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Ethics and Innovation in Surgery

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FROM THE EDITOR

Responsible Progress in Surgical Innovation: A Balancing Act

Catherine Frenkel

Doctors' desire to innovate is fueled by the moments when patients look to them for solutions and they have none to give. Quick adoption of new technologies, however, can be a double-edged sword. The potential to help future patients must be weighed against the risks of harming those who currently seek care. Medical innovation pits beneficence and nonmaleficence against one another in the name of progress, creating tension between physicians' most fundamental values.

During my surgery rotation in the third year of medical school, I became acutely aware of how subjective the decision to operate may be. Many times, the decision to enter the OR is equivalent to choosing between life and death. I observed several instances in which surgeons who wanted to withdraw care were at odds with those more inclined to operate. Where some saw operations that prolonged agony, others saw opportunities for tiny victories that offered patients a little more time. There is no single formula to compare a patient's quality of life to the suffering that may possibly be caused by surgery. Whether we adopt or eschew new technologies, lives always hang in the balance.

The term "innovation" suggests advancement, just as "evolution" connotes progress toward something better. Scientific innovations are desirable because they create new possibilities and offer better performance; in the marketplace, consumers choose new over old. But the tendency to conflate "newest" with "best" can be dangerous in health care settings. This issue of *Virtual Mentor* explores the possibilities and perils of developing, testing, and embracing new procedures, devices, and techniques in the surgical suite. This month's contributors touch on innovations in surgery at every phase of their development, from design and research to FDA approval and postmarket adoption into clinical practice.

The first phase of innovation for surgical devices is their design and development. During this stage, business entrepreneurs and scientists unite to identify unsolved problems and develop widely applicable solutions. Kevin Z. Chao, Daniel J. Riskin, and Thomas M. Krummel explain how the Stanford Biodesign program teaches innovation as its students work to create new devices. A formal education in this field can encourage responsible innovation. The lengths to which device developers and their employees must go to ensure responsible use of their products are controversial. This month's health law article by Kristin E. Schleiter considers the phenomenon in which manufacturer's representatives join surgeons in the OR to ensure that devices function properly and are correctly employed. Court decisions

have clarified the point at which device makers cease to be held liable for the performance of surgeons who use their approved technologies.

In research on innovative surgeries, patient data is used to develop knowledge and new techniques for future application to patients with similar conditions [1]. Safeguards that protect patients from harm during research include the informed consent process and oversight by institutional review boards (IRBs). Research differs from other paths to innovation in surgery because IRB approval is required for trial protocols, subject recruitment methods, informed consent, and so on. A case commentary by Robert Sade asks whether surgeons in clinical trials have an obligation to provide information above and beyond what is on the IRB-approved consent form.

Innovation in surgery also occurs outside the research process. As Joseph Fins has written, therapeutic, validated surgery has the potential to become innovative, and perhaps experimental, depending on the situation [2]. Unplanned experimental innovations happen during emergencies, when surgeons follow protocol until lifesaving improvisation is required [3]. Informed consent is not typically feasible, but is considered implied because the alternative is immediate death or serious morbidity. Non-experimental innovations are the result of planned variations on accepted techniques. The changes predictably improve results but are sufficiently minor that consenting patients need not acknowledge them.

Somewhere between clinical improvisation and research lie instances in which proven protocols gain off-label use. When off-label use becomes widespread, the new application may re-enter the validation process. Caitlin Weber's piece examines the controversies surrounding FDA-approved products that are used to achieve new endpoints or applied to untested subsets of patients, such as children. Weber demonstrates that guidelines have yet to be clearly established for re-evaluation of procedures that become innovative when applied in a new context. The ethics of performing surgery off-label for new indications outside of the approved patient population is debated in the second clinical case. Commentaries by Robert E. Brolin, Angelique M. Reitsma, and Bruce Schirmer take different stances on the appropriateness of a new application for an approved and time-tested surgery: bariatric surgery as a preventive measure against type 2 diabetes.

Aspects of surgical protocol over which surgeons typically exercise autonomy—including favoring newer device brands over others—can influence a procedure's outcome. Device- or surgeon-specific variability within a given type of procedure is common but difficult to regulate. One possible way to oversee device selection without sacrificing physician autonomy is the model provided by national joint registries. As Fabian von Knoch, Anthony Marchie, and Henrik Malchau note, some devices are found to be defective or to cause complications for a particular group in the postmarket stage. Patients in countries with national registries greatly benefit from comprehensive tracking of success rates for new joint implants. In his case commentary, Charles Rosen strongly advocates that surgeons disclose the

experimental status of new devices and give information about their postmarket success rates during the informed consent process. The clinical pearl, by Allen Carl, delves into the spine stabilization technology featured in Rosen's commentary, explaining how the latest surgical techniques were developed and why they remain controversial.

Surgical innovation does not always involve new surgeries or implants; it may also refer to changes in the OR setting. The standardization of operating team procedures might, at first, be considered conservative by surgeons accustomed to a culture of autonomy and individualism. Julie Ann Freischlag points out that, in fact, OR safety measures are an innovative way of improving patient outcomes. As Ankur Aggarwal's piece on the history of surgery explains, similar safety-oriented changes were able to improve medical doctors' perception of surgery over the course of human civilization. Decried as dangerous butchery, last-ditch attempts to save lives with radical surgery were assaults on patients and "mutilation and suffering [were] caused by too late and hopeless operations" [4]. Advances in sterile technique and anesthesiology elevated surgery to a respected and trusted field with a high success rate.

Innovation in surgery has its costs to patients and surgeons as well. Thomas Starzl, one of the fathers of transplant surgery, notes that "hardly a transplant surgeons in that era [of the 1960s] escaped infection [with hepatitis]. My chief research technician...died from hepatitis and so did many others. Eventually, it was proved that a hepatitis reservoir existed in the transplant wards and clinics." Starzl, too, was infected with hepatitis [5]. His journey to success entailed great personal sacrifice, yet in his memoirs he insists that the benefits far outweighed the risks of the innovative procedures he performed. Medical advancements also have costs to insurance companies and the health care system. This month's medicine and society piece, by Joseph J. Fins, weighs the costs, literal and figurative, of controversial central thalamic deep brain stimulation (DBS). Fins persuasively argues that the advantages of DBS are substantial—not only in terms of therapeutic benefit, but also, surprisingly, economically.

Despite the promise of innovative surgery, its potential to do harm with untested, unsafe, or inappropriate procedures remains. If undertaken responsibly, innovation can promote the best interests of both the individual patient and society as a whole. Great ideas may spring from creativity, but it is only when coupled with vigilant attention to patient safety that they lay the groundwork for great progress.

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CLINICAL CASE
New Devices and Truly Informed Consent
Commentary by Charles Rosen, MD

Amy, a medical student, joins her attending physician to obtain informed consent from Mrs. Jones for spinal surgery. The surgeon explains the expected recovery and rehabilitation to Mrs. Jones, who is 70 years old, along with the probable consequences of forgoing surgery. She enthusiastically agrees to the surgery. Her husband walks regularly and she is eager to accompany him in his routine. The attending surgeon schedules Mrs. Jones to have dynamic stabilization system B, a newer class of pedicle screw, implanted into her spine.

Amy is worried that Mrs. Jones is not aware of her option to have a more tried-and-true system implanted instead of System B. System B is FDA-approved, but it is one of many dynamic stabilization devices for spinal fusion whose manufacturers the FDA is requiring to conduct postmarket surveillance of device fusion and adverse events, including failure rates. Recently, Amy read about several national record-keeping systems that track outcomes for other medical device implants. The Swedish hip register, for example, tracks hip implants for 10 years post-surgery. A physician expert in this register estimated that "the risk in the United States that a patient will need a replacement procedure because of a flawed product or technique can be double the risk of countries with databases…and doctors in Sweden are much less likely than American doctors to embrace new devices until registry data show they work." Is the surgeon ethically obligated to tell Mrs. Jones about the FDA surveillance and to explain the different stabilization systems to her?

Commentary
Yes, he is. In order to give truly informed consent, Mrs. Jones has the right to be informed, in lay terms understandable to her, about two crucial matters: the surgeon's reasons for preferring one device over the possible alternatives and the device's status and performance.

If a physician prefers one treatment over another, as in Mrs. Jones' case, the patient has a right to know why. Different procedures have different risks; some procedures are more or less familiar to or difficult for individual surgeons; and some surgeons want opportunities to try out new procedures. This is part of the basis upon which treatments are advised and, as such, the patient should know. For instance, if a surgeon does not recommend the best procedure for the patient because he or she does not perform it well, then the surgeon should make that known and maybe even refer the patient to another surgeon. As importantly, the surgeon is obligated to tell Mrs. Jones if he or she has received money from the company that manufactures the

device for any type of work, and how much. The quality of patient care must not be subordinated to other concerns.

In addition to disclosing financial involvement with the device manufacturer, the surgeon is definitely obligated to tell Mrs. Jones about alternatives, as well as the fact that the device has only been in use a short time and therefore has not stood the test of time as more established procedures have. Mrs. Jones should be clearly told that postmarketing surveillance is still being conducted on the device in question, and that questions regarding its efficacy are arising from financially independent sources. It is the responsibility of the surgeon to be knowledgeable about these issues in order to advise implantation of the device.

The surgeon must also remain aware of potential bias in device research and tracking. U.S. surgeons are often earlier adopters of new technology that may be problematic because they believe that what they read is true independent validation. The dearth of disclosure among high-profile, highly paid consultant physicians leads to a false impression that device research is unbiased. The objectivity of the reported data is also being questioned because of potential bias among researchers due to financial relationships with manufacturers [1, 2]. Also, surgeons in the U.S. don't have the government registries that other countries' surgeons have to quickly and objectively see outcomes and complications. Because such registries put inferior products at a disadvantage, manufacturers, and many medical society officers who are highly paid consultants for industry discourage them.

To address such issues, I founded and am president of the Association for Medical Ethics (AME), which has over 200 physician members from 11 different countries, and which is entirely self-funded. Ethical Rules of Disclosure were developed by AME after a joint symposium with the University of California, Irvine, School of Medicine [3]. These address such issues as specificity in disclosures: is reading a disclosure that says an author is a consultant for Company X the same as reading a disclosure that says the author received a million dollars last year from the manufacturer of the device being researched? No, it is not. If readers and patients knew the amount of money involved in such relationships, they would be better informed about the possibility of bias, intentional or unintentional, and might be more reticent to use devices. Patients comprehend these issues readily regardless of educational level.

Furthermore, apart from assessing potential bias, physicians should know if the quality of data is strong—Levels I and II—or weaker—Levels III, IV, V—when evaluating whether new procedures or drugs should be used. It is the objectivity of medical research that should be of paramount concern, more so than the famous author or institution from which the data comes.

Another important part of the surgeon's job in obtaining informed consent is speaking to the patient in understandable lay terms. Spouting technical language, though easier for the surgeon, can be alienating as well as be incomprehensible.

There is no reason that analogies and examples to explain procedures cannot be formulated. If being creative in explanations is required to ensure patient understanding, then it should be done. This will strengthen trust between patients and physicians by allowing patients to grasp the nature of the procedures they are having. In order to keep the art of medicine alive, that trust between physicians and patients cannot be abused. Patients like Mrs. Jones deserve no less than complete and understandable information in order to make their decisions.

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CLINICAL CASE
Prophylactic Bariatric Surgery
Commentary by Robert E. Brolin, MD, Bruce Schirmer, MD, and Angelique M. Reitsma, MD, MA

Mrs. Brown, who is 35 years old, has a BMI of 37. Her father struggled with diabetes mellitus type 2 for 30 years. She was his sole caretaker, nursing him through complications of peripheral neuropathy and helping him to complete his tasks of daily living after a leg amputation. Recently, he went into renal failure and died. Mrs. Brown also has a 45-year-old brother and several other first-degree relatives who have diabetes type 2 and are insulin dependent. Mrs. Brown confided her worries to her physician and was referred to a bariatric surgeon for a consultation. She says that she has worked with nutritionists and tried to exercise more, but her efforts have not been successful over the long term. Determined to avoid becoming a diabetic, she would like to have bariatric surgery. The surgery cured her friend's diabetes. With a BMI of 37 and no obesity-related diseases, Mrs. Brown does not qualify as a candidate for the surgery under the current guidelines. But were she either to gain weight (raising her BMI to 40) or develop diabetes (a condition which would lower the recommended BMI to 35), she would qualify for the intervention. She understands that insurance is not likely to cover the procedure, but money is not an obstacle. What should the consulting surgeon say to Mrs. Brown?

Commentary 1
by Robert E. Brolin, MD
The incidence of type 2 diabetes mellitus (DM type 2) in the U.S. is increasing at an alarming rate that appears to parallel the growing prevalence of obesity. The effectiveness of bariatric surgery in ameliorating DM type 2 has been well documented during the past 3 decades [1-3]. Although the mechanisms that induce weight loss among the various operations vary widely, any operation that results in substantial weight loss is likely to improve or resolve DM type 2.

The weight criteria that determine candidacy for bariatric surgery were first established in the 1970s. In that early era, the minimum weight for considering bariatric surgery was 100 pounds above one's so-called ideal body weight as established by standard life insurance tables [4]. In 1991, the NIH held a consensus development conference on gastrointestinal surgery for treatment of severe obesity. At the conclusion of that conference, the panel recommended that surgery could be considered for any patient with a body-mass index (BMI) equal to or greater than 40 for patients with a BMI between 35 and 40 who had medical diseases that most likely resulted from severe obesity [5]. These weight criteria—unmodified for nearly

2 decades—are still used by virtually all third-party payors who cover the costs of bariatric surgery.

Recently, several groups from abroad have published results of weight-loss surgery on patients with a BMI equal to or less than 35. One group prospectively compared outcomes after laparoscopic adjustable gastric banding (LAGB) and a diet/exercise program in patients with a BMI between 30 and 35. After 2 years weight loss, evidence of the metabolic syndrome and quality of life were significantly improved in the LAGB group compared with the nonsurgery group [6].

Prophylactic Surgery

The concept of "prophylactic surgery" is not new, and its use to avoid complications of the underlying disease has been ethically justified in a variety of areas. Until recently the strategy of repairing asymptomatic inguinal hernias to prevent incarceration was almost universally applied. Likewise, cholecystectomy is frequently recommended for asymptomatic gallstones to avoid subsequent complications. Repair of congenital atrial or ventricular septal defects in children is routinely performed to avert cardiopulmonary disease in adulthood, and incidental appendectomy to eliminate the potential for later appendicitis is still performed by many surgeons during abdominal operations for other causes. In each of these circumstances, the surgery is justified on the perceived basis of a favorable risk-to-benefit ratio.

Risks Associated with Bariatric Surgery

The perioperative risks associated with bariatric surgery have decreased substantially during the past decade. The mortality risk of all currently performed bariatric operations is less than 1 percent, ranging from perhaps 0.1 percent with LAGB to nearly 1.0 percent for biliopancreatic diversion with the duodenal switch (BPD/DS) [7-9]. The mortality rates of Roux-en-Y gastric bypass (RYGB) and the new sleeve gastrectomy (SG) fall somewhere in between [8-9]. Increased morbidity and mortality with RYGB is consistently correlated with male gender, age 50 years or older, and BMI equal to or greater than 50 [10, 11].

Prophylactic Bariatric Surgery

Assuming that Mrs. Brown in the case scenario we are asked to consider has made serious attempts at weight loss using dieting in conjunction with exercise and behavior modification, I believe it is ethical to perform bariatric surgery. The perioperative risks in a woman of Mrs. Brown's age who has a BMI of 37 and no overt comorbidities should be very low. Conversely, the potential benefit of avoiding DM type 2, with its attendant end-organ complications, seems worthy of pursuit. Mrs. Brown's strong family history of both obesity and DM type 2 suggests that eventual development of diabetes is likely. Moreover, in evaluating Mrs. Brown's lifetime health, the risks associated with clinically severe obesity (defined as BMI equal to or greater than 35) cannot be ignored. The mortality risk at her current weight is more than double that of a woman of the same age with normal weight [12]. Life table models suggest that a 40-year-old woman with a BMI of 40 will live

about 4 years less than her normal-weight counterpart [13]. Moreover, virtually all morbidly obese patients will develop obesity-related comorbidities over time. Our group reported presence of at least one obesity-related comorbidity in 95 percent of our bariatric surgery patients who were 45 years or older [14].

Selection of the most appropriate operation for Mrs. Brown requires a detailed discussion with her bariatric surgeon. Most bariatric surgery patients have a strong preference for a specific operation prior to their initial surgical consultation. Frequently these preferences are based entirely upon anecdotal information gleaned from other bariatric surgery patients and materials available through the internet. It is uncommon, however, for prospective patients to have a clear understanding of the risks of the various procedures or how specific operations produce weight loss. I would present both LAGB and RYGB as reasonable alternatives for Mrs. Brown. (Sleeve gastrectomy might also be considered, but the long-term results are unknown, and, although the BPD/DS provides excellent long-term weight loss in a clear majority of patients, the metabolic risk seems excessive for a woman without overt comorbidities and a BMI of 37 [15].)

Because there is no anatomical rearrangement or malabsorption with LAGB, improvement of DM type 2 is directly related to postoperative weight loss. LAGB requires considerable patient compliance in terms of the adjustments involved with tightening the band. Weight loss after RYGB is greater and more rapid than with LAGB. Moreover, DM type 2 may resolve immediately after RYGB prior to substantial weight loss [2]. These benefits must be contrasted with the long-term risks of slip or device malfunction after LAGB or the potential risks of marginal ulcer and vitamin and mineral deficiency that can develop after RYGB.

In summary, there is little if any justification for waiting until Mrs. Brown gains weight to perform bariatric surgery. The available data strongly suggest that the long-term mortality risk of not having bariatric surgery in qualified patients is significantly greater than having a gastric restrictive operation during the same time interval [1, 16, 17].

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Commentary 2
by Bruce Schirmer, MD

One can readily sympathize with Mrs. Brown's concern about (probably bordering on fear of) developing diabetes. She has seen the consequences of the disease over the long term and wishes to avoid a fate similar to her father's. Consequently, she has requested bariatric surgery to avoid becoming a diabetic. Mrs. Brown has evidence that bariatric surgery can work to reverse the diabetic state, and she has the

means to pay for the operation. From her point of view, this is a reasonable request, and she seeks the help of a bariatric surgeon who will perform surgery for her.

The patient is correct that bariatric surgery can eliminate the active disease state in type 2 diabetes patients. Blood glucose comes under control, medications are often eliminated, and hemoglobin A1c levels can fall to normal. The Roux-en-Y gastric bypass (RYGB) is the best operation for reversing the active state of diabetes and allowing patients to eliminate medications and insulin. Multiple large series in the literature have shown that about 85 percent of patients with type 2 diabetes, who have been on diabetes medications for 5 years or less, become euglycemic without medications after having RYGB [1-3]. Patients who have been on medications for longer periods of time are less likely (about 50 percent) to become medication free.

The mechanism by which RYGB reverses diabetes is still being investigated. Multiple observations by hundreds of bariatric surgeons on thousands of diabetic patients after RYGB confirm that the reversal of diabetes occurs in a much more rapid time frame than would be expected based on weight loss alone after the operation. Recent studies have shown that, in the animal model, diversion of the food stream from the duodenum and proximal jejunum produce amelioration of diabetes, which then returns if the operation which produced the diversion is reversed. In South America, RYGB has been performed on patients who are not obese but do have type 2 diabetes. The amelioration of symptoms in these patients has been as good as in the obese population, with only modest associated weight loss [4]. There is much more to say about these findings, but for purposes of this commentary, we can accept the fact that Mrs. Brown's belief in the operation's effectiveness in treating type 2 diabetes is well-founded.

Currently accepted guidelines for the performance of bariatric surgery are that a patient has a body mass index of 40 or a body mass index of 35 with a co-morbid medical condition caused by or exacerbated by obesity. These guidelines have been in place since an NIH Consensus conference in 1991 [5]. They have not yet been modified, though recent data, such as those collected in South America, suggest there may be appropriate indications for broadening the application of bariatric surgery beyond its present guidelines. At this time, however, no changes have been made to the standards.

In my opinion, the ethical dilemma in this case is a fairly straightforward one: should one perform bariatric surgery as a prophylactic procedure for someone who does not meet the currently accepted guidelines for bariatric surgery? While this may seem an ethical dilemma in some ways, there really is only one answer: no. Standards and rules are created for a purpose—to be followed. It would be easy to justify "fudging" just a little bit on an indication such as this. A surgeon could perhaps, if swayed by the patient, feel justified in performing bariatric surgery for her. After all, she is close to the BMI limit for surgery. Such a rationalization, however, can serve as justification for breaking all sorts of rules and standards. If it were appropriate to

operate on this patient with a BMI of 37 and no co-morbidities, then it would be easy to say that 36 would also be OK. Where would the rule-bending end?

The guidelines for performing bariatric surgery are, one could argue, arbitrary. They are based on a decision of a panel of experts rendered almost 20 years ago. Nevertheless, they are the only available guidelines, and they are recognized internationally. They form a distinct line in the sand over which one should not step without the expected consequences of potential legal or professional sanction. If Mrs. Brown were to have an operation and develop a complication, the surgeon would not be able to defend his decision to operate in a court of law.

As surgeons, we face many situations in which the recommendation for performing an operation is not strictly black and white. Guidelines for determining whether to operate do not always exist. This can even apply to fairly significant extirpative surgery, such as the performance of a mastectomy as a prophylactic procedure for a woman at extremely high genetic risk for developing breast cancer. Such surgery is felt to be justified by the potential loss if the woman were to have undetected breast cancer that developed beyond an early stage. Similarly, removal of the esophagus for severe dysplasia in the setting of Barrett's esophagus is justified because development of esophageal cancer would likely occur in a short time for such a patient, and that diagnosis would carry a significant percentage of death from the disease. Less severe operations, such as a cholecystectomy, may be thought to indicated or not indicated by different surgeons based on their individual interpretation of whether the patient has symptoms from the stones. For bariatric surgery, however, the guidelines are well established and understood. The decision in this case scenario is clear. Mrs. Brown should not be offered the operation.

While that is the long and short of this scenario, I would feel remiss if I were to ignore the significant ethical dilemmas that bariatric patients currently face in our society. The ongoing discrimination against people who are obese—the last unaddressed discrimination in our society—is the first dilemma faced by these patients. The second is the lack of understanding on the part of the public and much of the medical profession that obesity is a disease. Laziness, lack of discipline, and other negative character traits are not solely responsible for the condition of severe obesity in many of the patients who have that problem. Finally, the arbitrary determination for access to potentially lifesaving surgical therapy remains largely in the hands of insurance companies, which have enacted many measures to limit the ability of qualified patients to secure coverage for bariatric surgery. Special riders on insurance policies, blanket denials for minimally invasive "experimental" procedures after hundreds of articles in the literature have established their appropriateness, creation of special 6-month preoperative diet periods (which have been shown to decrease patient overall outcomes, not improve them), and other hurdles intended to minimize the number of procedures the company pays for are all ethical issues much more pressing than adhering to accepted guidelines for determining bariatric surgery candidates. Obesity is the second-largest cause of health care expenditures and morbidity after smoking, and probably will take first place in the near future. Its

worst form, severe obesity, is highly curable with surgical therapy. Yet, in 2009, less than 2 percent of the patients who qualified to undergo bariatric surgery in the United States received and benefited from it. Bariatric surgery is proven to be life-lengthening and highly capable of eliminating comorbid medical problems and vastly improving the quality of life for patients who undergo it. Any discussion of the surgery must underscore these points.

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Commentary 3
by Angelique M. Reitsma, MD, MA

Even after a lengthy debate between bioethicists, physicians and surgeons and a plethora of publications, there currently are no formal, federal regulations that apply specifically to surgical innovation [1-3]. Consequently, the gap between regulatory goals and professional reality still exists, and as some argue, is widening due to increasing call for evidence-based surgery [4].

To close the reported gap between research idealism and surgical innovation, several authors have presented solutions to this ethical challenge. Recently published recommendations from a multidisciplinary group, which included both surgeons and bioethicists, put forth some specific and detailed guidelines for surgical innovators [3]. These guidelines were designed to help surgeons determine at what point their efforts to improve their operative techniques and therapies become innovations that would warrant additional scrutiny and outside review. Basically, they explain exactly how and when such innovations become different enough to be viewed as a form of experimentation. This signifies a point at which clinical practice goes beyond the existing standard of care, and outside of the realm of tried-and-true treatments [3]. The guidelines that were firmly founded on earlier work [2], stipulate the following:

> 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 subject research, although they do not meet the criteria at the time they are performed. Example: A surgeon decides to perform Natural Orifice Translumenal Endoscopic Surgery, removing an appendix via a patient's vagina [3].

In earlier work published by two authors from the same group [1], an additional definition of innovation was offered. Innovative use of a procedure included its application to a disease or diagnosis for which it had never been used before. This particular situation appears to apply to the clinical scenario we are discussing—performing prophylactic bariatric surgery for diabetes mellitus type 2.

First, let us take a step back and frame the ethics of surgical innovation in general. Innovative or experimental surgery has the potential to provide great benefit to patients who undergo new, sometimes life-saving procedures. In and of itself, surgical innovation is not an unethical thing, but because its risks are partly unknown and its benefits equally so, because of the lack of existing evidence, it is ethically contentious. Striking the right balance between beneficence and non-maleficence is challenging. The flipside of non-maleficence, in the case of surgical innovation, is that not offering the latest available therapies to a patient may constitute doing harm. Performing an older procedure that is going out of fashion because of disappointing outcomes instead of a newer, more promising technique seems harmful. Surgeons are required to stay current with the developments in their profession, and adopt techniques that are proven superior to the existing ones. The importance of this is reflected in the obligation to earn continued medical education (CME) credits and in (medico-legal) licensing procedures. Not staying up-to-date and hanging onto obsolete techniques while being wary of innovation is not considered good surgical practice. This stance was underscored by some of the responses to a survey among US surgeons [1]. One respondent wrote: "Surgeons that do not innovate should be the ones that need to be regulated!" One might conclude that the balance between harming and doing good is indeed delicate, and perhaps even ambiguous, when it comes to innovative surgery.

Even more ethically ambiguous is prophylactic innovative surgery. Bariatric surgery in and of itself is not an innovative or experimental surgical procedure. It has been performed for a number of years, studied and evaluated for its merits. What is innovative is the application discussed in this case: performing bariatric surgery for a new diagnosis, essentially a possible future diagnosis, one that does not exist yet but is a possible occurrence, though by no means a certainty, at a later point in the patient's life. As is well established, diabetes mellitus type 2 (DM type 2) can develop over time in overweight individuals, particularly those with a family history

of the disease. While it would be wise for everyone to avoid becoming obese for a wide variety of health—and other related—reasons, anyone with a family history of DM type 2 especially should avoid obesity in order to have a better chance to ward off DM type 2. This can be done by adhering to a healthy lifestyle, which includes regular exercise (as little as a 30-minute brisk walk each day) and a wholesome diet. For most people, this should be adequate to retain a healthy weight and a normal body mass index (BMI), which subsequently diminishes the chances of developing DM type 2. Some might argue that for particular individuals, such as those with a predisposition toward weight gain and a family history of obesity or those who cannot exercise regularly because of severe physical limitations, these measures may not be able to control weight. For such individuals, bariatric surgery may be viewed as an extreme but appropriate measure to ensure the lowest calorie intake possible, leading to reaching a healthy weight.

Bariatric surgery significantly minimizes the size of the patient's stomach, thereby allowing only small amounts of food and drink to be taken in at one time. This makes it difficult for a person to eat large amounts of food throughout the day and, hence, reduces caloric intake, resulting in weight loss. But bariatric surgery is by no means a guarantee for continued weight loss or, better said, maintaining a healthy weight. Although the stomach may be small, patients who consume calorie-dense food and drinks and do not exercise enough will gain weight. We have only to look at the tabloids and see the celebrities who had their stomachs stapled, lost huge amounts of weight, and then gained some, sometimes a lot, of it back within years. This means that even after bariatric surgery, patients must be counseled about a lifelong healthy diet, learning which foods and drinks to avoid reversing the effects of the operation. Bariatric surgery in and of itself is no long-term guarantee for maintaining low weight and thereby indirectly minimizing the chances of developing DM type 2. Significant lifestyle changes would still be necessary to achieve that.

To offer this surgery to someone for the purpose of avoiding the potential long-term effects of her obesity, given this knowledge and the fact that this is a major surgical procedure with significant risk and morbidity, is not good surgical practice. With this in mind, I think it is clear that using bariatric surgery prophylactically in this case is not ethical and should not be performed.

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CLINICAL CASE
Technical Skill and Informed Consent
Commentary by Robert M. Sade, MD

Dr. Crick is participating in a randomized clinical comparison of percutaneous aortic valve replacement therapy with standard medical therapy in a group of patients with aortic valve disease and comorbidities so severe that they cannot undergo open aortic valve replacement. Dr. Crick's surgical team, part of a multi-institutional investigation, has sought and obtained IRB approval of the study. Each surgeon received didactic training and performed the first two procedures under the supervision of a surgeon experienced in the technique. Mr. Alton, 65, is the 15th patient on whom Dr. Crick will perform the procedure.

Without surgery, the patient has a 50 percent probability of dying in the next 18 months. Two of Dr. Crick's previous trial patients died following their surgeries, although their deaths may have been due to significant comorbidities. Four other operations resulted in paravalvular leaks that required further surgery. The other surgeons on Dr. Crick's team have had a lower rate of complications and the study's Data Safety Monitoring Board has cleared the group to continue the trial. Dr. Crick is confident that Mr. Alton will benefit from this procedure and that the study results will lead to greater benefits for future patients than the current medical standard. In providing information to Mr. Alton during the informed consent process, is Dr. Crick ethically obligated to divulge data about his experience with the procedure beyond what is outlined in the approved IRB consent form?

Commentary
The clinical investigation of a surgical device described in this vignette is unusual because reports of randomized clinical trials (RCTs) are much less common in the surgical than the medical literature: only 5 to10 percent of the research papers published in cardiothoracic surgery journals are RCTs [1], compared with about 24-35 percent in the medical literature [2]. There are good reasons for the relative paucity of surgical RCTs. A 10 mg tablet is a 10 mg tablet, no matter who prescribes it, but a particular surgical procedure varies considerably according to the surgeon's technical skill and techniques. Also, surgical proficiency changes with time, leading to improved outcomes as the surgeon ascends the learning curve. Finally, double-blind studies are nearly impossible in surgery for the obvious reason that the surgeon always knows which techniques and devices he or she is using. Target populations in surgical investigations are often quite small, making accurate statistical analysis difficult [3]. This problem can be overcome by using multi-institutional design to increase numbers of subjects, as was done in this case.

Surgeons are motivated to pursue good outcomes for their patient-subjects, as those are good outcomes for the surgeons themselves. Other motivations, however, may cloud the surgeon's judgment. For example, the patient-subjects in the vignette study are not candidates for standard open-heart aortic valve replacement, so recruitment into the study will increase the number of operations surgeons perform and, consequently, will augment their incomes [4]. Intangible motivations such as enhancing the reputation of the surgical group and of individual surgeons through participation in a large research project can also lead to a biased presentation of the benefits and risks during the informed consent process, in order to recruit a large number of patient-subjects [3]. A surgeon must constantly guard against such biases during the informed consent process, in both research and clinical surgery.

None of these potential conflicts of interest is likely to occur in this RCT, however, because none of the potential subjects is initially under the primary care of the surgeon—they are under the care of a cardiologist, and the informed consent process for inclusion in the study will be undertaken by the cardiologist or the cardiologist's designee, not by the surgeon, who is likely to see the patient for the first time after informed consent and randomization. The surgeon will, of course, provide a separate informed consent process before the surgery is undertaken, but at that point, the potential for bias is minimal.

As the study progresses and information regarding outcomes becomes available, conveying new information to the patient-subject could be biased by the possibility that the patient-subject might choose to withdraw from the study, thus potentially harming the reputation of the surgeon or group of surgeons or weakening the trial. The question raised at the end of this vignette is whether Dr. Crick has an ethical obligation to provide the patient-subject new data in addition to the information contained in the IRB consent form. Dr. Crick does have such an obligation, because providing relevant new information is required by Food and Drug Administration and Department of Health and Human Services regulations that control informed consent in studies involving human subjects: "A statement that significant findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject" [5, 6]. In Mr. Alton's case, the question is whether there are any significant new findings, and, if so, precisely what they are. While overall trial results may track the expectations asserted in the IRB consent form, Dr. Crick has experienced a higher complication rate than the other surgeons in the group; perhaps Mr. Alton should be apprised of this new information.

I suggest that these data need not—and perhaps should not—be reported to Mr. Alton because the fact that Dr. Crick's complication rate is higher than that of the other surgeons in the group should not be considered a "significant finding," for several reasons. First, the Data Safety Monitoring Board (DSMB) is responsible for ensuring the safety of all patient-subjects in a clinical trial, including determining whether a particular surgeon is not competent, and it made no such determination regarding Dr. Crick. The standard for acceptable performance of a surgeon in clinical

surgery and in surgical research is neither excellence nor superiority: it is competence [7]. Dr. Crick meets that standard, so information about complication rates is not a significant finding. Moreover, each surgeon-investigator received didactic training and expert supervision of the first two procedures; this is less experience than is often required in surgical research protocols, suggesting that the surgeons in the study are broadly experienced in open-heart surgery and have had demonstrably good results.

Second, we know that Dr. Crick's complication rate is higher than that of the other surgeons in the group, but we do not know whether the group's complication rate is much higher, much lower, or about the same as those of surgeons in the study's other participating institutions, so Dr. Crick's rate may be well within acceptable range or may even be better than the average rate of all surgeons. The DSMB has recommended that Dr. Crick's group continue the trial, suggesting that the group's overall complication rate is not egregiously high compared with that of surgeons in other institutions.

Third, this higher rate of complications could be explained by Dr. Crick's learning curve—along which progressive improvement in outcomes is expected—having a lower slope than those of the others in the group, given that learning curves differ among even the most accomplished surgeons. Alternatively, this higher rate might entirely disappear after those data are risk-adjusted for comorbidities and other risk factors. The higher complication rate could be due merely to chance variation in outcomes; Dr. Crick has done 14 percutaneous valve replacements, but this is far too small a number to permit statistical analysis that could reliably differentiate these outcomes from those of other surgeons in the group or from those of all the surgeons in participating institutions.

This complication rate alone says nothing about Dr. Crick's competence as a surgeon or the benefits of percutaneous aortic valve replacement, so to provide Mr. Alton with the results of Dr. Crick's specific procedures would be misleading at best, and could lead to a poorly informed—and therefore unwarranted—decision not to participate in the study, which would do a disservice to Mr. Alton.

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MEDICAL EDUCATION

A Patient-Centered, Ethical Approach to Medical Device Innovation

Kevin Z. Chao, MD, Daniel J. Riskin MD, MBA, and Thomas M. Krummel, MD

Students, residents, and fellows are in the front lines of patient care, confronting countless unmet clinical needs daily. Usually these needs are recognized momentarily and forgotten quickly, with attention diverted to the next consult or procedure. Often the need is missed completely. Medical trainees are all too familiar with the 2 a.m. page about the confused elderly patient who fell on the way to the bathroom, screaming baby with challenging IV access, or conversation with a cancer patient when no further allopathic treatment options are warranted. Each is an opportunity to ask, "Can we do better?" Those in the trenches are best positioned to identify problems and develop solutions. The guidelines for developing needed solutions to these unmet needs that follow come from a program dedicated to that specific purpose.

Demystifying Medical Device Innovation

To those outside the industry, medical device innovation can be daunting—where does one even begin? The process is undoubtedly arduous and full of uncertainty, but Paul Yock, MD, director of Stanford's Biodesign Program and inventor of many catheter-based technologies, believes it can be taught. The Biodesign Program, now in its 9th year, brings together students and postgraduates in medicine, engineering, law, and business to embark on a 1- to 2-year fellowship in medical device innovation. The focus is on early-stage device development, from need identification, to concept and prototype development, to completion of a business plan [1]. Along the way, the fellows learn about intellectual property, the regulatory pathway, reimbursement patterns, and market evaluation and apply this knowledge to their fledgling projects. Dr. Yock emphasizes that the program is about education—by understanding the process, an innovator can maximize his or her probability of success. But Dr. Yock will also note with a smile that a dozen or so companies have developed out of the Biodesign Program.

Challenging Conventional Wisdom

More than 50 years ago, when he was still a scrub technician at a Cincinnati hospital, Thomas Fogarty, MD, imagined using a tiny balloon at the end of a thin rubber tube to extract clots from the inside of blood vessels. His prototype was the cut fingertip of a size-5 surgical glove tied to a urethral catheter. Surgeons scoffed at his naivete. "Only one so uninformed and inexperienced would dare do such a thing" [2]. Conventional wisdom held that manipulating the inside of a vessel, much less scraping it with a balloon, was dangerous. Surgery was the only way, even if it required slicing up a major vessel, putting the patient through hours of general

anesthesia, and substantial risk of losing that limb. Undeterred, Dr. Fogarty—then just "Tom"—persisted. His invention became what is now known as the embolectomy balloon catheter, a device used in hundreds of thousands of cases a year and whose underlying technology is the cornerstone of endovascular therapy.

As physicians, our pledge to "first, do no harm" can put us at odds with our natural drive to explore new ways to improve the care we give our patients. A novel treatment, especially a device-based one, inherently carries new risk. The more novel the idea, the more risky it often is. The original problem or unmet clinical need must have the potential to bear a solution that justifies the risk of trying something new.

Challenging conventional wisdom in medicine is difficult, especially for those still in training who are struggling to master accepted practice, prognoses, and pathophysiology. This preoccupation with committing tradition to rote memory may deter the young trainee from questioning the status quo. It is precisely this category of innovator, however, who is unaware of what cannot be done and unhindered in recognizing the true clinical need, the root cause, current solutions, and potential better options.

Focusing on the Patient

Navigating the difficult process of medical device innovation while maintaining an unwavering moral clarity is an immense challenge and responsibility. Stanford Biodesign's philosophy is that innovators must focus on the needs of the patient [1]. When confronted with competing interests, recognize that gray areas exist and that each innovator will be guided by his or her own ethical compass and unique set of values. Having a mentor, insightful colleague, or supportive innovation network can help assure that energy is devoted to areas that offer high potential for success and that the process maintains the highest ethical standards. As a concrete ethical framework [3, 4], we follow the four foundational principles of biomedical ethics established by the Belmont Report in 1979 [3,5]:

Beneficence. Aiming to do good for patients is the underlying motivation in solving any unmet clinical need.

Nonmaleficence. "First do no harm." Most devices carry inherent risk, and the potential benefit must justify the potential risk.

Respect for autonomy. Respecting others' rights to make their own, fully-informed choices demands that innovators be completely transparent with anyone who could be affected by the technology, informing them of potential risks, benefits, and alternatives. It also demands disclosing all conflicts of interest.

Justice. Justice requires commitment to deciding fairly among competing interests, sometimes through third-party arbitration, in resolving conflict. It also calls for reasonable, nonexploitative, and well-considered procedures to be administered fairly.

Confronting Ethical Challenges

Innovators may encounter ethical challenges at any phase of the innovation process. A common dilemma for physician-innovators is participation in early-stage evaluation and development of their own ideas and technology [7, 8]. In preresearch phases, the physician is on his or her own in framing an ethical procedure. Often a promising device has several suspected flaws that can only be tested and mended through more experience with its use in patients. At this stage, an institutional review board (IRB) becomes involved, but the need to strike clinical equipoise remains. Is there honest professional disagreement among clinicians about the preferred treatment? Do informed professionals have no preference between the standard and innovative treatments? If the device in question were a cell phone, the deliberation would be far less weighty. But because human lives are at stake, medical device entrepreneurs must be rigorously vigilant about the potential effects of their decisions.

Moving from Development to the Clinic

Only a small fraction of ventures are successful. With idea in hand, one must seriously vet the opportunity in terms of market, competitive landscape, and technology risk; bring together the right people; and raise sufficient capital from the right investors. "Sufficient" generally means "a lot of money," more than what grants and donors can typically provide. Exactly how much depends on the nature of the venture. How technically complex or invasive is the technology? How many patients will need to be studied and for how long? What kind of business model drives revenue?

In most cases, getting a device to market is only the beginning. From there, the battle increases in intensity. How will the company drive adoption, secure reimbursement from payers, beat out its competitors, and continue innovating? Many medical device start-ups raise tens to hundreds of millions of dollars from investors. At later stages, most founders will have lost control of the company to investors. The innovator must recognize that investors are most interested in making a return on their investment—that is their fiduciary duty to their limited partners. The innovator must strike a balance between meeting the needs of patients and those of current or future investors. Often these duties are aligned, but conflicts of interest can arise.

Making an Impact

Medical device innovation is undoubtedly arduous, but physicians owe it to their patients and to the next generation of doctors to question the status quo continually. There are many ways to improve the lives of patients—innovating medical devices is one way that can affect many. Medical trainees and anyone who still practices with curiosity and wonder should recognize a clinical need when confronted by one, challenge conventional wisdom, be alert to new opportunities. If you think there is a better way, write your ideas down. At first, the idea may be criticized as heretical. That's okay. It would not be revolutionary otherwise.

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Daniel J. Riskin, MD, MBA, is an acute care surgeon and health care technology entrepreneur. He has developed four health care products and launched three companies dedicated to improved patient care. He has received awards for his work in innovation from *Technology Review*, the American Medical Association, and U.S. Trust and has spoken on medical technology innovation at the National Institutes of Health, NASA, the Defense Advanced Research Project Agency (DARPA), Stanford, Harvard, and MIT.

Thomas M. Krummel, MD, professor and chair of surgery at Stanford University school of Medicine in Palo Alto, is an internationally regarded pioneer in the application of virtual reality, simulation, and performance metrics in surgical education.

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THE CODE SAYS
AMA *Code of Medical Ethics*' Opinions on Patenting Procedures and Devices

Opinion 9.08 - New Medical Procedures
In the ethical tradition expressed by Hippocrates and continuously affirmed thereafter, the role of the physician has been that of a healer who serves patients, a teacher who imparts knowledge of skills and techniques to colleagues, and a student who constantly seeks to keep abreast of new medical knowledge.

Physicians have an obligation to share their knowledge and skills and to report the results of clinical and laboratory research. Both positive and negative studies should be included even though they may not support the author's hypothesis. This tradition enhances patient care, leads to the early evaluation of new technologies, and permits the rapid dissemination of improved techniques.

The intentional withholding of new medical knowledge, skills, and techniques from colleagues for reasons of personal gain is detrimental to the medical profession and to society and is to be condemned.

Prompt presentation before scientific organizations and timely publication of clinical and laboratory research in scientific journals are essential elements in the foundation of good medical care. [Updated June 1994.]

Opinion 9.09 - Patent for Surgical or Diagnostic Instrument
A physician may patent a surgical or diagnostic instrument he or she has discovered or developed. The laws governing patents are based on the sound doctrine that one is entitled to protect one's discovery. [Report issued prior to April 1977.]

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JOURNAL DISCUSSION
Risks and Benefits of Innovative Off-Label Applications
Caitlin E. Weber

Dresser R. A regulatory and legal perspective: issues in off-label device use. In: Altman LK, Mussallem MA, Dresser R, et al. Outside the operating room—economic, regulatory, and legal challenges: a collection of perspectives and panel discussion. *Cleve Clin J Med*. 2008;75 Suppl 6:S61-70; discussion S70-S73.

FDA-approved therapies occasionally prove insufficient to treat certain diseases or specific patient populations. In such cases, physicians often turn to drugs or devices that have been approved for use in other settings. Such off-label applications of therapy carry a number of potential risks and uncertain benefits, given the lack of evidence and oversight supporting their use. This article examines some of the major ethical challenges associated with off-label innovation in the context of the controversial off-label use of drug-eluting stents, along with the somewhat more promising use of recombinant activated clotting factor VIIa (rFVIIa) in pediatric patients, a group that poses unique challenges when it comes to innovation.

Ethical Challenges in Off-Label Therapies
In her discussion of the ethical issues associated with off-label device use, Rebecca Dresser draws attention to the complex interaction between law and medical ethics that arises when regulatory practices and the drive for innovation come into conflict with one another [1]. She approaches this issue through a discussion of drug-eluting coronary stents (DES), FDA-approved devices for the management of certain forms of coronary artery disease, specifically small, newly diagnosed blockages.

Since the approval of DES in 2003, it has been increasingly used off-label for high-risk diseases, such as large blockages or small blockages in patients with comorbidities. These indications are quite different from the relatively low-risk conditions for which the device was approved. In 2007, a number of negative case reports led an FDA advisory panel to issue a tentative warning concerning off-label use of DES, citing adverse effects including "increased risk of thrombosis, death, or myocardial infarction compared with on-label use" [1]. A recent study by Carlsson et al. that analyzed outcomes of over 30,000 Swedish patients who received a stent in the past 7 years supported the panel's conclusions by demonstrating a statistically significant higher risk of myocardial infarction associated with the off-label use of the device when compared with on-label use [2].

Despite studies such as Carlsson et al.'s, Dresser points out that insufficient evidence concerning off-label applications continues to be a significant barrier to safe off-label

use of DES in patients with arterial blockages. She estimates that more than half of all patients receiving DES today are receiving them off-label, suggesting a very real need for better regulation and oversight. Although several professional groups, including the American Medical Association and the American Academy of Pediatrics, have issued general recommendations concerning off-label therapies, most choices fall to individual physicians who must balance their patients' medical needs with the limited data supporting most off-label uses [1].

Dresser describes a number of significant challenges to obtaining the data necessary to remedy the lack of evidence supporting off-label DES use. Even when a drug or a device has not been FDA-approved for a specific application, manufacturers are often permitted to discuss off-label uses with physicians [3]. Furthermore, with off-label use already so common, there is little financial incentive for product manufacturers to fund the clinical trials needed to test efficacy and safety, making such research costly and impractical. An additional confounding factor lies in the immense difficulty of conducting research in certain patient populations: most clinical research is done with adults and as a result there are fewer therapies explicitly approved for use in children and older adults, necessitating more off-label applications for these patients due to insufficient on-label options [1].

The willingness of individual physicians to implement off-label therapies without sound clinical evidence varies widely. When physicians do use these treatments, the process of gaining informed consent becomes exceedingly problematic. Dresser observes that there is no legal obligation on the part of the physician to inform patients of the off-label status of a therapy. As a result, many patients could be receiving devices such as stents without understanding the nature (or in some cases, lack) of clinical evidence supporting the physician's choice of treatment—a practice in clear conflict with the fundamental principle of respect for persons underlying all ethically sound medical decision-making.

Pediatric Medicine and the Need for Innovation

Off-label therapies occupy a unique position within the context of current medical innovation. New applications of old therapies have paved the way to important medical advances, as evidenced by the numerous drugs designed for the treatment of one condition and later shown to be beneficial in the treatment of another. Surgical innovation has followed a similar pattern, from early surgeons' developing novel ways to tie a knot to the introduction of robotic surgery in recent years [4]. In order to move from research toward innovation, new ideas must be applied directly to patients, a practice with some unavoidable degree of risk. For most devices and drugs, this transition is carefully regulated through the three phases of clinical trials and FDA approval, but, in the field of pediatrics, the difficulty of conducting the required trials with children has necessitated a different approach.

The responsibility to respect the patient's right to autonomy becomes more complicated when treating young patients who lack the ability to make informed and rational medical decisions on their own behalf. As Riskin et al. acknowledge, this

has required physicians to favor "the best interests of the child" over "respect for autonomy" (a standard component of caring for adult patients) when insuring the ethical treatment of children too young to provide informed consent [5]. Generally, parental permission and child assent determine these "best interests." While this approach may be sufficient for some medical decisions, such as choosing between various on-label therapeutic options, it seems inadequate when discussing enrollment in a randomized controlled trial. While a 12-year-old may understand that a trial is experimental or even wish to be enrolled in one out of altruistic motives, not all do, and it becomes difficult to justify more innovative approaches in patients who are unable to comprehend the nature of the intervention. Apart from the ethical questions raised by research using young children, clinical trials can be extremely expensive and cost often becomes a prohibitive feature [5].

With such insufficient research concerning the use of certain drugs and devices in children, doctors treating sick children may be forced to choose between an off-label use of a therapy proven to be effective in adults or a potentially less effective on-label option. Krummel explains this dilemma by providing the example of chemotherapeutic drugs, the vast majority of which have not been approved for use in children due to the costs and risks associated with conducting the needed trials for FDA approval [6]. Despite this fact, pediatric cancer patients do receive chemotherapy because the risks of administering even an off-label drug are deemed slight when compared with those of untreated cancer.

Responsible Applications of Innovative Therapies

Though Dresser's concerns about off-label innovation in the use of DES are sound, pediatric medicine requires a different approach. As long as issues like cost, safety, and ethical treatment of the patient drive most research to be conducted in adult populations, physicians will have to rely on technological and medical advances tested in adult patients, carefully applying them to younger children without the prerequisite clinical trials. As Krummel points out, this is not necessarily a bad thing, for "children have benefited enormously from the duality of technology development, in which a technology developed for one population—either adult or pediatric—ends up benefiting both populations" [6].

One notable example of successful off-label innovation is rFVIIa. Originally developed as a hemostatic agent for a specific subset of hemophilia patients, rFVIIa has been used over the past decade to treat conditions for which it has not been FDA-approved. These off-label uses include platelet disorders, disseminated intravascular coagulation, and the management of excessive bleeding during surgery in some patients without coagulation disorders [7, 8]. While there are several scenarios in which prospective randomized trials have demonstrated either no benefit or considerable harm associated with the off-label use of rFVIIa [7], its use in children with excessive bleeding has been associated with significant clinical benefit thus far [8]. These promising results obtained by Young et al. support the conclusion reached by Riskin and his colleagues that pediatric medicine occasionally demands that risks be taken with off-label treatments in order to provide clinical benefit. While the

success of such innovation can vary greatly depending on the specific off-label application being considered, the large number of articles and case studies published on this topic has made it possible to identify those patients who will receive the greatest benefit from off-label use of rFVIIa [7].

While all off-label applications require a great deal more evidence, oversight, and post-market surveillance than on-label use [1], and carry potential risks, they should not be dismissed altogether. Further research assessing the safety of therapies such as rFVIIa and DES is important if their approved on-label uses are to be expanded to encompass current and consistently successful off-label uses. Likewise, any potential off-label use should be carefully considered in light of all available evidence, as well as a respect for the rights of the research subject and patient.

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CLINICAL PEARL
Development and Use of Dynamic Spine Stabilization Devices
Allen Carl, MD

To understand the evolution of dynamic spine stabilization devices, it is helpful to look into the history of spine treatment concepts. Dynamic spine stabilization devices evolved from prior spine stabilization implants involving surgical fusion.

There are two general categories of surgical treatments for spinal problems and pain: (1) decompression of neurologic structures for sciatic and nerve pressure problems, and (2) stabilization/reconstruction or realignment of bony components for structural problems. Treatment alternatives within each category are many, varied, and continually evolving.

Spine stabilization is employed for the structural concerns—instability, pain, and misalignment—in category (2), and, in the past, fusion was the key component in this surgical intervention. Fusion involves joining motion segments (a disc and the vertebrae above and below it) together so that they no longer move at the affixed sites, improving stability and alignment and relieving pain. Original efforts at spine treatment typically followed traumatic events which left bony alignment with suboptimal support. As this technology evolved, it began to be used not only following trauma but also to treat deformity and degenerative/aging problems. Advances in engineering and biomechanic improvements also contributed to its broader use.

The concept of fusing motion segments to improve stability and relieve pain was supported by past clinical and radiographic observation that reduced mobility and sometimes autofusion are part of natural aging. Autofusion was noted to be accompanied by diminished pain but was often also accompanied by overall reduction of activity associated with the aging process.

As engineers developed better materials and improved stabilization support constructs to enhance fusion techniques, earlier methods—which had been seen as an improvement over nonsurgical treatments—came to be considered suboptimal. The earliest stabilization devices to enhance and support fusion also came to be thought suboptimal and this gave way to further advancements in fusion technology. After more data collection, it has been found that, while advanced materials have resulted in better structural constructs, they have not produced a satisfactory level of clinical improvement. (It should be understood, however, that not every fusion relieves pain and not every failed fusion results in continued pain.) With time, those segments that fused successfully were subject to wear from the segments above and below them,

possibly accelerated because of the fusion. So, more recently, surgical resources have been directed toward developing mechanical reinforcements that maintain motion and enhance and support moveable surfaces. Initially this was attempted by disc replacement, but the technique evolved into use of posteriorly supported motion-retention constructs as well.

The general thinking about structural spine treatment, then, has changed from the earlier notion that the "advantages" of natural aging and degeneration could be achieved through a fusion procedure to current techniques for resurfacing and preserving spinal motion through replacement and motion segment support.

These new mechanical constructs, however, face challenges of their own. Once an "old-style" fusion is solid, the structural implants are no longer subjected to mechanical stresses. In newer motion-retention devices, the implanted device must withstand mechanical forces and loads for a much longer time and continue to perform satisfactorily.

Posterior Motion-Retention Devices (PMRDs)

The augmentation or supplementation of motion through posterior motion activity has developed along several lines. Early engineering assessments looked at how posterior motion joints (facets) wear and whether they are subjected to any greater specific mechanical stresses such as flexion/extension, shear, or axial rotation. Studies in the literature have not found that any one particular motion needs to be augmented or supplemented, and there is some belief that wear is related to both genetics and life experience, so no one solution will work for all patients. It is also speculated that, as early wear takes place, the patient's body may compensate by greater degeneration and arthritis and, subsequently, reduced motion.

The cost to develop a spinal implant is high, and the investment, risky. Large companies have been averse to developing these technologies in light of stringent government and insurance company regulations. They seem to be more interested in acquiring the technology once it has been designed and approved.

Posterior motion-retention devices (PMRDs) developed from posterior fusion implants, but an understanding of the basic science and mechanics of wear seemed to be lacking. This gap has been filled by creative design solutions. PMRDs are used primarily to augment posterior motion in wearing and degenerating joints and to slow wear and add support. The typical spine implant fusion construct employs mobile-headed screws that affix to the spinal posterior elements of the spine and span a motion segment with a rigid rod. The rigid rod is then locked into the screw head with a capture device, and biologic bone-healing material is placed across the motion segment to encourage a fusion to develop. Some device companies have substituted a more malleable, flexible or stress-sharing support member for the rigid spanning rod. Even though these implants do not mimic typical spinal motion, they may off-load spinal joint motion and help in pain relief.

Government and insurance regulations stipulate that fusion must accompany placement of spinal implants, but some surgeons circumvent these regulations by placing minimal amounts of bone material or biologic constructs, so the likelihood for solid fusion is low and the support members will still allow motion. The motion, however, may not provide the support the spine needs and might be too restrictive or not restrictive enough. If industry were to advise not using bone for such surgeries, it would be suggesting non-FDA-approved treatments and could be held liable. Most so-called "soft fusion" or nonfusion surgical techniques are considered off-label, and surgeons who use them expose themselves to liability, should a support member fatigue and break. Industry has been supplying these flexible members without directly advocating avoiding fusion, which is why the government is watching fusion outcomes closely. Surgeons who use PMRD implants must code their fees to include a fusion procedure, or insurance companies might not pay.

PMRDs are also being developed by privately funded companies, often with venture capital support. These PMRDs are more sophisticated than existing flexible implants manufactured by large device companies in attempting to customize support for specific posterior motions—flexion and extension, axial rotation, and shear. The FDA demands rigorous scientific methodology in manufacturers' studies of safety and efficacy. Study protocols, determined in concert with the FDA, are designed to prove that outcomes with the new techniques are equivalent to those in fusion techniques. More recently, insurance companies have been modeling their coverage on Medicare rulings, a distinct hurdle because Medicare only judges technologies that affect its typically older patient population. Medicare also demands that technologies accepted for patient use have outcomes that are superior—not just equivalent—to existing technologies.

These private companies have limited resources, usually only enough money to develop one product to a given stage before requiring more funds. Hence, they must come up with creative patient study designs that have a good chance of statistical success. This practical need has prompted clinical studies in which placement of a structural support device such as a PMRD (typically used for mechanical back pain) is coupled with decompression surgery for leg and buttock pain, or what is considered neurologically mediated pain. This is done because relief of neurologically mediated pain is achieved more consistently, so the surgery has a higher likelihood of outcome success and thus economic success.

In summary, the efficacy of treating low back pain by fusion is being questioned, and attempts are being made to solve structural problems through the use of motion retention devices. As a response to the stringent regulation of experimental technologies, industry has developed implants that can be used off-label but marketed in a way that avoids perception or direct evidence of off-label use, prompting the government to step up its oversight and evaluation of outcomes. In some cases where motion-retention devices are used off-label without fusion material being placed, surgeons may be charged with fraud.

The lack of basic science understanding of spine degeneration, such as knowledge about genetics and biochemical and biophysical causes of pain, may be one reason why engineering structural principles alone have not led to success.

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HEALTH LAW

Liability of Industry Representatives in the OR

Kristin E. Schleiter, JD, LLM

It is increasingly common for representatives of pharmaceutical and medical device companies to attend surgeries for the purpose of observing the use of the company's product or calibrating the product for the surgeon's use. The presence of these representatives in the operating room is at times so crucial that without it, the surgery could not proceed [1]. Indeed, the AMA *Code of Medical Ethics* states that "[m]anufacturers of medical devices may facilitate their use through industry representatives who can play an important role in patient safety and quality of care by providing information about the proper use of the device or equipment as well as technical assistance to physicians" [2]. A few courts have tackled the question of whether liability can attach to medical device or pharmaceutical companies for the actions or omissions of their company representatives who are present in the operating room.

These cases generally fall into two categories. First are those in which plaintiffs allege that the maker of the medical device or pharmaceutical had a duty to prevent the doctor from using its product [1]. Courts have held that a pharmaceutical or medical device company has no duty to supervise or prevent a doctor's use of those products. Second, plaintiffs have alleged that industry representatives undertook the unauthorized practice of medicine [1]. On this issue, courts have ruled that a company cannot be held liable for the unauthorized practice of medicine merely because its representative is present in the operating room. Rather, the representative must participate in the actual treatment of the patient or exercise medical judgment. The following cases present examples of both theories of liability.

Protecting the Patient-Physician Relationship

Courts have held that pharmaceutical or medical device manufacturers have no duty to supervise a doctor's use of the company's products or otherwise prevent a doctor's use of those products. Such a duty would require the company to interfere in the patient-doctor relationship and exercise medical judgment, both of which the manufacturer is prohibited from doing.

Kennedy v. Medtronic is an Illinois case that involved a death resulting from the cardiac physician's installation of a Medtronic-manufactured pacemaker into the wrong side of the patient's heart. Medtronic supplied a clinical specialist who attended the surgery and checked the leads to ensure that they were properly calibrated and functioning. Several months after the surgery, when the unresponsive patient was brought to the hospital, the surgeon discovered his mistake and

implanted a new pacemaker. The patient later died of renal and congestive heart failures. The physician admitted that he deviated from the standard of care by inserting the pacemaker lead into the left ventricle [3].

The patient's daughter sued the device manufacturer, claiming that, by sending a representative to the surgery, Medtronic had voluntarily assumed a duty of care for her father. As such, she argued, Medtronic should have warned the decedent of the dangers inherent in proceeding with the surgery under the conditions present at the clinic. (Part of the conflict revolved around the quality of the health care facility at which the surgery was performed.) Medtronic responded that it had no duty to prevent physician malpractice or guarantee against it. Medtronic further argued that it was exempt from having to warn the decedent or his family of any dangers in proceeding with the surgery [3].

The Illinois Appellate Court found that, for two reasons, Medtronic did not owe the plaintiff's father a duty of care. First, the decedent's injuries were not reasonably foreseeable by Medtronic, for Illinois law did not impose a duty to anticipate the negligence of third parties [3]. Second, the burden and consequences of imposing a duty on Medtronic to monitor the conditions under which a physician performs surgery would be substantial because Medtronic would be required to interfere in the patient-physician relationship [1,3]. The court felt that it would be unreasonable—and potentially harmful—to require a clinical specialist such as Medtronic's representative to delay or prevent a medical procedure simply because she believed the setting to be inappropriate or the doctor unqualified. Requiring such screening would also risk imposing liability on a manufacturer in the event that a manufacturer's representative refused to provide a device to a physician who the representative deemed unfit to implant the device, and the patient suffered adverse medical conditions as a result. According to the court, the patient's physician with knowledge of the patient's medical history is the person best suited to determine a patient's medical needs [3].

The court also found that Medtronic's representative had not voluntarily undertaken a duty to do anything more than insure the leads were properly calibrated [1]. This limited and clearly defined role did not entail a duty for the placement of the lead into the correct ventricle of the patient's heart [3]. Since the representative had not performed her role negligently, liability did not exist [1].

In *Swayze v. McNeil Laboratories*, the Fifth Circuit Court of Appeals considered whether a pharmaceutical company has a duty to affirmatively prevent a doctor's misuse of the company's products. The plaintiff in Swayze was the mother of a boy who died as a result of an overdose of an anesthetic manufactured by McNeil Laboratories [4]. An unsupervised nurse anesthetist, rather than a surgeon or anesthesiologist, had miscalculated the patient's dosage and administered the anesthetic. Though this use of unsupervised nurse anesthesists was revealed to be a statewide practice, McNeil denied any knowledge of the practice. The plaintiff alleged that McNeil knew or should have known of this practice, and so had a duty

to: (1) warn patients directly of the risk of misuse, (2) take additional steps to enforce the requirement that only a physician administer the anesthetic, or (3) withdraw the anesthetic from the market [1, 4].

The court found that McNeil had no duty to enforce its warnings, much less directly warn certain patients, reasoning that it would hesitate to encourage or require a drug manufacturer to intervene in an established patient-physician relationship [4]. It would be impractical and unrealistic, the court stated, to expect drug manufacturers to police individual operating rooms to determine which physicians adequately supervise their surgical teams [1, 4]. The court took note that the harm in this case did not come from adverse side effects of the drug but from the unsupervised administration of the drug [4].

The court also held that McNeil also had no duty to remove the anesthetic from the market [4]. The court reasoned that the problem lay with individual physicians, not the drug itself, and that manufacturers cannot control the individual practices of the medical community [1].

Differentiating between Presence and Practice

Courts have held that companies are not liable for the unauthorized practice of medicine merely because their representatives are present in the operating room. Rather, the representative must participate in the actual treatment of the patient or the exercise of medical judgment for liability to attach.

In *People v. Smithtown General Hospital*, the Supreme Court of New York considered whether the actions of a general sales manager, who scrubbed in on a surgery to help remedy a problem with his company's prosthetic hip, constitute the practice of medicine [5].

Smithtown involved a total hip arthroplasty gone awry and a sales manager's attempt to remedy the situation. The sales manager who supplied the instrumentation was present during the initial surgery and was called back after a post-operative x-ray showed that the patient's hip joint had been dislocated. The sales manager returned in time to scrub in and observe the follow-up procedure. The surgeon attempted to remove the prosthesis with a mallet, but failed. At that point, the general manager offered to lend a hand and was ultimately successful in removing the prosthesis with the surgeon's mallet [5].

Before the prosthetic could be reinserted, it had to be cleaned to remove cement that had cured in it. In an effort to clean the prosthesis, the surgeon fractured the patient's femur. As tension in the room rose and the surgeon contemplated another course of action, the sales manager said that he could "fix the thing" (i.e., the prosthetic hip). With the surgeon's consent, he spent more than 3 hours removing the cement with tiny curettes, during which time the surgeon reportedly left the operating room. The general manager also treated the patient's broken femur. When asked whether he or the physician put the prosthetic device in, the general manager replied, "I did." The

general manager had not attended high school or college and had no training in paramedical techniques; his knowledge came "exclusively from reading orthopedic journals, looking at training films, and from implanting prostheses in cadaver bones as a training exercise" [5].

Interestingly, the plaintiff did not bring action against either the general manager or the medical device manufacturer, choosing to sue only the health care professionals who were present during the surgery. The health care professionals were charged with acting in concert with one another in the commission of second-degree assault—not medical malpractice—for allegedly allowing the general manager to participate in a meaningful way in a surgical procedure without the patient's consent [5].

The court defined the practice of medicine as "diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity, or physical condition" [5]. The court held that, in this case, the physician "abdicated his role as surgeon in that operating room and permitted the judgment and skills of a layman to prevail." The general manager's involvement in the procedure "extended far beyond instruction as to the use or manner of implant of the device he sold." The court held that a jury could conclude that the salesman's actions constituted unlawful engagement in the practice of medicine [1, 5]. With regard to the charge of assault, the court held that, while the defendants' conduct might encourage a malpractice suit, it did not carry the requisite "unlawful intent" sufficient to warrant criminal conviction [5].

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POLICY FORUM

Encouraging Teamwork to Decrease Surgical Complications

Julie Ann Freischlag, MD

Much work has been done and reported concerning safety in the operating room, and many of those reports identify potential dangers. And yet, adverse incidents and bad outcomes due to communication errors continue to occur in all centers. Why? Do surgeons really believe it can't happen to them? Do they think it's everyone else's problem? Do they believe they can just *think* "safety," and safety will happen?

For the past 6 years, we at Johns Hopkins have focused on operating room safety. We began with a presurgery "time out" and expanded that to a "briefing." At the beginning of the retraining, we closed the operating rooms for 4 hours and mandated that all members of the teams—surgeons, nurses, and anesthesiologists—attend classes by aviation industry experts who taught us about checklists and made us realize the importance of communication between the members of the team. The main purpose of briefings is to enhance this communication among operating room team members. Prior to identifying the patient and the procedure and gathering the equipment and other needed items such as implants, each member of the team introduces him or herself to the others and states his or her role. The person's name and role is then written on an electronic board in the room that can be updated in real time and is easy to read.

Introduction of the briefing session is a cultural change, a process that most change management consultants say takes 7 years, on average, to happen. Apparently that's how long it takes for people to forget that they ever did things any other way. Our medical students and residents, of course, will know no other way; they will be the leaders in communication in the operating room and on the inpatient floor. They understand the process of hand-offs, for example, whereas older surgeons tend to "cover" their patients even when they are not in the hospital and sometimes not even in the city, state, or country. When those surgeons were trained, it was a sign of weakness not to be available at all times.

We have also developed a debriefing process at the end of the case where nurses, anesthesiologists, and surgeons are asked what could have been done better. Were all the instruments available? Did they all work? Was the patient adequately prepared? Then the transition to the next level of care is discussed. Will the patient go to the intensive care unit, the floor, or home? What medications will they need? What are the concerns of each of the health care deliverers in the room? Has the family been updated and where are they?

Debriefing is toughest when the case did not go well or the patient is not doing well. The focus then must be on the patient's transition to the next level of care. If there is a mishap or miscommunication—a piece of equipment not working, unanticipated blood loss, lack of experience in the nursing team—those things are difficult to discuss in the heat of the moment. Regrouping hours to days later, prior to the next case, with that surgeon and team is key to making sure that things will go better the next time.

Despite our focus on briefing and debriefing, we still wonder whether the quality of these activities is uniformly excellent in each and every room. When we talk to the nurses who circulate in many ORs and see many versions of the process, we hear that inadequate attention is paid to the process by some teams. We have made a video for teaching medical students, residents, and new staff, and we have shared the video with other institutions. We are now going to have observers in some operating rooms watching the briefing and debriefing sessions and adherence to sterile technique. In other rooms, we are going to use video cameras to record the briefings and debriefings so that we can review the activity afterwards and use our reviews as a teaching tool. We also think that, if our team members know we are watching, perhaps they will raise the bar a bit and do an even better job.

Communication problems are the source of more than 70 percent of the errors that occur in the operating room and intensive care unit. With the need to work around the hours that the surgery residents are restricted to, hand-offs need to be done in a standard manner. Our interns wrote a paper identifying the 10 most important components of surgery hand-offs. Changing the culture demands involvement of the new generation, so we had them publish the guidelines themselves.

The Future for Safety in Surgery

Improvements in OR safety should involve patients, too. Patients now know that they should have their operation site marked, that they should receive antibiotics, and that we should wash our hands before examining them. They should realize that having the best available surgeon and team is critical. They should know more about expected outcomes of their surgeries, short and long term. They should take reponsibility for their preoperative care—exercising, stopping smoking, losing weight, and knowing their medications, even those they buy over the counter—and comply with pre-operative instructions.

Surgeons also need to do more. They need to be more transparent with their patients by telling them about all options for their care, including not having surgery. They need to communicate well and often through appointments, telephone calls, e-mails, and texting. The world has changed, and so should the way we communicate with our patients. All nonurgent communication can be dealt with electronically. In my experience, it is a rare patient who abuses or overuses this method of communication. We must have others—nurse practitioners, physician assistants—help us to communicate. Printed materials and Web sites can also be useful sources of information for our patients and their families, answering commonly asked

questions. Many of us have been surgery patients or have had a loved one who has been. These experiences make us better surgeons. Safety is up to all of us.

Julie Ann Freischlag, MD, is The William Stewart Halsted Professor, chair of the Department of Surgery, and surgeon in chief at The Johns Hopkins Hospital in Baltimore.

Further Reading

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MEDICINE AND SOCIETY

Deep Brain Stimulation: Calculating the True Costs of Surgical Innovation

Joseph J. Fins, MD

For over a decade I have been part of a clinical trial at the vanguard of surgical innovation, the application of central thalamic deep brain stimulation (DBS) in severe traumatic brain injury. Our work resulted in a 2007 paper in *Nature* that indicated that DBS may promote functional recovery from severe traumatic brain injury years after injury [1].

As a physician-ethicist and co-investigator, I framed the historical [2-5], ethical, [6-10] and policy [11-14] issues necessary for the design and conduct of the research that resulted in the publication. These issues related to invasive research in a decisionally incapacitated subject who could not give consent, the role of surrogate decision making, and the proportionality of the study. Our goal was to design a study that would maximize potential benefits and minimize risks.

This study was instructive in these ethical domains, as well as in scientific domains related to disorders of consciousness and mechanisms of recovery. More recently, however, the study has helped illustrate how society assesses the economics of surgical innovation in marginalized populations. In this paper I focus on this theme and consider the interplay of ethics and economics in innovative surgical research, paying particular attention to the interests of patients and their families [15].

Let me begin with a review of the case report. The subject was a 38-year-old who had remained in the minimally conscious state (MCS) for 6 years after having been assaulted. MCS is a disorder of consciousness functionally above the vegetative state [16]. MCS patients have definite, albeit intermittent, evidence of consciousness. They may show intention, attention, and memory and have awareness of self, others, or the environment, but only episodically [17].

The subject had an initial Glasgow Coma Scale of 3. He progressed to MCS in 3 months. Upon study enrollment, he sometimes followed commands with eye movements. He could neither communicate nor take food by mouth and was dependent upon tube feedings [1, 10].

Over the course of the DBS study, the subject manifested improved levels of arousal, motor function, swallowing, and expressive speech, assessed by objective measures, including the JFK Coma Recovery Scale-Revised [18]. Now he is more mobile, can eat food by mouth, and can communicate in short sentences. He also regained

aspects of personal agency and is now able to express a preference when prompted [10].

Since publication of the research paper on this case, I am invariably asked about the costs of DBS and whether it was worth it. Although this is understandable, given the austerity of the times and the broader debate about distributive justice in health care, the question strikes me as problematic. Generally we do not bring cost into the equation when considering early clinical trials. The Food and Drug Administration does not weigh cost considerations when granting either an investigational new device (IDE) or new drug exemption (IND). At this stage of innovation, a premium is placed on discovery, recognizing that costs need not be assessed until after interventions are validated. Moreover, prices should come down as methods are refined.

So why the inevitable question? In my view, it is a proxy for deeply held, unexamined biases towards patients with severe brain injury and a belief that nothing can or should be done. These views date back to landmark legal cases like *Quinlan,* which asserted a right to die based on an irretrievable loss of a "cognitive or sapient life" in the permanent vegetative state [19, 7]. Although the *Quinlan* court's establishment of patients' or surrogates' right to withhold life-sustaining treatment was an ethical good [20], generalizing hopelessness to all severe brain injury was not [7]. By failing to distinguish between vegetative and minimally conscious states [21], we deprive patients in the latter of access to emerging modalities that might promote recovery [22].

Although these biases are expressed toward patients with severe brain injury, the lesson for surgical innovation is a generic one: when assessing new devices or techniques for marginalized populations (with chronic or out-of-fashion conditions), it is critical to consider costs and benefits free of unexamined biases. Anything less is discriminatory and unjust.

If we overcome these biases and actually apply objective standards to a hypothetical cost-benefits analysis of DBS in MCS, it is possible to imagine that up-front costs of patient assessment, DBS surgical implantation, and follow-up could result in a cost-effective intervention. As one colleague of mine, Dr. Frank Levy, put it in an October 2009 e-mail, those who purport to believe in cost-benefit analysis have a responsibility to apply those methods. They cannot just invoke their prejudices and stop there; they are obliged to collect and examine the data.

To this end and for the purposes of this analysis, let us postulate that DBS will be established as a viable therapy for MCS, with a significant number of subjects in clinical trials having had improvements comparable to those of the first subject. If we take this hypothetical—and I stress it remains hypothetical early in this work—as a predicate for a cost-benefit analysis, we can immediately see that DBS effects should decrease the fixed costs of institutional care.

The benefits seen in our first subject, if replicated, could have significant economic implications. His enhanced mobility reduces his need for prophylactic anticoagulation and its associated risks and costs. His nutritional status is improved with oral food intake, raising his albumin. This benefit, along with his enhanced mobility, decreases his risk of bedsores and accelerates healing when they do occur. His ability to swallow and manage his secretions—along with removal of the PEG and, again, his mobility—make it less likely he will develop an aspiration pneumonia. His cognitive improvements now allow him to respond to questions about pain, discomfort, and a whole range of symptoms. This should help his doctors diagnose brewing conditions more quickly and cost-effectively. Finally—and perhaps most critically—his enhanced cognitive abilities and growing ability to speak allow for more meaningful interactions with his family and loved ones.

Much of this can–and should be—cost out. If and when this intervention is validated, health economists will need to calculate the decreased incidence of the aforementioned complications of chronic care (e.g., the cost of a bedsore or hospitalization for aspiration pneumonia) in an appropriately sized cohort and weigh these fixed costs for this population against the putative decreased morbidity seen with DBS. Only then can an objective cost-benefit analysis be offered for this intervention.

Some might worry that the advent of DBS for MCS creates an application that will expand markets and expenditures, but severely brain-injured patients—and the cost associated with their chronic care—are already in the system. Their existence is a consequence of failed efforts in acute care to achieve better functional outcomes. In these circumstances, an effective therapy for MCS would not *create* a clinical need but rather *respond to unmet ones* brought about by acute care technologies that can save lives but not completely mend them.

The medical ethicist in me hopes that a validated therapeutic intervention for MCS would be sustained by humane intent alone. But I am not so naive as to think that good intentions alone will win the day. Too many patients in MCS are neglected and isolated in chronic care, receiving what is euphemistically called “custodial care,” minimally conscious but mistakenly diagnosed as being vegetative [23]. One recent study estimated that error rate at an appalling 41 percent [24].

Against such odds, an eventual cost-benefit analysis of DBS for MCS could be instrumental, if this surgical innovation matures into a safe and effective therapy. When that occurs, a robust cost-benefit analysis would be helpful. Objective data might demonstrate, notwithstanding some recent critiques of medicine’s technological imperative [25], that medical innovation can sometimes be both humane and affordable. That is an important lesson for medicine and society.

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HISTORY OF MEDICINE

The Evolving Relationship between Surgery and Medicine

Ankur Aggarwal, MS

Despite today's technically advanced approaches and methods for treating the human body, the end goal of medicine remains the same as it has been from the earliest of times, even before the existence of a Hippocratic Oath. In fact, as one source says, "an innate instinct for self-preservation [exists] among all mammals," and there is no reason to doubt that early *Homo sapiens* possessed the rudimentary skills to try to preserve life in case of an injury [1]. As humans moved away from the hunter-gatherer society and into settled social groups, individuals focused their energies on specific tasks, and occupations began to take shape. Medicine followed the societal trend of specialization and, as knowledge grew and technology advanced, the number of different ways to treat the same problem proliferated. Contemporary medicine encompasses many types of care, and today's physicians compartmentalize the body, concentrating on small areas and specific modalities of treatment.

Medicine's two branches—the less invasive medical methods and the more invasive surgical methods—have been around since before the existence of written language. Surgery, however, was not viewed as belonging to the same sphere as medical treatments until relatively recently, and, even now, a sharp distinction exists between surgeons and other medical doctors. Analyzing the history of surgery can help explain the separation between medical and surgical treatments and why the two fields, although viewed quite differently, fit under the umbrella of medicine.

Surgery—i.e., the use of physical objects in a normally traumatic way to provide treatment—is not new. Evidence exists that circumcisions were done in Ancient Egypt using sharpened rocks and crude stone instruments as long ago as 10,000 BCE [2]. Skulls from ancient civilizations show holes to excavate clots and relieve abnormal intracranial pressure, a process known as trephination. These early peoples had some idea that elements in the body can cause harm and that their removal could decrease pain. While the methods worked often enough to encourage their continued use, most of the time they made the situation worse. For illness with no obvious cure, there was always prayer. Native Americans were well known for using surgical methods in conjunction with religious intervention to heal wounds received in war [3].

The separation of religion from medicine occurred in Ancient Greece [4]. Not only did the Greeks rely on physical methods of treatment and evaluate them empirically, they tried to understand why people were getting sick. Their answer—the Theory of the Four Humors/Elements and how the balance of these humors affects health—

governed treatments during that time period and became the basis of today's internal medicine.

Greek physicians dabbled in surgery but mostly turned to less invasive treatments such as ingestible herbs and topical applications of salves and poultices. Hippocrates preached about the merits of a"suitable diet, rest, and exercise" [5]. While surgery was sometimes effective, especially in the removal of foreign objects, it was not the focus of physicians' practice. In fact, early versions of the Hippocratic Oath warned physicians against the use of surgery [6]. The warning was meant to force doctors to acknowledge their limitations and also reflects the fact that so little was known about surgery at the time that it was considered unwise for physicians to engage in it.

Like other formal studies, surgery and medicine took a step backwards during the medieval era, surviving in limited areas of the known world, such as Southern Italy, the Byzantine Empire, and the Arabian countries. It was not until the Renaissance that medical knowledge started to flourish again. New universities gave those who wanted to practice medicine a forum for practical as well as theoretical learning through public dissections and an emphasis on the importance of anatomy. The Renaissance approach to learning stressed "seeing to believe," and firsthand accounts, rather than what was passed down from previous generations, came to be considered the basis of knowledge. Concepts of physiology were formed "as the secrets of anatomy began to be revealed in even greater detail" [7]. Both medicine and surgery increasingly emphasized empirical observation, a path that would lead them to the scientific disciplines they are today in Western societies.

Universities established during the Renaissance did not offer formal education to surgeons, however. The manual nature of surgical work caused it to be viewed as a trade rather than an art and thus unsuitable for teaching in universities. Instead, surgical skills were learned by apprenticeship. Though leading French and Spanish physicians were often experts in anatomy and practiced both gross dissection and as well as some surgery, their real interests lay strictly in the field of medicine. Most physicians still felt that "there [was] no more science in surgery than in butchering" [8]. The same was true "in England, [where] people never accepted…that surgeons were the equals of doctors…and the internists…formed an association which eventually became the Royal College of Physicians." [9]. To help bolster their standing and give them some credibility and political power, the surgeons joined the Company of Barbers and formed the United Company of Barber Surgeons in 1540, a group dedicated to performing surgery and extracting teeth [10].

The distinction between surgeons and physicians was maintained in hospitals, the establishment of which began during medieval times and continued through the Renaissance. At first, hospitals were small places, often located in churches, but the 12th and 13th centuries saw the formation of many large hospitals throughout Europe, especially in London [11]. Hospitals gave physicians a specific place in which to practice. In contrast, the barber-surgeons plied their trade in commercial

establishments, identifying themselves with the red-and-white-striped poles still used by some barbers today.

In England, the reputation of the surgeons began to rise slowly during the Renaissance, as they gained the respect of various kings and made breakthroughs like raising the success rate of Caesarean operations. Surgery also owes much to Ambroise Pare, regarded by many as one of the Renaissance's greatest surgeons. He trained with the barber-surgeons and became a field surgeon in the French army. He wrote several books on anatomy and wound treatment in the field. Though he had no formal education, he was made a member of the College of Saint Come in Paris, an unheard-of event at the time. Eventually Pare became the personal physician to four successive French kings [12].

In addition to improvements in surgery itself, two medical advances—effective anesthesia and antiseptic techniques—greatly benefited patients undergoing surgery. Previously, hashish, mandrake, and opium were the only drugs available to induce analgesia. Into the late 18th and early 19th centuries, many patients died from the intoxication effects. Producing effective analgesia and paralysis with less risk increased the willingness of patients to undergo surgery. Joseph Lister's mid-19th-century advances in bacteriology, the prevention of hospital-induced infections, adequate prevention and treatment of wound infections, and antiseptic methods of performing surgery helped decrease the complication rate, increasing the likelihood hospital patients would actually benefit from surgical treatments.

Eventually, surgeons were given more formal standing and established respected professional societies. In 1745, English barbers and surgeons parted ways and formed separate groups; the Company of Surgeons received its royal charter in 1800, expanding from the Royal College of Surgeons in London to the Royal College of Surgeons of England in 1843 [13, 14]. By the beginning of the 19th century, training had unified so that surgeons and medical doctors went through the same medical school or university training, received the same degree authorizing them to practice medicine, and practiced in the same institutions. For the most part, surgeons and internists are now both known as "doctors." Even now, some separation remains. In England, internists are given the title "Doctor" while surgeons are often referred to as "Mister," a throwback to the age of barber-surgeons.

Many of the 20th century's greatest life-saving interventions—from organ transplantation and open heart surgery to laser and laparoscopic surgery—were surgical techniques and devices, and the technological explosion of the 21st century leaked into surgery, leading to procedures never previously thought possible. Perhaps the words of one medical historian are correct: "Surgeons have always been quick to adapt to new technology…it should perhaps be noted that physicians were rather more tardy" [15].

As surgery continues to advance, cases that involve minimal access, laparoscopic instruments, and even robotics are becoming common. Internists have even begun to

take up certain surgical techniques. Cardiologists can place stents in the coronary arteries and perform femoral cut-downs to gain access to the aorta; gastroenterologists use endoscopes to look at and treat almost all the parts of the digestive tract and to place feeding tubes; and interventional radiologists drain abscesses, insert and remove feeding tubes, break up clots, and even fix aortic aneurysms using various endovascular techniques [16]. Internists and other medical specialists can no longer be said to diagnose and treat illnesses using only their knowledge of physiology and pharmacology.

Is surgery's transition from outsider to insider to "top dog," so to speak, beneficial? A surgeon's salary is almost directly proportional to the number of procedures he or she completes. Thus, a surgeon has a financial self-interest that may come ahead of the patient's well-being. At the same time, a medical doctor who uses an invasive procedure will earn substantially more than he or she would for delivering less invasive care. If anything, some internists may have a greater incentive for using surgically based procedures. Whether this trend benefits the patient and should be embraced or rejected is a question that requires more thorough analysis. But surgery and medicine are joining hands to find new and better ways of treating patients. It is time to stop defining a patient's treatment as either surgical or medical and to use the two approaches in conjunction to provide the best care possible.

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OP-ED

Total Joint Registries: A Foundation for Evidence-Based Arthroplasty

Fabian von Knoch, MD, Anthony Marchie, MD, MPhil, and
Henrik Malchau, MD, PhD

Total joint arthroplasties are a common and effective treatment for end-stage osteoarthritis. In the United States alone, there are more than 200,000 such primary total hip replacements done each year for those older than 80 years [1], and the number is expected to reach 600,000 annually by the year 2030 [2]. The exponential rise in primary arthroplasties is expected to double the number of revision surgeries in the next two decades [3, 4]. This anticipated rise in caseloads and the use of new, evolving implant technology demand a reliable and objective method of monitoring and feedback.

Outside the U.S., such monitoring and feedback already exist in the form of national joint registries. The Swedish Knee Register, established in 1976, was the first, followed by the Swedish Hip Register in 1979 [5, 6]. Since the early 1980s, a host of national registries have been established in Europe, Canada, and Australia. Registries like the Nordic Arthroplasty Registry Association are now expanding past the traditionally national scope [7]. Efforts are underway to launch an American National Joint Registry in the summer of 2010.

Registries thus far have proven to be powerful surveillance systems, improving outcomes and cost-effectiveness for total joint replacement surgeries. Effective registries provide: (1) timely feedback to surgeons and industry; (2) a sentinel for complications; (3) a reduction in patient morbidity; (4) the monitoring of new surgical techniques and implant technology; and (5) indications of poor implant design [8].

The Components of a Registry

Over time, it has become clear that there are four essential components of the successful registry: (1) organizational control and funding; (2) participation on the part of surgeons and hospitals; (3) data management; and (4) a mechanism for timely feedback.

Most registries are run by national orthopaedic associations, and are funded by their respective national governments [9]. Widely considered successful, the Swedish Hip Registry is owned by the Swedish Orthopaedic Association, and financed by Sweden's Board of Health and Welfare. On the other hand, the National Joint Registry of England and Wales is managed (and funded) by the United Kingdom Atomic Energy Authority. Not surprisingly, there is local concern for the lack of

joint replacement expertise and surgeon representation on its steering committee, and the overwhelming wish of the U.K.'s orthopedic community is to have a surgeon-run national registry [10]. Obviously, adequate funding of a registry is also critical to survival. The German National Registry, which was initially financed by industry and surgeons, eventually succumbed to a lack of private funds [9]. It therefore appears that long-term success of any registry would require the stable funding afforded by government in one way or another.

Participation in a registry by surgeons and hospitals has generally been voluntary. Expert consensus in fact recommends that the participation rate be at least 85 percent so data are not skewed by unreported revisions or complications [8]. The voluntary system may allow participation rates to be low, as is the case in Canada, which is not ideal. In Finland, Slovakia, and Denmark, however, participation is mandated by law [9].

Data management involves collection, validation, and analysis. Data are collected prospectively, and usually submitted via electronic means. Information would, for example, include a patient identifier, surgeon identifier, date of operation, diagnosis, procedure, surgical approach, and implant specifications [9]. Currently, revision surgery is the main indicator of failure of the primary procedure in most registries [8]. There is now a movement to include patient-derived outcomes data along with radiographic details to help improve the sensitivity of assessment.

Needless to say, the utility of the registry data depends on its accuracy and completeness. Validation exercises suggest that there may be an error rate of about 1 percent in recording surgery dates and sites of implant [11]. Thus, at every stage of data collection and entry, there need to be mechanisms for regular validation in order to minimize error propagation. Once the data are stored, qualified personnel need to test the external validity of these data cross-sections, and put quality control mechanisms in place prior to analysis. Data are normally presented as survival analyses with time to first revision, and analyzed using Kaplan-Meier statistical methods [8].

Though registries serve multiple functions, a national registry's primary objective is to inform surgeons, industry, and the lay public about the performance of different surgical techniques and implant designs. This process is intended to promote best practices and evidence-based medicine by presenting objective and unbiased information. It is important that underperformers not perceive negative feedback as punitive, but rather as constructive, with the shared goal of improving patient outcomes in mind. Most reports are compiled annually and published in peer-reviewed journals, and are accessible via the Web sites of the various national joint registries themselves [9, 12].

With new and evolving implant technology, a national registry represents a powerful surveillance system for quality control. The response to lipid contamination of Sulzer Orthopaedic components in 2000 is a prime example of this process [13]. There were

17,500 contaminated Sulzer total hip arthroplasty components implanted in the U.S., 3,000 of which were later revised. By contrast, as explained in a 2002 conversation with Dr. Henrik Malchau, Swedish surgeons were notified by their registry of the unacceptably high failure rate at about the same time, and the implants were discontinued after only 30 were used (with 5 patients later requiring revision surgery).

Registry feedback has also had a tremendous impact on the use of hip resurfacing in Australia. Beginning in the late 1990s there was a resurgence in its use (especially for patients younger than 55 years old), and the procedure accounted for almost 10 percent of all arthroplasties done in 2006 [14]. The survival of these metal-on-metal bearing implants was followed closely by the national registry, and it was noted that women who had had resurfacing were twice as likely to have revision surgery as women who had had conventional total hip replacement (i.e., 4.2 percent versus 2.0 percent). Because information about the gender-related failure and increased revision risk was disseminated quickly, there has been an overall decline in the use of resurfacing in Australia; particularly on women (from 28.8 percent in 2007 to 23.6 percent in 2009) [15].

Feedback has also been a catalyst for improvement programs. One local hospital was identified by the Swedish Hip Registry in 2005 as having an unacceptably high revision rate due to dislocation (4.8 percent, as opposed to the national average, 1.4 percent) [16]. A site-specific program was immediately implemented to improve patient education, patient selection, and pre-operative templating and to increase the use of cup-positioning instrumentation, use of larger femoral heads, and capsular and piriformis tendon repair for the posterior surgical approach. There have been no revisions due to recurrent dislocation since 2006. As a matter of fact, it has been surmised that the Swedish Hip Registry has helped to reduce Sweden's national revision burden by 2.5 times (from 17 percent in 1979 to 7 percent in 1997) [17].

Socioeconomic Implication

The economic burden of revision surgery is significantly lower in countries with registries, such as Sweden, than in the United States, which does not yet have a national registry. There was a 16.9 percent revision rate in the U.S. from 1992 to 2000 for patients who were older than 65 years and had had a primary total hip replacement [1]. At the same time in Sweden, there was a revision rate of only 6.4 percent for the same demographic group. Each percentage point reduction in revision surgeries saves an estimated $42.5 million to $112.6 million annually [1]. A 10 percent reduction in the U.S. revision rate would approach Swedish standards and could save upwards of $1 billion each year.

Figures also indicate that most hip arthroplasties in the U.S. are done by surgeons who do fewer than 20 such procedures per year [18]. The majority of all revision procedures are performed in centers that have fewer than 10 revisions annually [18]. Most arthroplasty research and outcomes studies, however, are conducted by surgeons who perform many replacement procedures in tertiary or quaternary

centers. The patient outcome in these centers may not necessarily reflect the average outcome across the nation. A national registry would help identify unsafe outliers in the system.

Conclusion

These data strongly suggest that the presence of national joint registries has had a positive effect on overall outcomes for arthroplasty patients. The regular feedback has provided information to surgeons, industry, and the lay public regarding the performance of various surgical techniques, implant designs, and associated complications. Registries have also been a critical sentinel, warning of early implant failure and potential harm. Valuable demographic information on patients has helped determine current and future needs of the population. The demand for both primary and revision arthroplasty surgery are only expected to rise in the future, and national registries will help ensure that evidence-based best practices and technology are allowed to flourish.

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