Surgical innovation or surgical evolution: an ethical and practical guide to handling novel neurosurgical procedures

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Object. Surgical innovation is an important driver of improvements in technique and technology, which ultimately translates into improvements in patients’ outcomes. Nevertheless, patients may face new risks of morbidity and mortality when surgical innovation is used, and well-intentioned surgical “experimentation” on patients must be regulated and monitored. In this paper the authors examine the challenges of defining surgical innovation and briefly review the literature on this challenging subject.

Methods. Using examples from the field of neurosurgery and in part from the personal experience of the senior author, the authors develop a model of levels of experimental acuity of surgical procedures and offer recommendations on how these procedures would best be regulated.

Conclusions. The authors propose guidelines for determining the need for regulation of innovation. The potential role of institutional review boards in this process is highlighted.

KEY WORDS • institutional review board • novel therapy • surgical innovation

It should be abundantly clear to every clinician that to conduct research in humans investigators must obtain approval of the protocol from the appropriate IRB. The IRB review of a research protocol is primarily aimed at minimizing risks to the patients from unproven therapies and ensuring that the patients understand, as fully as possible, what their options and risks are. Requirement for IRB approval is articulated clearly by institutions’ codes of research conduct and in published frameworks guiding the ethical conduct of biomedical research.9,17,36,37,54 What is not so clear, however, is which surgical procedures require an IRB examination or some other form of formal regulation. Furthermore, there is mounting evidence that IRBs are under significant strain, exhibiting inadequate levels of performance,5 and are in need of significant reform.46

When the surgical procedure is part of an RCT in which an experimental treatment is tested, such as high-activity brachytherapy for malignant brain tumors, the requirement of IRB approval would seem to be clear.29,44 Nevertheless, most surgical innovation does not take place in the context of an RCT.3,24 Some innovations represent variations in an accepted procedure, such as the application of a stereotactic frame to the placement of intraventricular catheters; this innovation is likely to facilitate a reduction in the number of passes through the brain, thus decreasing the risk to the patient.30 On the other hand, the use of a stereotactic frame may increase the possibility of infection by introducing more opportunities for a breach of sterile technique as the frame is moved in and out of a sterile field and the points of fixation to the base ring must breach the drapes. Another modification is introduced when a stereotactic frame is used to drill the guide hole for the catheter, but is removed before formal draping, thus avoiding breaches of sterile technique and decreasing the risk of infection.2 Does a surgeon require approval from the IRB or another committee or supervisor for such procedures? Similarly, the increased use of minimally invasive surgery has led to a trend toward shorter hospitalization stays, and certain procedures that previously were considered inappropriate for outpatient surgery are now performed in that manner.7,11 Does a surgeon need approval from the IRB or another source for this type of innovation or is this simply the natural evolution of the art and science of surgical practice in action?

Much of the literature on surgical innovation is commentary and/or focuses on specific cases. We propose a number of distinct scenarios of severity, or acuity, regarding the need for regulation of innovative procedures (Table 1). Using examples from the field of neurosurgery and partly from the personal experience of the senior author (M.B.), we explore the need for IRB approval and other forms of regulation in surgical innovation, from an ethical and practical perspective. We will attempt to construct a framework that addresses essentially all situations in which surgical innovators could find themselves.

Practice, Innovation, or Research: Practical Problems Associated With the Assessment of Surgical Innovation

Consideration of widely accepted and binding international agreements on bioethical principles governing hu-
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<table>
<thead>
<tr>
<th>Procedure</th>
<th>Description</th>
<th>Example</th>
<th>Authors &amp; Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>new procedure (never performed previously) elective urgent</td>
<td>neuronal cell transplant</td>
<td>Kondziolka, et al., 2000 Steiger, 2001</td>
</tr>
<tr>
<td>B</td>
<td>fairly new procedure that is part of an RCT</td>
<td>leaving patie to stop bleeding brachytherapy</td>
<td>no specific publication†</td>
</tr>
<tr>
<td>C</td>
<td>amendment to the technique of an established op</td>
<td>microsurgical lumbar discectomy</td>
<td>Laperriere, et al., 1998 Williams, 1978</td>
</tr>
<tr>
<td>D</td>
<td>amendment to other features of an established op</td>
<td>outpatient brain tumor surgery</td>
<td>Bernstein, 2001</td>
</tr>
<tr>
<td>E</td>
<td>new procedure to an individual surgeon</td>
<td>surgeons first complex instrumented spinal fusion</td>
<td>no specific publication</td>
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* MCA = middle cerebral artery
† This maneuver was performed by the senior author circa 1990, but may have been performed by other surgeons as well.

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Every application of a surgical procedure may raise different challenges, requiring an instant innovation. Drawing the line between what would be an experimental form of care and what is merely a slight alteration, which could be classified under the rubric of standard care, may be difficult.

One example with a legislative basis can be found in a paragraph from the Civil Code of Quebec; it states: “care considered by the ethics committee to be innovative care required by the state of health of the person concerned does not constitute an experiment” (Article 21, Paragraph 4, Civil Code of Quebec).12

When innovative care does not constitute a formal research protocol, the cost of care is covered by hospital budgets.12,39 This has several implications. In an era of technological advances with an ever-increasing pressure on finite health care resources, there is a growing demand to rationalize clinical practice.4,10,15,19,20,32,39,45,50 Apart from the obvious obligation to apply the most scientifically sound treatment available to the patient’s problem,18,34,35 public accountability is an important consideration when resources might be diverted from other worthy social causes.17 Minimization of the potential impact of conflict of interest on the part of the innovator (for example, potential publication or financial gain) can be addressed by third-party adjudication of outcome parameters1 and by rigorous peer review by journal editors, reviewers, and members of the profession while innovation is in the development stage.24 Confounding factors at this stage include the tendencies for an innovative technology or technique to evolve, its applications to be altered, and the experience of innovators to increase with improved performance (progression along the learning curve).5,38 Although undertaking a formal assessment at too early a stage may give a distorted picture that is biased against the new technology or technique,38 in the interest of patient safety, the IRB should insist that the surgical innovation be tested in a formal research study.36,54 The degree of urgency should be determined by how radical the new procedure is.38

It is useful to differentiate between an innovation in technology and one in technique.40,50 Before the former can be introduced into surgical practice rigorous training is required, such as taking defined courses to study the equipment, visiting a center where the equipment is currently being used, acclimating oneself to the equipment with the aid of a proctor, and finally independent operating with review.26,32,33,34,35 The surgeon’s institution should require any combination of the aforementioned training as a minimum for an innovation in technology. Innovation of technique, when conducted by an experienced surgeon, probably does not require the same degree, rigor, or urgency.

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of institutional review. Nevertheless, it is the responsibility of the institution and the profession at large to scrutinize the procedure in the interests of patient safety. In a situation in which the innovation has achieved sufficient success such that there is uncertainty as to which therapy (novel or standard) constitutes the best treatment, an RCT should be conducted to compare the two therapies.

In certain instances the pressure to obtain institutional or peer review of an innovative therapy is not as rigorous as it should be. This may occur more often in privately funded surgical practice than in publicly funded practice. Regulation of innovative surgery and, as a result, patient protection is then achieved only by the apparent necessity of avoiding malpractice litigation. This is unsatisfactory because the fiduciary relationship between a physician and patient is damaged when avoidance of litigation rather than beneficence is the motivator for regulation of innovation. Litigation tends to set only the minimum standards for acceptable patient care.

Possible Scenarios

A New Procedure (Procedure A)

This type of procedure is new to all surgeons (Table 1). It is imperative to subdivide this scenario into elective and urgent situations. In the first case, we must ask: Should IRB approval be required for an elective novel procedure such as transplantation of cultured human neuronal cells to treat patients with major stroke? The obvious answer would be “yes.” The demonstration in preclinical studies that the procedure has potential value and a favorable risk/benefit ratio and the assessment that the procedure is the sole therapeutic option are all prerequisites for IRB approval. In such a scenario the IRB would be placed in a position to examine a novel and exciting treatment and contribute to the initiative by ensuring an optimum risk/benefit ratio and the best possible informed consent process, as well as providing ongoing monitoring.

Some could argue that an alternate approach would be for respected peers of the surgeon to endorse the proposed procedure and for formal permission to be obtained from the surgeon-in-chief. Unfortunately, this approach could certainly be associated with some bias depending on the surgeon-in-chief’s attitude, level of conservatism, and trust in the track record of the surgeon involved in the innovation. Appropriate informed consent from each patient would be a prerequisite and the IRB should be sent a copy of this form. Oversight of the surgeon’s experience with the new procedure by a committee or a respected individual (perhaps a senior surgical innovator) would be necessary.

In an emergency situation, the decision to undertake a novel neurosurgical procedure that involves significant risk cannot wait for IRB approval because of the extremely short time lines available. Numerous examples exist in everyday practice such as the first time a dental mirror was introduced into the operative field so that the surgeon could see around a corner deep in the brain, and stopping an intractable hemorrhage from a hole on the side of an artery with a cloth surgical pattie because it is the only thing that worked. In the latter case the hole was created by an aneurysm clip, which tore off a small but wide-based aneurysm from the parent artery. The maneuver was performed some years ago by the senior author without any knowledge of whether it had been performed previously. It would be considered unorthodox at minimum and definitely would introduce some risk of infection due to a retained foreign body.

These innovations could not possibly be assessed by an IRB because of the urgency of the situation. The recommended course of action taken to address the problem would be discussion with an experienced colleague if possible. Some objectivity and experience could be introduced to help solve the problem, and the principles of nonmalfeasance and beneficence would be honored, although informed consent would not be possible. The procedure ultimately undertaken in the emergency case was, in the surgeon’s judgment, the one least likely to be associated with complications, even though there was some risk involved in its undertaking.

The surgeon’s mandate should be to do the best for the patient, using the best clinical judgment tempered by clinical experience and knowledge of one’s surgical limitations. If time and opportunity allow, requesting feedback and support from an experienced colleague is highly desirable to provide a more objective assessment of the problem and its possible solutions.

Arm of an RCT (Procedure B)

The surgical arm of an RCT represents the archetypal or “paradigm” case requiring IRB approval (Table 1). In any situation in which there is clinical uncertainty about which of two or more treatments is superior and patients are randomly assigned to treatment groups, the most rigorous safeguards must be in place to protect patient safety and autonomy. The legitimacy of the RCT should be based on evidence of systematic preclinical development, the performance of phase I and II clinical studies, and the availability of appropriate technology. Neurosurgical examples would include the study of extracranial–intracranial arterial bypass as a treatment for cerebral ischemia and the two randomized studies of the use of interstitial brachytherapy as a radiation “boost” for de novo malignant gliomas. The IRB should fill an important role in addressing the ethics of the standard therapy arm in an RCT, particularly vis-à-vis the use of placebo controls.

Eventually many novel procedures undergo proper scientific testing in the setting of an RCT; however, many procedures do not, for a variety of reasons including the tremendous difficulty and expenditure of time, energy, and resources required for the proper conception and execution of an RCT.

Amendment to the Technique of an Established Operation (Procedure C)

Should IRB approval be required for an amendment to an established operative technique (Table 1)? Common sense would suggest that it would depend on how major or radical the amendment is. For example, the stereotactic technique is basic to neurosurgical practice. Its application to the insertion of an Ommaya reservoir would be expected to increase the accuracy of catheter placement with very little additional risk to the patient, except, perhaps, the possible increased risk of infection. The risk of infection can be addressed by appropriate adjustments, that is, further technical amendments that ultimately remove the frame from

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the operative field.\textsuperscript{2} No mandatory requirement for IRB approval is probably necessary if the innovations are not radical and are performed by a surgeon with established experience in stereotactic technique, thus resulting in a favorable risk/benefit ratio for the patients.\textsuperscript{2,17} The same situation applies to the introduction of the operating microscope for routine neurosurgical procedures, such as microsurgical lumbar discectomy.\textsuperscript{32} What is required of such an innovation is the surgeon’s demonstrable familiarity with the technology, which can be enhanced with a period of training, proctoring, or supervision mandated and regulated by a professional or local training body.\textsuperscript{26,31} This simple but elegant innovation revolutionized the technique of an exceedingly common procedure performed by neurosurgeons and orthopedic surgeons.

Also within this category is the introduction of novel technology to enhance a standard neurosurgical operation. An example of this would be the introduction of open magnets located within the operating room so that real-time magnetic resonance imaging can help guide the removal of a brain tumor.\textsuperscript{4} This novel technology is associated with obvious surgical advantages for patients. It is beneficial for the surgeons as well because it allows them to view changes in real time that would be difficult with the naked eye, which is such a crude tool for distinguishing the interface between normal brain and intraxial tumors. Nevertheless, IRB approval would likely be required, partly because of the possibility of risks and complications not previously encountered, such as a missile injury to the patient or staff if a magnetic object is accidentally introduced into the field of the magnet.

Amendment to Other Features of an Established Operation (Procedure D)

An example in this category (Table 1) would be the combination of a standard neurosurgical operation such as craniotomy for tumor resection and a stereotactic brain tumor biopsy performed on an outpatient basis.\textsuperscript{13} Is this surgical innovation or purely evolution of the art and science of neurosurgery, and what should be the role of the IRB or other formal regulation? In this case the senior author has experience in stereotactic technique, thus resulting in a favorable risk/benefit ratio for the patients.\textsuperscript{2,17} The same situation applies to the introduction of the operating microscope for routine neurosurgical procedures, such as microsurgical lumbar discectomy.\textsuperscript{32} What is required of such an innovation is the surgeon’s demonstrable familiarity with the technology, which can be enhanced with a period of training, proctoring, or supervision mandated and regulated by a professional or local training body.\textsuperscript{26,31} This simple but elegant innovation revolutionized the technique of an exceedingly common procedure performed by neurosurgeons and orthopedic surgeons.

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New Procedure to an Individual Surgeon (Procedure E)

Once neurosurgeons have been licensed by fulfilling the requirements of a recognized residency training program and passing the requisite examinations, they are qualified to function independently in the jurisdiction covered by their licensing body. Does this imply that the neurosurgeon is qualified to undertake all neurosurgical procedures? Neurosurgery is becoming increasingly specialized and complex, and not every training program exposes neurosurgical trainees to every surgical procedure. Many residents who have recently completed their training are not competent to deal with certain complex neurosurgical cases independently. A resident may not have performed a particular procedure a sufficient number of times to achieve competency and/or the procedure may be so complex that it is primarily performed by staff neurosurgeons alone or in teams. Examples would include removal of a complex arteriovenous malformation, major brachial plexus reconstruction, odontoid screw placement, and endoscopic third ventriculostomy. For general neurosurgeons who are not fully comfortable with such an unfamiliar procedure, it would be unethical to perform it and expose the patient to unnecessary risk.\textsuperscript{31,32}

The same argument would hold for a situation in which a resident, who is supervised by a staff surgeon, undertakes a procedure with which he or she is not yet comfortable. There would be no role for an IRB in sorting out this issue; the problem is one of surgical qualification and not innovation or research. Additional training, such as a clinical fellowship with recognized experts may be required for some procedures, and for others tutelage by an experienced colleague on a number of cases might suffice. Ultimately permission could be obtained from one’s senior peers and the surgeon-in-chief as described earlier in Procedure A, Elective.

Recommendations

When considering surgical innovation the verdict of history would argue against initial rigid control. Nevertheless, the great benefits of heart surgery, total hip replacement, transplant surgery, and numerous neurosurgical examples have not been achieved without the costs of patient morbidity and mortality. Many previous innovations would possibly not be acceptable to today’s IRBs. The benefits of increased scientific knowledge and technology should and
can be extended to patients with minimal risk, a requirement consistent with the frameworks guiding the ethical conduct of biomedical research.

The surgeon’s mission is to achieve the best results for the patients, and common sense and knowledge of one’s own surgical limitations are paramount for safe surgery. Innovation is a normal part of human nature, especially for academically and technically driven people such as neurosurgeons, and innovation is essential as new situations and challenges arise. Many innovative techniques and technology are born of immediate necessity, but many others can be developed with the luxury of planning and preparation.

Recommendations for the Surgical Innovator

We make the following recommendations. 1) All procedures that are performed as part of an RCT should be scrutinized by the IRB. 2) A brand new procedure that is scheduled to be performed electively should probably be reviewed by the IRB and sanctioned by one’s senior peers and the surgeon-in-chief. 3) Procedures that represent major modifications to accepted surgical procedures should similarly be examined by the IRB and sanctioned by one’s senior peers and the surgeon-in-chief. 4) Minor or evolutionary modifications may be exempt from IRB approval. One can never be too careful, however, and if there is any question, sending a brief protocol to the IRB does not represent a great expenditure of resources or time. Sanction by one’s peers and the surgeon-in-chief might be appropriate in these cases. 5) Finally, for procedures which represent personal innovation for a surgeon in doing a standard but complex procedure for the first time, the IRB has no role.

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