ensured that his patient knows that part of the proposed surgery is innovative, and the patient agrees to try it.

Informed consent is an important, sometimes neglected, accompaniment to major innovations. As noted by one court, “when a physician contemplates a novel or investigational procedure he must inform his patient of the novel or investigational nature of the procedure. Absent this, he has committed a battery [4].” Other courts agree: “in order for a physician to avoid liability by engaging in drastic or experimental treatment, which exceeds the bounds of established medical standards, his patient must always be fully informed about the experimental nature of the treatment and of the foreseeable consequences of that treatment [5].” Some courts have found that at least some off-label uses of devices do not require special disclosures [6, 7], but the trend is fairly strong toward disclosure [8–12].

The Downside of Surgical Innovation

We also know that surgical innovations can fail, even those that initially appear very promising. As noted by Henry Beecher in 1961 [13, 14], “[v]arious surgical procedures have been recommended and carried out for the relief of angina pectoris,” including ligation of the internal mammary arteries—a procedure that became widely used until finally shown to be no better than placebo. Indeed, “[t]he history of surgery abounds with examples
of operations that were fashionable at the time and then abandoned after being found to have no specific effect. Examples include nephropexy for so-called ‘floating-kidney,’ colectomy for epilepsy, and laparotomy for abdominal tuberculosis ‘to let the air in’ [14].” Even well-accepted contemporary surgical procedures have been shown, on closer and more rigorous examination, to be no better than placebo [15, 16]. As suggested by some commentators, surgery may itself be the placebo [13, 14]. As the case before us in this debate would indicate, even theoretically attractive, thoughtfully conducted innovations can bring nasty surprises [17].

Nothing—not the greatest care nor the most extensive regulation—can avoid all the risks and adverse outcomes that can accompany surgical innovation. And yet, the fact that we cannot avoid all risk does not mean we cannot reduce it. Where a surgeon contemplates a significant change from prevailing practice, he may needlessly exacerbate the risks when he declines to seek an honest evaluation from colleagues. Moreover, the one who is most enthused about the idea may be least likely to see its potential drawbacks, and the one who has been most immersed in the idea can, at a certain point, be least likely to see its alternatives and potentially helpful improvements. Martin McKneally [18] has discussed the need for “a systematic approach to the introduction and evaluation of new surgical procedures.” He does not recommend formal regulation such as government might impose, but rather a collegial sort of oversight in which such procedures would be reviewed and quite possibly improved before introduction on patients [18, 19]. As he suggests, an idea that cannot withstand collegial scrutiny before a human being has been exposed to the inevitable risk of any innovation may not be quite such a great idea after all. And if the innovation is truly as promising as the originating surgeon believes it to be, then a careful look by his colleagues can not only reaffirm its theoretical merits but may also, by infusing the broader perspectives from others’ clinical experience, introduce significant improvements before it is tried in vulnerable human patients.

Amplifying on McKneally’s lead, I shall propose a mechanism considerably less formal than an IRB process, yet potentially as or more effective in protecting those patients who may be early recipients of surgical innovation. I will describe, first, what kinds of innovations should be subjected to formal collegial review before human implementation; second, what should be included in such a review; and third, how such a review process should be enforced within the profession.

This proposal does not suggest that surgical innovations should routinely be subjected to the rigors of formal clinical research (which would then require IRB review). Although arguably more surgical innovations should ultimately be evaluated by disciplined, gold standard research, the challenges are formidable and in many instances, probably insuperable [20–27]. Rather, I will recommend a fairly informal collegial review of major innovations, a kind of in-house “curbside consult” designed to improve good ideas and weed out those that fellow surgeons consider too risky or still too unrefined to try on patients. As suggested by Spodick [28], “experience suggests that we may always have Sacred Cows. But we should demand quality control of the Sacred Cowboys who milk them and market the products.”

**A Mechanism for Reducing Risks by Requiring Review**

**What to Review**

Clearly, it would be unwieldy, unnecessary, and in most cases, impossible to review every prospective innovation in surgery. A good surgeon must adapt procedures to any patient’s anatomic anomalies and idiosyncrasies, a process of “custom innovation” that often cannot even be anticipated, let alone prospectively reviewed. And many other modifications are incremental refinements more than significant changes. Evolving practical experience often shows the need for such refinements and renders their desirability obvious. And because they are small, they rarely bring significant unanticipated risks.

Rather, the collegial review I propose would be applied to the major innovations—those that are substantial enough that a conscientious surgeon must think them through in advance, conceive of them from start to finish (including potential problems and their solutions), and likely test them in the laboratory. These are the innovations that, if successful, would be good candidates for publication in a professional journal, to share with colleagues, and hopefully, improve practices to help patients elsewhere.

By being both significant and novel, these innovations will also carry potential for unexpected complications—like those Dr Outinfrunt saw when severe aortic incompetence developed when the stronger material from the patch tore away from the thin aortic leaflet.

Hence, we might suggest a rule of thumb: if a contemplated innovation would be important enough to share after the fact if successful, then it is significant enough to be evaluated before the fact to increase its chances of success and reduce its odds of adverse outcomes.

**How to Review**

The surgery departments within any institution in which significant surgical innovations are likely to be contemplated should establish a mechanism for assembling a group with the appropriate expertise to evaluate prospectively the kinds of innovations just described. Mainly, these institutions will be academic hospitals. The membership need not, and probably should not be fixed, but rather should include whoever has the necessary expertise to review and perhaps improve the particular innovation in question, including persons from outside the institution who could participate by electronic or telephonic communication.

The review should include, though not be limited to:

- ensuring that current management truly is inadequate or problematic [29];
- ensuring that the theoretical merits of the proposed innovation withstand scrutiny;
- identifying any need for further theoretical examination, and specifying improvements that might reduce risk and enhance likelihood of success [23];
- assuring that preparatory studies with animals or cadavers, or both, are adequate and identifying any need for further testing;
- making appropriate refinements on the original idea;
- crafting suitable criteria for patient selection and for surgeon selection (the surgeon who conceives the idea may not always be the best one to undertake it);
- determining the kind and amount of training that should be undertaken by the surgical team before human testing [29];
- determining the adequacy of local resources such as equipment and nursing personnel;
- stipulating what sort of information should be provided in the consent process (the review committee may wish to approve a written consent form); and
- specifying a reasonable interval(s) at which to require follow-up information about each patient's outcome.

As suggested by the last element, the review process should not just be prospective. It should be retrospective. When the innovative procedure is completed and a patient's outcome is reasonably clear, the same group should reassemble to discuss:

- how well the realities matched the hopes;
- any unanticipated problems;
- whether this innovation warrants repetition; and
- if so, what sort of patient would be suitable, and how best to address whatever problems arose during the prior patient's operative procedure and postoperative care.

Needless to say, any unexpected longer-term complications, such as happened with Dr. Outinfrunt's patient, should be reported to the review group for additional retrospective review.

**Enforcement Options**

Enforcement mechanisms would not inquire into the details of whether the review group has performed adequately, but rather would inquire whether the review has taken place in good faith. As noted above, the proposed mechanism does not envision a formal, IRB-like review. It is simply a process to ensure that the innovative surgeon has input from colleagues when he wants to do something adventurous.

Various mechanisms could ensure reviews are conducted. Theoretically, government could issue regulations, or large agencies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) might step in. I would not recommend either, however. If the collegial review process described above were mandated from outside the surgical realm, it could easily spawn inflexible bureaucracy and the gamesmanship that often follow. Quickly, form could dominate substance.

I would prefer essentially market-based structures that could foster genuinely effective review, based on mutual respect and collegiality. For instance, professional organizations such as the American College of Surgeons, the American Association for Thoracic Surgery, and the Society of Thoracic Surgeons could state clearly that they expect institutions whose surgeons engage in significant innovation to establish such review mechanisms. Professional journals that publish case reports or retrospective analyses of case series featuring innovative procedures could require that such a review was undertaken as a condition for publication, just as many today will not publish research unless it was IRB approved [30].

In addition, because many innovative procedures will take place at academic institutions, residency accrediting bodies could require such a mechanism in any program undergoing the (re)accreditation process. Detecting failure to comply could be relatively straightforward. Within a given surgical field, those who undertake the accreditation visits are most likely to be familiar with the published literature in that field. When a journal article appears that discusses the rationale, technique, and results for an innovative procedure, these people will know it and will expect the institution to produce appropriate documentation of its collegial review process. Sanctions for noncompliance can mirror those applied to any other significant failure within a residency program, from remedial actions to probation to, if warranted for repeated and unremediated violations, loss of accreditation.

One other source of informal enforcement can come from the broader community. Business firms increasingly encourage their employees to seek health care at the best institutions in the belief that higher quality health care is not only medically better but, in the long run, also more economic. The LeapFrog Group [31], for instance, is a group of more than 170 major corporations and organizations that buy health care. Their goals include (1) reducing preventable medical mistakes and improving the quality and affordability of health care, and (2) rewarding doctors and hospitals for improving the quality, safety, and affordability of health care.

LeapFrog disseminates information about hospital quality ratings to member organizations, for instance, and gives employees incentives to seek higher quality care. Once IRCs are established as a best practice, it is reasonable to expect that corporations such as those belonging to LeapFrog or any similar organization may include IRCs as a criterion for identifying its preferred providers.

**Conclusion**

Surgery cannot progress without the creative efforts of its best surgeons constantly considering how to improve patients' care. Even as these efforts should be encouraged, major innovations can carry significant hazards.
Surgeons need to monitor and guide that progress. Truly, two minds are better than one, and collective wisdom should be sought before a surgeon exposes a patient to the risks that inevitably accompany the potential benefits of a new procedure or a new use of an existing device. The innovation review process described here does not represent a stifling bureaucracy imposed from outside. Rather, it calls upon surgeons to collect their best wisdom as they push forward the boundaries of professional practice.

Con

Michael J. Mack, MD

Surgical innovation has resulted in remarkable advances in the treatment of human disease and suffering. This is particularly true in the past 50 years of cardiac surgery, from the invention of the heart-lung machine, development of heart and lung transplantation, and ventricular assist device therapy to coronary artery bypass and valve surgery. These advances have occurred through a complex system that strikes an effective and productive balance of fostering innovation and introducing new therapy into clinical medicine in an efficacious manner while ensuring patient safety. Professor Morreim is now proposing to upset that delicate balance between innovation and regulation by introducing another bureaucratic layer of committees, which I am afraid, will stifle the innovative process [32].

This is the first that I have become aware of this proposal. But it strikes me that although is hard to argue with the concept of an IRC in theory, the barriers that would be constructed to successful adoption and implementation of innovation by these regulatory bodies, however informal, are such that what will be created is a quagmire of ineffectiveness. Idealism is directly proportional to the distance from an issue. Although the proposal is well intentioned and sensible in theory, my view is that it is an unnecessary intrusion into an intricate, balanced system that is already working and serving patients well.

Innovation Versus Research

Morreim and other ethicists make a distinction between innovation and research [33, 34]. Innovation is defined as a change in therapy to benefit an individual, whereas research is a “protocolized” study, the goal of which is to gain knowledge but not necessarily benefit the individual being treated. This distinction was first made in the Belmont Report by the National Commission for the Protection of Human Subjects of Medical and Behavioral Research [35]. The Report defined three classes of clinical activity: research, practice of medicine, and “innovative therapy,” which is defined as “nonvalidated practices.” Innovative therapies are characterized by being both novel and nonvalidated, which have attributes of both research and clinical practice. Because of concerns that innovative therapies might be applied in an unsupervised manner, the Belmont Report recommended that “significant” innovations be incorporated early in a research project to establish safety and efficacy while retaining the original therapeutic objective [36].

I would rather submit that this is an artificial distinction, and both processes—whether innovation or research, no matter how informal or formalized—are in fact embodiments of the scientific method. The four stages of the scientific method are (1) observation and description of a phenomenon, (2) formulation of a hypothesis to explain that phenomenon, (3) use of that hypothesis to predict the results of a new phenomenon and (4) performance of tests to assess the results of that prediction. The scientific method is the bedrock of every innovation that occurs in surgery, either informal in the surgeon’s mind or formalized in a research protocol. To create a “gray zone” between what constitutes clinical practice and research endeavors that requires regulation is at least nonproductive and at most counterproductive. As Chalmers [37] has stated: “The practice of medicine is in effect the conduct of clinical research . . . Every practicing physician conducts clinical trials daily as he is seeing patients. The research discipline known as the ‘clinical trial’ is the formalization of this daily process.”

Evaluation of New Technology and Techniques in Surgery

To dissect this issue further, it may be helpful to examine how new technology and techniques are introduced into surgery. Innovation in surgery is a complex process that is different from the introduction of new therapies in other areas of medicine. In the world of drug therapy, a standardized treatment—a pill—can be introduced into a study population and its effect, beneficial or otherwise, be determined by appropriate trial design; however, the evaluation of effectiveness is much more complex and difficult in surgery. Variables that need to be accounted for in surgery include not only the innovative technique or device and subsequent iterations of both but also surgeon expertise, the procedural learning curve, the disease being treated, and the ability to distinguish the effects of the therapy from the disease being treated. Operations are not standardized, and one cannot separate the operative procedure from the surgeon performing it. Surgery is a not a pill and, therefore, cannot be evaluated as a pill; it is an iterative process, as is the sustaining technology to facilitate it.
The standards applied to nonsurgical medical research are not generally applicable to the design of surgical research. These difficulties impact the ethics of surgical innovation. Whereas the randomized clinical trial is the highest order of evidence-based medicine, there are many factors that make implementation of that research tool difficult in surgery [38]:

First, it is generally impossible to achieve full blinding in surgical research.

Second, surgery has a powerful placebo effect that may exist independently of the general efficacy of an operation.

Third, as Francis D. Moore has observed, “the most remarkable and effective extensions of surgery have often not required elaborate statistical analysis for their establishment.”

Fourth, there are situations in which randomized clinical trials may be both impractical and ethically dubious. The advisability of a trial is open to serious questions when thousands of patients must be treated to establish statistically significant but otherwise small differences.

Fifth, randomized clinical trials may be impossible when the newer treatment for a given condition is in a state of rapid evolution. The introduction of off-pump coronary bypass surgery is a case in point here.

Sixth, it is often difficult to launch controlled studies of surgical innovation after the new device or technique has become popular. This has been commonly termed “lost opportunity.”

Seventh, it is often difficult to justify the use of a “placebo,” that is a sham procedure in surgery despite its scientific desirability. Although the recent Veteran’s Administration trial of arthroscopy for degenerative joint disease answered a valuable research question, it is difficult to justify the hazards of anesthesia and incisions for no potential therapeutic benefit on an individual basis [39]. Furthermore, Only a small number of patients screened are actually entered into these trials, raising the issue of generalizability of findings for the trial to the population at large. In a meta-analysis of nine trials comparing coronary artery bypass surgery with percutaneous coronary intervention, only 4% of screened patients were entered into the trials, yet we extrapolate the results in a few to the population as a whole [40].

Regulation of Surgical Innovation

Innovation involves iterations of both device and techniques and significant oversight is already in place to regulate both. The US Food and Drug Administration (FDA) at the federal level, medical boards at the state level, and credentialing committees at the local hospital level provide appropriate oversight of medical practice and innovation. Furthermore, professional societies provide practice guidelines for the adoption and implementation of new technologies and techniques. The recently published guidelines for the introduction of percutaneous heart valve therapy [41] and those for thoracic aortic endografting [42] in the clinical practice are current examples. IRBs provide oversight of research at universities and community hospitals alike. Those IRBs include lay individuals to oversee innovation and research. Lastly, research studies include data safety monitoring boards to adequately protect patient safety.

The FDA, according to its mission statement, is responsible for “protecting public health assuring the safety, efficacy, and security of . . . medical devices. . . .” The FDA is also responsible for “advancing public health by helping to speed innovation . . . [43].” In recognition of the different levels of significance, there are different regulatory paths providing different levels of scrutiny by which new devices are approved by the FDA. The most stringent of these is the Pre-Market Approval, which is the process by which the FDA evaluates and regulates the safety and effectiveness of medical devices that support and sustain human life and are of substantial importance in preventing impairment of human health. Clinical studies on human subjects are less stringently regulated by the Individual Device Exemption (IDE) pathway. A more lenient regulatory process (510K) is available for devices that are substantially equivalent to already legally marketed devices.

Once FDA approval is gained, there are specific labeling or clinical indications for which the drug or device has been approved; however, significant off-label use of drugs and devices is frequently the standard of care in clinical medicine today. As an example, of approved pharmacologic agents, the use of 90% of the fluoroquinolones, 50% of the cancer drugs, and 75% of the seizure medications is off label [44, 45]. Similarly, 99% of the use of thalidomide is off label, as is 46% of all pediatric drugs and 25% of all adult drugs. In many conditions for which a drug is prescribed, it is both logistically impossible and financially unfeasible to test the drug or medical device for each indication. This off-label use is both legal and ethical [46]. Such an issue also exists today with many surgical devices, including ablative devices for atrial fibrillation.

Innovation Review Committees

Into this elaborate and effective regulatory structure, we now must consider adding another layer of review, the IRC. Morreim makes a number of assumptions of the practicality of implementing IRCs that are simply not true [32].

First, she claims that innovations are most likely to be contemplated in academic institutions, and therefore, appropriate personnel would be available to form committees. Although that may have been true in a bygone era, nonacademic institutions are frequently at the forefront of innovation and research, from laparoscopic cholecystectomy to coronary stent trials to off-pump coronary artery bypass surgery, because academicians and patients have moved to private practice settings.

Second is the assumption that the review would be collegial and altruistic. Many motivations form opinion—not all of which are consensus, expressed, and beneficial. The assumption that there would be unbiased, beneficent peers willing to “curbside consult” in the current
practice environment is not realistic. The obligate waiting period for the formalization of a process that currently occurs on an informal basis and works well would only stifle and not foster innovation. The curbside consult process that presently exists informally is indeed one of the factors responsible for the current ethical introduction of innovation into surgery.

Next is the opinion that the noninnovator would add balance to the assessment. The spectrum of practitioners range from the innovators to the early adopters to the late majority and the laggards. An IRC composed of laggards would be counterproductive to the process and not only not balance innovation, but would halt progress.

Opinion Regarding the Hypothetical Case
My opinion regarding the hypothetical case presentation posed to us of Dr Outinfrunt is that he acted in a moral and ethical manner despite the fact that his innovation did not work [47]. He used an approved device in an off label use, which is legal and ethical. He was experienced and knew the shortcomings of the current therapy. He performed appropriate due diligence to test the device in the new application in a cadaver lab before the procedure, and he obtained informed consent from the patient about the use of this innovate device. He had a reasonable expectation of success that was based on the experience in the use of the device by others in other indications. The failure indeed may not have been related to the device itself, but rather to the suturing technique, to the disease process, or other patient factors. There is no evidence that he did this for self-gain, and he acted by all accounts in his own patient’s best interest. It is unlikely that there would have been other individuals in his institution with the requisite expertise to render an opinion of value and comprise an IRC. Moreover, if an IRC had existed in his institution, he would have in all likelihood still received approval to proceed with his innovative procedure.

Innovation is hard work. The easy path is to perform the standard proven operation despite its known inadequacies. The extra effort Dr Outinfrunt expended in his attempt to improve his patient’s outcome was laudable and the ultimate expression of individualization of care. It arose from the drive to make a difference and make a contribution to the human condition.

Conclusion
The expansion of oversight systems to surgical innovation that does not fall into the category of research will serve only to stifle the advancement of surgical science. Innovation in surgery should be promoted, not impeded. Friedman [48] has stated in his treatise on political and economic systems, *The World is Flat: A Brief History of the Twenty-first Century*, that excessive regulation tends to hurt most the very people it is supposed to protect. To promote innovation, one needs a regulatory environment that allows an easy start and adjustment to changing circumstances and opportunities and the ability to innovate. Lack of economic development in many African and Middle Eastern countries can be traced to excessive regulation. The same dynamics hold true for surgical innovation as they do for economic development. Adequate regulation of surgical research and innovation that does not fall in to the category of research already exists. Let’s not fix something that isn’t broken.

Concluding Remarks
Robert M. Sade, MD

Dr Morreim has proposed an intriguing idea aimed at improving outcomes for patients who undergo innovative surgical procedures: prior review of the innovative idea by a suitably expert group, which she calls an Innovation Review Committee (IRC). She intends her loosely structured review process to be used for major innovations only, defining a major innovation as a new procedure or device usage that is clearly not research, must be planned in advance, and if successful, is likely to be important enough to share with colleagues through publication in a professional journal. After review, the group would make nonbinding recommendations to enhance the likelihood that the innovation would be successful and decrease the likelihood of unanticipated complications. After the outcome of the procedure is known, the group would reassess to assess the degree to which the initial expectations for the procedure were met, examine any unanticipated problems, and opine whether the outcome justified repetition. She envisions that such reviews could be required by journal editors, by a national professional society such as the Society of Thoracic Surgeons or the American Association for Thoracic Surgery, or by Residency Review Committees, which would have the wherewithal to ensure that the reviews actually occur.

Dr Mack takes exception to this proposal. He describes the existing regulatory environment, including various levels of oversight such as the FDA, state medical boards, hospital credentialing committees, professional society practice guidelines, and IRBs. He rejects Dr Morreim’s assertion that a collegial review group can easily be constructed and suggests that the delays engendered by a formal review would be lengthy and obstructive compared with the informal consultations that already occur. He suggests that IRCs with noninnovator members would be counterproductive and bring progress to a halt. Ultimately, he sees the IRC as regulatory excess attempting to fix a well-functioning system that is not broken.
Dr Morreim, however, does not claim that the system is broken; rather, she recites evidence of unanticipated adverse consequences of several well-known innovative procedures and suggests that the IRC could be part of an overall effort to improve the quality of surgical care. Clearly, her intention is benevolent; however, one might ask: Which alternative weighs more heavily in the balance of benefits and harms: the potential benefit (improved outcomes) of innovative procedures, or the potential harms (a stifling new layer of review)? A glimpse backward into the mid-20th century might be instructive.

An urgent need for oversight of clinical research was recognized in the wake of World War II. The Nuremberg trials of 1947–48 shed light on atrocious human experimentation during the Nazi regime. The revelations of those trials resulted in drafting of the Nuremberg Code, the first international guide to the ethics of human research [49]. Building on that foundation, the Declaration of Helsinki in 1964 promulgated more detailed guidelines [50]. In 1966, Beecher [51] reported a study of 22 human experiments published in several of our foremost journals, conducted in leading medical schools, and funded by federal agencies and major foundations. All were done without the consent of the subjects, mostly children and institutionalized mentally deficient adults, few of whom could have understood the nature of the experiment. Subsequently, the National Institutes of Health published guidelines for human experimentation, followed soon by the FDA’s guidelines for informed consent in clinical drug trials. Within a few years, the Belmont Commission [52] published its well-known report, which provided the foundation for the development and publication of the Common Rule, the set of federal regulations that has established prescriptive guidelines for clinical research in the United States [53].

Both the Nuremberg trials and the Beecher paper revealed horrific unethical human experimentation and provided great impetus for the regulation of human subjects research and the development of IRBs. This brief retrospective prompts the question: What is the impetus for the development of IRCs? Is there evidence of widespread misdeeds associated with surgical innovation? Certainly, all innovations do not result in positive outcomes is to be expected whenever new territory is explored. If we must have some sort of prior review or regulation of innovative surgery, Dr Morreim’s suggestion makes sense—but must we have prior review?

The horns of the dilemma presented by this debate are two unpleasant choices, both arising from inadequate information: we are impaled on one horn by the discomfort of abandoning a well-known, comfortable process of innovation that we believe has served our patients well, and on the other horn by the possibility that our process has serious flaws that might be easily repaired with a relatively innocuous fix. Unlike research, our current process of innovation operates almost entirely under the radar screen. It provides no information about the nature of major innovations actually attempted, how many there are, and their outcomes. The only innovations we hear about (outside of weekly service conferences) are the successes, and then, only those that are important enough to warrant publishing. As a result, Dr Morreim has no horrendous Nuremberg or Beecher experiences to support her case, and Dr Mack has no recounting of the (hopefully) negligible number and severity of harms of innovations-gone-bad to bolster his. Dr Mack cannot confidently assure us—his assertion to the contrary notwithstanding—that the system is not broken, nor can Dr Morreim persuade us that it is.

The resolution of this dilemma, like that of all clinical conflicts, lies in choosing the alternative that will ultimately be best for our patients. But which is the right alternative? There seems only one objective way to make the choice. Some brave soul or institution that is committed to attempting to improve the lot of patients and is persuaded by the case Dr Morreim has made must undertake a major innovation, an administrative trial, so to speak: designing and executing a study of an innovation review process such as she has suggested. I have neither the skill nor the temerity to suggest what the design ought to be, how or which outcomes ought to be measured, or what, if any, controls would be appropriate. Until the results of such an administrative trial are available, however, I am afraid we are stuck with (or on) the horns of this dilemma.

References

5. Ahern v. Veterans Admin, 537 F.2d 1098, 1102 (10th Cir. 1976).