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Ethics in the Practice of Surgery

Upcoming Issues of *Virtual Mentor*

November: Research Ethics
December: Standards of Care: An Ethical Examination
January: Special Theme Issue on Internal Medicine

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From the Editor

Ethics in the Practice of Surgery

The theme editor introduces a special issue focusing on the ethical issues that arise in the practice of surgery.

I am not a surgeon. I am a philosopher by trade, but the practice of surgery fascinates me. How does a surgeon balance the usefulness of clinical evidence with the need to improvise according to unpredictable complications? When can surgery, so often associated with saving lives, be useful for care at the end of life? How much risk should research subjects be exposed to in the hopes of confirming (or disconfirming) a clinical hypothesis? What value, if any, would a regulating body like the FDA have for surgery? What should surgeons do when they confront the limits of their own competence? And where are those limits, anyway? These questions (and others) inspired this issue of *VM*.

As usual, the clinical cases deal with specific patient-physician relationships, and each case in this issue focuses, in one way or another, on communication: a low-risk diagnostic biopsy is considered while a patient is under general anesthetic (and cannot be asked about his wishes), a patient's parent asks a third-year resident about her competence to perform the surgery, and a terminal patient requests a palliative surgery of dubious effectiveness. These should serve as reminders of the importance of communication in the relatively brief and sometimes intense interactions between patients and surgeons.

Most of the articles in the rest of the issue deal directly with the ethical means of achieving surgical ends. The usefulness of an FDA-like regulating body is considered, the limited effect of evidence-based surgery (EBS) is explained, and guidelines for surgeons in the increasingly complex system of health care are suggested. The need for the Joint Commission on Accreditation of Healthcare Organizations' recent "Universal Protocol" is identified, and some clinical indications for palliative surgery are endorsed. However, our Medicine and Society feature discusses the ethical issues raised by a new challenge for the profession of surgery—surgeon participation in reality television. Finally, in the Medical Humanities essay, one man's means of confronting the predicament of being a surgeon are expressed.

I'll leave my description of this issue at that, and close by letting you know what you should learn this month:

1. Understand the obligations conferred by the consent form for surgery as they apply to surgeons and surgery residents.

2. Learn how surgery residents should respond to patients' questions about their expertise.

3. Identify the role of the surgeon in communicating with patients about palliative surgery.

4. Identify the obstacles to establishing an FDA-like agency for approval of surgical techniques and technology.

5. Understand the challenges to recognizing the limits of one's competency.

6. Understand the arguments for and against placebo controls in surgery research.

Abraham P. Schwab

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Clinical Cases

The Unnoticed Mole

Surgeons should not make medical decisions for a patient while the patient is under anesthesia.

Commentary by Avram Kraft, MD

Erik was referred to Dr. Slosson's office by his family doctor.

"Hello, Erik, I'm Dr. Slosson. I understand that you've been referred to me because of a recurrent pilonidal cyst that's a little difficult to remove."

"Yep."

"Well, let's take a look."

After confirming the diagnosis, Dr. Slosson informs Erik that there are 2 surgery alternatives at this point. "After removing the cyst and cleaning out the area, we can fold some tissue over the wound and sew it closed. There is a 10 percent chance of recurrence and a shorter healing time. Or we can pack the wound with bandages that will have to be changed 2 or 3 times a day and let the wound close on its own. This only carries a 5 percent chance of recurrence, but has a longer healing time. I'm comfortable with either procedure."

"Well, I say better safe than sorry. Let's do the second procedure. I don't want to go through this discomfort again."

Dr. Slosson nods and tells Erik to schedule the surgery on his way out of the office.

A few days later, Erik arrives at the hospital at 8:00 AM with his wife Vicki. Vicki waits by Erik's bed as they prepare to administer the anesthetic. Dr. Slosson confirms with Erik that he prefers the procedure with longer healing but lower chance of recurrence. Erik agrees and signs a number of consent forms. A nurse's aide escorts Vicki to a waiting room down the hall.

In the OR, Dr. Slosson completes the procedure, and just as he is about to leave the bandaging to a resident he notices an irregularly shaped mole on the small of Erik's back. He knows Erik's wife is just down the hall, and Erik obviously has no problems sharing his medical information with her. Dr. Slosson is only a general surgeon, and he does not have a background in dermatology. He does not know whether Erik has any other risk factors for melanoma, but upon a further examination, Dr. Slosson also notices a dozen or so other moles on Erik's neck and shoulders. Removing the mole would leave only a tiny wound in comparison with the wound from the cyst.

What should Dr. Slosson do?

Commentary

The starting point for our exploration of Dr. Slosson's care of Erik and of any potential ethical issues that could arise in this patient's care begins with our understanding the patient's problem and the goal of his caregiver's treatment. The presenting problem is defined at the first encounter. Dr. Slosson introduces himself and states Erik's problem as a

recurrent (italics mine) pilonidal cyst (presumably previously infected and treated) which Erik confirms with a "yep" answer. We're assuming that Erik's referring family physician chose Dr. Slosson because he is a capable general surgeon. To his credit, Dr. Slosson presents his treatment options clearly and succinctly including benefits and risks and without bias, allowing Erik to make a choice, which Erik does. The choice is reconfirmed preoperatively by Dr. Slosson in the presence of Erik's wife, Vicki. We assume that the individual responsible for anesthesia has spoken with Erik before any mind-altering substances have been given. Consents are signed, but what is essential is that communication has taken place. In what appears to be a comfortable flow of events, Erik is taken to the OR and his wife to the waiting area. The pilonidal surgery proceeds smoothly. To this point, every apparent detail has been managed attentively and deliberately and the criteria of ethical conduct, including informed consent, have been met.

The next matter to evaluate is the options the operating surgeon will thoughtfully consider when he notices the mole in the "small of Erik's back" as well as a "dozen or so" additional moles. The limiting factor here is not that Dr. Slosson is "only a general surgeon." General surgeons probably see and excise as many moles (nevi) and skin lesions as do plastic surgeons or dermatologists. The question at hand is what is appropriate in this setting medically and ethically. Can Dr. Slosson biopsy or even excise the skin lesion that most concerns him? Sure he can, but should he without consent? Clearly the answer is "no." First, what about the role of the patient's family practitioner; perhaps he has measured and followed this nevus and the other nevi, for years. Wouldn't a phone call be prudent? Second, Vicki is just down the corridor. Surely, if the surgeon thought that he had no other option, he could break scrub, talk with the patient's wife, obtain her permission to do the excision, have a consent signed and then proceed. All the while, the surgeon may be thinking that he just completed a potentially contaminated operation in local proximity to "the small of the back." Regardless, this is not the optimal time to do an additional unplanned, non-urgent procedure even though it appears to be low-risk. The most careful approach is talking with the referring physician and then following an algorithm of sensible choices, including Erik's input.

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Clinical Cases

The Reluctant Resident

Surgery residents should always answered truthfully when asked by patients about their experience with surgical procedures.

Commentary by Jeffrey L. Ponsky, MD

Kelly is still upset over yesterday's events as she gets ready for her shift. A simple laparoscopic appendectomy, and the attending had to take over. "I was having trouble," she reminds herself. And that wasn't the first time. "I mean, a second-year surgery resident is supposed to be able to do a laparoscopic appendectomy." She starts to review what happened just before the attending took over when her pager beeps at her. She heads down to the ER.

The surgeon meets her outside the exam room. "Patient's name is Emily Blanchard. She's 14, and started feeling pain in her periumbilical area last night. This morning the pain localized to her lower right quadrant, and on exam, she has rebound tenderness. She has a temperature of 100 degrees and her white blood count is 12. I'm guessing it's appendicitis, but that's what you're here for."

"Have you ruled out the possibility of an ectopic pregnancy?" Kelly can't believe that 2 cases of appendicitis would present in 2 days.

"She says she hasn't been sexually active."

Kelly enters the exam room. "Hi, Emily. I'm Dr. Washington, but you can call me Kelly. How long have you been in pain?"

"Since last night."

"Can you show me where it hurts?" Emily points to her right side, slightly above her hips.

As Kelly lightly presses on the area she asks, "Does this hurt?"

Emily nods.

Kelly orders an ultrasound to confirm an inflamed appendix and rule out gynecological complications. After she completes the ultrasound and confirms the inflamed appendix, she and Emily make eye contact. "Well, Emily, it looks to me like you've got appendicitis, which means we'll need to remove your appendix. I'd like to talk to one of your parents about it, is one of them here?"

"My dad's in the waiting room," Emily mumbles.

"Is it alright if I bring him back here?" Kelly asks.

"Sure."

A nurse brings Mr. Blanchard into the room and Kelly calls for the attending surgeon. When both of them have arrived she informs them of her diagnosis and the need for surgery. Mr. Blanchard catches the attending's eye and asks, "Are

you going to be the surgeon?" The attending shakes his head, "Dr. Washington will be the operating surgeon under my direct supervision." Kelly feels the blood rush to her face. Mr. Blanchard looks her in the eye and asks, "Have you done this before?"

What should Kelly do?

Commentary

A resident must deal with myriad frustrations and conflicts as he or she progresses through training. This case demonstrates 2 such situations. Kelly is struggling to gain technical competence in the performance of laparoscopic appendectomy; clearly she has not yet attained this and is frustrated by her lack of progress. This frustration is typical among residents as they strive to learn new technical procedures and must be "rescued" to complete them. What is crucial is that they recognize this frustration as the norm, and know that to attempt these techniques without assistance until they have gained competence and confidence is dangerous for the patient and unethical. If a procedure is completed, but poorly and without assistance, it jeopardizes patient safety and does little to advance the skills of the resident.

Kelly is fortunate that her attending surgeon has so properly included her in the operating team, so that, later, when asked if she has performed this surgery before, she can truthfully reply, "Yes, but always with the assistance of an attending surgeon." She is thus being honest and ethical. Kelly will soon attain competence in this and other procedures. However, a career in surgery is a continuous learning process and Kelly should seek and enjoy the assistance and advice of an attending or more experienced surgeon often throughout her residency and the rest of her career.

An excellent surgeon is not threatened by the advice or assistance of others.

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Clinical Cases

Palliative Surgery

Physicians must express compassion when discussing risk and success rates of palliative surgery.

Commentary by David P. Jacques, MD, and Murray F. Brennan, MD

Dr. Ramirez, a GI surgeon at Lutheran Hospital got a call from the medical director of Sunset Hospice, Dr. Whitehead. "I've got a patient here that I want you to look at. Her name is Mrs. Macias; she's 59 and was diagnosed with Stage IIIb ovarian cancer 3½ years ago. She's now Stage IV with distant metastases. She had an initial debulking surgery followed by 3 rounds of chemotherapy with disease recurrence. To be honest, she's doing better than I expected, given the late diagnosis. Her current prognosis is for 3-6 months, and she requested that we stop aggressive treatment. For the last few months she's been able to stay with her sister."

"Has she changed her mind about aggressive therapy?"

"No, but the cancer has spread through her abdomen and she's developed a couple of bowel obstructions. We had to admit her to hospice care for an IV and NG suction. She's had bouts of nausea and vomiting with some colicky pain. She's been refractory to pharmacologic therapy and doesn't want a PEG tube because she'd like to eat food normally. I'm not sure if she's a good candidate for palliative surgery or not, but she's requested it, so I'd like you to come and take a look."

Dr. Ramirez agrees and visits Mrs. Macias that afternoon.

When he arrives, the hospice director isn't around, so Dr. Ramirez looks through Mrs. Macias's chart. Just as he's finishing up, Dr. Whitehead comes in.

"So what do you think?"

"Looking through her chart, it doesn't look like she's a particularly good candidate for palliative surgery. She's got at least 2 different obstructions, mild to moderate ascites, a pleural effusion, and her functional score is lower than I'd like."

"Well, let's go in and talk to her," Dr. Whitehead responds.

As they enter her room, Mrs. Macias looks up and says, "Are you the doctor who's going help me eat again."

Dr. Whitehead responds, "Well that's what were here to talk about."

"I'll be honest," Dr. Ramirez says, "I'm worried about the toll the surgery will take on your body, given your weakened condition right now. And I'm also concerned that the surgery might not accomplish what you want it to, at least not right away. You may not be able to eat right away or even eat what you want. It will take at least a month to recover from the surgery, if everything goes smoothly. And a number of complications could occur, some of which are very painful and others that may keep you from eating."

Mrs. Macias gives Dr. Ramirez a hard look. "I have been living through medical treatments for too many years and

now, now I am getting ready to die. I love the taste of food and even if it's just for a little while, I want to enjoy myself at least a little bit. I'm not asking you to save my life, I'm asking you to let me have some meals with my visitors before I die."

Commentary

How do we assist a patient's transition from a reasonable desire to a more realistic expectation without eliminating all hope? This is the challenge faced by Mrs. Macias and her surgeon, Dr. Ramirez. The case frames the problem in human terms—our patient only seeks an operation for the modest gain of an opportunity to eat with her friends in her final days. Who among us in medicine would not feel compassion in such circumstances and not be tempted to defy the futility of the situation?

There is a popular business book, *Getting to Yes*, that describes the negotiation process as 2 parties try to find common ground and cut the deal that gives both groups a victory. Mrs. Macias's doctors are struggling with Getting to No. The American College of Surgeons Statement on Principles Guiding Care at the End of Life cite the important need to recognize the physician's responsibility to forgo treatments that are futile. In this case, the presence of distant metastases, multiple sites of small bowel obstruction due to tumor implants, ascites, and a poor performance status argue strongly that the solution to the problem requested by the patient, an operation, has an extremely low probability of providing the desired outcome. Faced with such futility, it is seldom reasonable to proceed with a surgical intervention. This course of action should be abandoned, but the patient should not.

In approaching such circumstances it is critical that the patient, physician team, and family have appropriate expectations about anticipated outcomes from the various treatment options that are to be considered. This requires a very detailed discussion with Mrs. Macias about her current needs, placed in the context of the ability of the health care team to meet her expectations. In framing such a discussion, it is important that everyone share the same information. In our studies of palliative surgical decision making, we have tried to identify the probability of successfully relieving the targeted symptom at 30 days and describe its durability at 100 days, along with the probability that the patient will experience a new or recurrent major symptom during that period. In addition, the associated morbidity and 30-day post-operative mortality would be described to complete the value equation that must be considered when making such challenging decisions.

The probability of relieving this patient's obstruction with a major operation is extremely limited. The probability that the effects of the surgery would last for the duration of her life is even less likely—when performed in the setting of ascites, the probability of complication is nearly 50 percent, and the probability of 30-day post-operative mortality is approximately 10 percent. This does not mean that alternative care options should not be considered. Mrs. Macias describes a need for the social value of eating. This is a fundamental human concern, and efforts to assist should not be discarded, even as the means are reconsidered. The placement of a PEG tube may allow her to avoid impending vomiting and permit some modest oral intake. In this way we can set expectations in such a way that we do not promise what we cannot deliver.

In summary, I would sit down with the patient, her family, and her hospice physician and have a frank discussion about the inherent limitations in providing for her needs while empathically avoiding her abandonment of hope. When the proper time is shared with the patient and the expectations are managed appropriately, these decisions often become more straightforward than they first appear. So, yes we can and will help.

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The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental. The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.

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Journal Discussion

Some Ethical Concerns about Placebo Operations

Placebo controls n surgical research can be performed ethically when certain criteria are met.

Luke P. Brewster, MD

Weijer C. I need a placebo like I need a hole in the head. *J Law Med Ethics*. 2002;30:69-72.
PubMed Google Scholar

Miller FG. Sham surgery: an ethical analysis. *AJOB*. 2003;3:41-48.

There is a difference in kind and degree between a surgical and a pharmaceutical placebo. A sugar pill has no inherent risk, while a sham operation often does. There is, however, some agreement that placebo-controlled trials can be ethically acceptable in medical research. Usually this agreement depends upon the existence of clinical or procedural equipoise and an appropriate risk-benefit ratio. The degree of appropriate risk and whether this risk-benefit ratio pertains to the subject group collectively or to the individual research subjects are not settled issues, so it seems fair to ask what the appropriate criteria for placebo-controlled surgical trials might be.

Recently, fetal neuron transplant studies for patients with Parkinson's disease (PD) have stimulated the bioethical community's interest in the use of placebo control arms in surgery research. In these trials, the control group receives anesthesia, partial burr holes (not penetrating the skull), antibiotics, and immunosuppressive agents similar to those given to the treatment group, but without the transcranial needle injection of fetal neurons.

In discussing Peter Clark's [1] opinion of these trials, Charles Weijer points out that placebo operations as a control are not a requirement for scientifically acceptable research, even though a placebo control of some kind is sometimes needed [2]. Traditionally, placebos have been justified by comparison to everyday risk—if the placebo contains no greater risk than an individual encounters on an average day, then the placebo is acceptable. Obviously, all surgical placebos exceed this risk and fail to meet this standard. Weijer proposes that the risk-benefit ratio is an inappropriate comparison for nontherapeutic procedures because a direct benefit does not exist. Instead, he argues that risk should be counterbalanced by knowledge gained instead of benefit to the subject. For these fetal neural transplant trials, he argues that the potential for knowledge is too low compared to the risks involved for the placebo control to be ethically acceptable, and he also argues that patients not undergoing any sort of operation would serve as a more pragmatic control group.

Franklin Miller supports the structured use of placebo-controlled surgical trials [3]. He claims that when patients consent to research they are not owed the same duties by the research physician as by their treating physician (even when these are one and the same person). Miller distinguishes between the clinical obligations of beneficence and nonmaleficence, on the one hand, and, on the other, the obligation to minimize risks for research subjects—a standard accepted by many in the scientific community [4,5]. Weijer elsewhere indirectly challenges this risk-minimizing standard on legal and ethical grounds by emphasizing the continued clinical obligations of physician-scientists to their (and presumably other physicians') patients as research subjects [6,7].

Undoubtedly certain safeguards, such as using an objective third party to obtain consent from the patient/subject, may help subjects understand the different roles a physician-scientist plays.

Miller also claims that the ethical requirement that clinical research minimize risk is proportionate and not absolute. Accordingly, acceptable risk may exceed that of everyday activities, and the acceptability of this risk should be judged by the appropriate IRB. By highlighting a less risky intervention (arthroscopic knee incisions) [8], he suggests that placebo-controlled surgical trials with appropriate informed consent and a favorable research risk-benefit ratio are ethically acceptable and provide meaningful medical knowledge.

All surgical incisions have an intrinsic cost to the patient or subject, and the risk to both the treatment and control group subjects in surgical trials is such that the overall risk-benefit ratio may not favor one group over another; this is sometimes the case in pharmaceutical trials as well. Accordingly, a collective risk-benefit or risk-knowledge ratio that considers both the treatment and control groups together along with the clear and full disclosure of the consent form [3, 6] as it pertains to the risks and benefits for both the treatment and control groups should be considered when determining whether such a study is clinically and ethically acceptable.

When properly designed and implemented, randomized placebo-controlled surgical trials can yield important clinical or scientific knowledge in an ethically acceptable manner.

References

1. Clark PA. Placebo surgery for Parkinson's disease: do the benefits outweigh the risks? *J Law Med Ethics*. 2002;30:58-68.
   View Article PubMed Google Scholar
2. Weijer C. I need a placebo like I need a hole in the head. *J Law Med Ethics*. 2002;30:69-72.
   View Article PubMed Google Scholar
3. Miller FG. Sham surgery: an ethical analysis. *AJOB.* 2003;3:41-48.
   View Article PubMed Google Scholar
4. Swerdlow PS. Use of humans in biomedical experimentation. In: Macrina FL, ed. *Scientific Integrity: An Introductory Text with Cases*. Washington DC: ASM Press; 2000;73-99.
   Google Scholar
5. Declaration of Helsinki, 2002. Accessed August 29, 2004.
6. Freedman B, Glass KC, Weijer C. Placebo orthodoxy in clinical research II: ethical, legal, and regulatory myths. *J Law Med Ethics*. 1996;24:252-59.
   View Article PubMed Google Scholar
7. Miller PB, Weijer C. Rehabilitating equipoise. *Kennedy Inst Ethics J*, 2003;13:93-118.
   View Article PubMed Google Scholar
8. Moseley JB, O'Malley K, Petersen NJ, et al. A controlled trial of arthroscopic surgery for osteoartritis of the knee. *N Engl J Med*. 2002;347:81-88.
   View Article PubMed Google Scholar

Questions for Discussion

1. Do you agree with Weijer that knowledge should be substituted for benefit in the risk-benefit ratio criterion for determining whether a surgical trial is ethically acceptable?
2. By arguing that the obligation to minimize risk is not absolute, does Miller give too much priority to patient autonomy in determining ethically acceptable research?

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Medical Education

Acknowledging the Limits of Individual Competence

Surgeons must know their clinical strengths and weaknesses in order to improve their skills and increase patient safety.

Robert S. Rhodes, MD

Mark Twain said that to be a physician requires the right combination of confidence and ignorance. The confidence part of the combination grounds one of the more important aspects of medical care—providing reassurance. Such reassurance is needed by both the "worried-well" and by those with serious illnesses that need complex care. Surgeons often must maintain their confidence in the face of uncertainties. Though uncertainties result from many factors, this essay focuses on uncertainty that arises from limitations in the surgeon 's knowledge or judgment. Specifically, it examines the challenge of recognizing and acknowledging these limitations. Put succinctly, it is difficult to know the limits of your own knowledge and gain insight into why you cannot recognize situations for what they are.

The last several decades have seen a substantial increase in the understanding of learning and error and how they affect human performance [1]. A key feature of human learning is that competence can be represented as a progression through stages of competence and is not a discrete state, the opposite of which is incompetence. Experts are distinguished from those with lesser degrees of competence by the number and complexity of rules they use to evaluate and solve problems. Acquiring the knowledge that forms the basis of these rules and the skills of increasing competence requires "deliberate practice" [2]. Errors are more likely to occur when, regardless of their level of competence, individuals attempt to deal with new or unusual situations. In the face of uncertainty, the tendency is to cling to one 's initial hypothesis often in the face of astoundingly contradictory information. This tendency is known as confirmation bias. Stated another way, believing is seeing [3].

Another limitation of competence results from the complexity of health care delivery. One cause of this complexity is the fact that the average physician now interacts with 16 other health care individuals; in 1900, that number was 3. Moreover, each of these 17 individuals tends to play an increasingly critical role in overall care. As a result, health care outcomes are now as much a function of the system of care as they are of individual physician care, and the increasing numbers of involved individuals makes it easier for errors to occur in the system.

The need for surgeons to acquire the relevant knowledge and skills is self-evident; the socialization into medical practice, however, often intimidates individuals into hiding or ignoring their deficits—no one wants to be a weak link. As a result, surgeons may perform tasks using less than optimal processes. But even sub-optimal processes may achieve successful outcomes, and when they do succeed, they may be reinforced. This is particularly troublesome because it runs counter to a surgeon 's ethical obligations to patients, other members of the health care team, and to society to teach safe and effective techniques to future generations [4]. When errors do result from sub-optimal individual or systemic process, they often are compounded by failure to disclose. This problem is reflected in surveys of patients ' and physicians ' attitudes toward the disclosure of medical errors. The disparity identified in these surveys suggests that physicians may not be providing the information or emotional support that patients involved in medical error need and deserve [5].

Accordingly, we should acknowledge that: (1) errors cannot entirely be avoided (ie, to err is human), and (2) efforts to minimize errors must address the systemic causes. Indeed, the observed relationship between volume and outcomes that have been noted for certain complex surgical procedures [6] already suggest some features of better systems of

care. For example, better outcomes for some procedures are more closely correlated to hospital volume than to surgery volume.

One key to improving the systems of care is for surgeons to change their roles from that of autonomous, authoritarian captain of the ship to that of leader of the team. As a leader, the surgeon must ensure that all team members have situational awareness, increasing the probability that errors will be quickly spotted and providing the team with an opportunity to recover (ie, prevent error from causing an adverse outcome). Optimizing situational awareness requires that each team member be willing to communicate his or her concerns and uncertainties to the team leader. In turn, the team leader must recognize such communications as an opportunity for team learning.

The importance of teamwork in the operating room is demonstrated by a study of learning minimally invasive cardiac surgery [7]. Fast-learning teams were characterized by members who had worked together in the past, were together in the early learning phase before new members were added, scheduled procedures in close succession, discussed each case before and after, and carefully analyzed the results. Faster learning occurred even when the surgeons on these teams were not as technically adept as those on slower learning teams.

Such findings suggest 2 ways of improving care. First, surgeons and other health care team members must be willing to acknowledge their shortcomings. Only then will they be able to practice the appropriate processes and achieve better outcomes. Given the increasing pressures on faculty time, simulators may play an important role here by providing opportunities for deliberate practice. The key word is *deliberate* because it emphasizes that practice focuses on specific weaknesses and aims at specific improvements. Second, surgeons must recognize the importance of systems of care and understand that the team concept is essential for optimal care. If surgeons continue to dwell excessively on their personal responsibility and the potential legal consequences, they will remain reluctant to engage in appropriate practice changes and improvements to the health care systems in which they operate.

References

1. Reason JT. *Human Error*. Cambridge University Press: Cambridge, England; 1990.
   Google Scholar
2. Ericsson KA. The acquisition of expert performance: an introduction to some of the issues. In: Ericsson KA, ed. *The Road to Excellence. The Acquisition of Expert Performance in the Arts and Sciences, Sports and Games*. Mahwah, NJ: Lawrence Erlbaum Associates;1996:1-50.
   Google Scholar
3. Way LW, Stewart L, Gantert W, et al. Cause and prevention of laparoscopic bile duct injuries: analysis of 252 cases from a human factors and cognitive psychology perspective. *Ann Surg*. 2003;237:460-469.
   View Article PubMed Google Scholar
4. McKneally MF: Professional obligations of surgeons. In: Mc Grath M, ed. *American College of Surgeons Ethics Curriculum for Surgical Residents.* Chicago, IL (in press).
5. Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients ' and physicians ' attitudes regarding the disclosure of medical errors. *JAMA*. 2003;289:1001-1007.
   View Article PubMed Google Scholar
6. Birkmeyer JD, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. Surgery volume and operative mortality in the United States. *N Eng J Med*. 2003; 349: 2117-2127.
   View Article PubMed Google Scholar
7. Pisano GP, Bohmer RMJ, Edmondson AC. Organizational differences in rates of learning: evidence from the adoption of minimally invasive cardiac surgery. *Manage Sci.* 2001;47:752.
   View Article Google Scholar

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Clinical Pearl

Surgery for Bowel Obstruction in Ovarian Cancer

Palliative surgery can be considered for terminally ill patients with bowel obstruction if the patient is likely to benefit from the surgery.

Jennifer Reenan, MD

Introduction

Unfortunately, bowel obstruction is a common sequela of advanced abdominal or pelvic cancers, including ovarian cancer. This challenging complication adversely affects both length of survival and quality of life. Reports suggest that from 5.5 percent to 51 percent of ovarian cancer patients with Stage III or Stage IV disease develop a malignant bowel obstruction [1]. Of course, the obstruction may be due to benign, non-cancerous causes such as adhesions, hernias, edema, inflammatory bowel disease, or radiation-induced strictures. Typically, however, in the case of gynecological cancers, the obstruction is related to tumor growth and blockage [2].

Ovarian cancer tends to spread regionally by local extension into the peritoneum, and tumor deposits may occlude both the large and small intestine at either single or multiple sites.

Clinical Features

Clinical features vary depending on the site of the occlusion with obstructions higher in the gastrointestinal tract (such as the duodenum or proximal jejunum) causing intense nausea and vomiting. A small bowel obstruction will also induce some moderate abdominal distension with hyperactive bowel sounds on auscultation and abdominal pain. Occlusion of the large intestine is associated with more significant abdominal distension.

Suspected bowel obstruction in the terminally ill cancer patient should not be considered an emergency, inasmuch as the course of the obstruction is generally gradual. Compression of the lumen tends to occur insidiously and often remains partial [3].

Signs and Symptoms of Bowel Obstruction

- Nausea and vomiting (worse with duodenal or jejunal obstruction)
- Abdominal or visceral pain (often near site of obstruction)
- Abdominal distension (worse with obstruction in large intestine)
- Absent bowel sounds (complete obstruction)
- High-pitched or tympanic bowel sounds (partial obstruction)
- History of infrequent bowel movements and flatus (partial obstruction)
- History of absent bowel movements and flatus (complete obstruction)
- Anorexia

Treatment

When the presence and location of malignant bowel obstruction have been verified through radiologic evaluation, the

goals of treatment must be considered carefully in patients with end-stage ovarian cancer. Improved survival may be a secondary gain. The primary aim of intervention, whether medical or surgical, is usually improvement and palliation of symptoms. Individual patient values and goals become especially important at the end of life. Some patients, such as Ms Macias (from this month's clinical case), may desire a return, even if brief, to eating and enjoying a regular diet. Others may wish to remain at home for hospice care, which can be difficult in the case of recurrent obstructive episodes.

Medical Management. Medical management for bowel obstruction in the terminally ill patient is appropriate for situations in which the patient's condition prohibits invasive treatment or when the patient refuses such treatment. Some common pharmacological therapies for relief of symptoms associated with a malignant bowel obstruction are:

- Analgesics (such as opioids)
- Anti-emetics (such as metaclopromide)
- Anti-secretory drugs (such as octreotide, a synthetic analog of somatostatin)
- Anti-cholinergics to slow down peristaltic contractions (such as scopolamine)
- Corticosteroids to decrease peritumoral edema and for anti-emesis activity
- Fluids to prevent dehydration and electrolyte imbalances (controversial for hospice patients)

Endoscopic Management. These procedures may be useful for patients who are refractory to medical management but are considered poor candidates for surgery. Endoscopic therapies can also benefit patients who refuse more invasive surgical correction. The 2 chief methods of endoscopic management are endoscopic stent placement and percutaneous endoscopic gastrostomy (PEG) placement. While PEG placement can be very effective at relieving the symptoms associated with obstruction and in enabling home hospice, it does not usually allow the patient to return to a regular oral diet [4].

Surgical Management. If the obstruction is amenable to surgical correction and the patient is deemed an appropriate candidate, surgery may be recommended for relief of a malignant bowel obstruction. Overall, however, success following surgery is greatly variable, with significant morbidity and mortality risks which must be discussed with the patient. Both the operative mortality (9-40 percent) and complication rates (9-90 percent) are high, with survival in the 3- to 6-month range [3]. Complications include re-obstruction, pain, wound infection, and the development of intestinal fistulae.

A survey of Society of Surgical Oncology members found that increasing patient survival received the lowest priority scores when physicians were asked what they considered to be important goals to achieve in performing palliative surgery [5]. Success should be evaluated in quality-of-life terms, outcomes (symptom control, comfort, restoration of diet, maintaining function, decreased hospitalization etc.) which may vary depending on the goals of the patient. Estimates of success, in terms of quality of life, for surgical palliation of bowel obstruction also vary greatly.

Other Options. A nasogastric (NG) tube may provide temporary relief from the abdominal symptoms of bowel obstruction but should not be used long-term in the terminally ill patient. Most patients find NG tubes very uncomfortable.

Indications for Palliative Surgery

There is no clear consensus in the literature on indications for palliative surgery for the correction of bowel obstruction in the terminally ill cancer patient [6]. During evaluation for surgical candidacy, 3 key questions need to be considered:

1. Is the surgery technically feasible?
2. Is the patient fit, both physically and emotionally, for surgery and recovery?
3. Is the patient likely to benefit from the surgery?

One group, after a review of the literature and panel discussion, has attempted to delineate absolute and relative contraindications to palliative surgery for the correction of bowel obstruction [3]. A slightly abbreviated version of

their tables follows (content not substantially altered):

Absolute Contraindications to Surgery.

- Laparotomy demonstrating that further corrective surgery was not possible
- Previous abdominal surgery showing diffuse metastatic cancer
- Involvement of the proximal stomach
- Intra-abdominal carcinomatosis with severe motility problem
- Diffuse palpable intra-abdominal masses
- Massive ascites which rapidly recurs after drainage

Relative Contraindications to Surgery

- Extra-abdominal metastases producing difficult-to-control symptoms (ie. dyspnea)
- Non-symptomatic but extensive extra-abdominal metastatic disease (ie. pleural effusion)
- Poor general performance status
- Poor nutritional status (marked weight loss, cachexia, hypo-albuminemia)
- Advanced age in association with cachexia
- Previous radiotherapy of the abdomen or pelvis

References

1. Davis MP, Nouneh D. Modern management of cancer-related intestinal obstruction. *Curr Pain Headache Rep.* 2001;5:257-264.
   View Article PubMed Google Scholar
2. Clarke-Pearson DL, Chin NO, DeLong ER, Rice R, Creasman WT. Surgical management of intestinal obstruction in ovarian cancer. I. Clinical features, postoperative complications, and survival. *Gynecol Oncol.* 1987;26:11-18.
   View Article PubMed Google Scholar
3. Ripamonti C, Twycross R, Baines M, et al. Clinical practice recommendations for the management of bowel obstruction in patients with end-stage cancer. *Support Care Cancer*. 2001;9:223-233.
   View Article PubMed Google Scholar
4. Gemlo B, Rayner AA, Lewis B, et al. Home support of patients with end-stage malignant bowel obstruction using hydration and venting gastrostomy. *Am J Surg.* 1986;152:100-104.
   View Article PubMed Google Scholar
5. McCahill LE, Krouse R, Chu D, et al. Indications and use of palliative surgery: Results of society of surgical oncology survey. *Ann Surg Oncol*. 2002;9:104-112.
   View Article PubMed Google Scholar
6. Ripamonti C. Management of bowel obstruction in advanced cancer. *Current Opinion Oncol.* 1994;6:351-357.
   PubMed Google Scholar

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Health Law

When Residents Assist in Surgery

A surgical patient must be informed if anyone other than the attending physician will take a significant role in the surgery.

Melissa Junge

Ms Belin was referred to Dr. Dingle, a general surgeon, for removal of her gall bladder. After an office consultation, they agreed that Dr. Dingle would do the surgery, and it was scheduled. The surgical procedure is a laparoscopic cholecystectomy, which involves making incisions in the abdomen and inserting at least 3 ports. Carbon dioxide is introduced into the abdomen to expand the area and make it more visible when a camera is inserted through 1 of the ports. The camera displays the interior on 2 high-definition television monitors. The procedure requires 3 physicians; 1 to operate the camera, 1 to retract the organs and tissues in order to isolate the gall bladder and the structures that connect it to other organs and tissues, and 1 to cut and clip the connecting structures and remove the gall bladder through a port.

The written consent that Ms Belin signed authorized Dr. Dingle "and/or such assistants as may be selected and supervised by him" to perform the laparoscopic cholecystectomy. The form has a place for "Special remarks or comments by patient," which was left blank. Ms Belin was insistent that Dr. Dingle do the actual cutting and removal of the gall bladder, although she was aware that one or more residents would assist him given that 3 surgeons are required to perform the operation. Ms Belin requested and received verbal assurances from Dr. Dingle that he would perform the procedure and only use the resident for assistance when absolutely necessary. She requested this because she was aware that the hospital was a teaching hospital which often used "inexperienced residents" to assist in surgery. There was no indication on the written consent form as to what Dr. Dingle and the assistants he selected and supervised were to do during the surgery.

When in fact the surgery occurred, Dr. Dingle was assisted by a medical student and a resident, Dr. Magnuson, who was just beginning her fourth year of residency training. The student was responsible for operating the camera, which was done properly. Dr. Dingle did the retractions and Dr. Magnuson dissected the gall bladder and removed it. She and Dr. Dingle regarded the surgery as routine and without incident. However, one of the connecting structures that needed to be dissected was the cystic duct, which runs from the gall bladder to the common bile duct. The common bile duct runs from the liver to the intestines. Instead of dissecting the cystic duct, Dr. Magnuson dissected and clipped the common bile duct, which resulted in the drainage of bile into Ms Belin's abdomen. The drainage led to a great deal of pain and discomfort. As a result, Ms Belin underwent extensive corrective surgery at another hospital.

Ms Belin filed a suit against Dr. Dingle, Dr. Magnuson, and Mercy Hospital. She brought 3 causes of action, 2 of which were not surprising; however, the third was unexpected, and became the main issue eventually addressed by the Court of Appeals of Maryland [1].

The first cause of action was negligence in the performance of the surgery. Recovery for malpractice "is allowed only where there is a relationship of doctor and patient as a result of a contract, express or implied, that the doctor will treat the patient with proper professional skill and the patient will pay for such treatment, and there has been a breach of professional duty to the patient" [2]. The plaintiff must show that the doctor's conduct—the care given or withheld by the doctor—was not in accordance with the "degree of care and skill which is expected of a reasonably competent practitioner in the same class to which [the physician] belongs, acting in the same or similar circumstances" [2].

Despite Ms Belin's request, it would not have been possible for Dr. Dingle to do *both* the retraction and the dissection and removal. Ms Belin's expert witness, Dr. Goldstone, agreed that it would not breach the standard of care for the resident to do the cutting and clipping and the attending surgeon to do the retracting, "provided there isn't some previous agreement that this would not occur" [3]. The jury found in favor of the defendant-physicians (surgeon and resident) because the dissection of the bile duct is a common risk associated with the surgery.

Although the jury found in favor of the surgeon and resident in this case, a resident can under certain circumstances be held liable for negligence. Moreover, the surgeon is said to be in control of the operation and, therefore, is often held responsible for a resident's negligent actions during the surgery.

The second cause of action was negligence based on the lack of informed consent. Ms Belin argued that although Dr. Dingle agreed to do the actual cutting and removal of the gall bladder, resident Magnuson did the cutting, clamping, and stapling. Had she been aware of the active role to be played by Dr. Magnuson, she would not have consented to having the surgery performed at that hospital or by Drs Dingle and Magnuson. Unlike the traditional action of negligence, a claim for lack of informed consent focuses not on the level of skill exercised in the performance of the procedure itself but on the adequacy of the explanation given by the physician in obtaining the patient's consent.

In response to this cause of action, the court stated that "[a] physician who agrees to a specific allocation of responsibility or a specific limitation on his or her discretion in order to obtain the consent of the patient to the procedure and then, absent some emergency or other good cause, proceeds in contravention of that allocation or limitation has *not* obtained the informed consent of the patient" [4]. Dr. Dingle argued that patients should not be allowed to "choreograph" surgical procedures. However, the court did not view Ms Belin's case as having the pernicious effects suggested by Dr. Dingle; ie, of permitting patients to "choreograph" surgery and unduly restricting the flexibility that the surgeon must retain. "The surgeon does not have to agree to any such limitations, and, presumably, few, if any, of them will so agree" [4].

The court's primary issue for review was the third cause of action: breach of contract. This cause of action is not typical in cases between patients and physicians. The court was to decide "[w]hether a physician who, as part of his or her contractual undertaking with a patient, agrees to an allocation of tasks between the physician and other physicians, may be liable for breach of contract if that agreement is violated" [5].

Ms Belin supported her claim by stating that she had an oral contract with Dr. Dingle and in consideration of that agreement, she agreed to allow Dr. Dingle to perform the surgery. Dr. Dingle then breached that contract by permitting Dr. Magnuson to perform the cutting and clipping. Dr. Magnuson made a mistake in cutting and clipping the common bile duct which, even if not negligent, might not have been made by Dr. Dingle, a more experienced surgeon.

Dr. Dingle responded that creating a duty to disclose a resident's precise role "would permit patients to choreograph how an operation is to be performed negating all possibility of informed medical judgment occurring during the operation" [5]. He denied that he ever had the conversation testified to by Ms Belin and stated that he never would have agreed to the conditions she alleged. Dr. Dingle indicated that, if faced with that demand, he would have offered Ms Belin only 2 options, "allow me to do what I thought was best unrestricted, or to get another surgeon" [6].

Courts have universally recognized that, except in emergency or gratuitous situations, the relationship between doctor and patient is a contractual one, either expressly or by implication. Furthermore, a growing number of courts have held that there may be a separate breach of the contract action when the doctor contravenes a contractual agreement. "A doctor and his patient are at liberty to contract for a particular result and, if that result is not attained, a cause of action for breach of contract results" [7]. Additionally, the court stated that "[b]ecause the doctor-patient relationship is normally a contractual one, it is permissible for the parties, if they choose to do so, to define with some precision the role that the doctor is to play" [8].

The court noted that the parties may have conflicting interests; the doctor wanting as much flexibility and discretion as possible, and the patient, if choosing the physician because of some special confidence in that physician's particular abilities, desiring that the selected physician oversee and personally perform the most difficult part of the procedure. A violation of a specific allocation or understanding may constitute the lack of informed consent, negligent delegation,

and a breach of the contract, not to mention a claim of misrepresentation or fraud. This is of particular importance inasmuch as breach of contract, misrepresentation, and fraud are not typically covered by a physician's liability insurance.

Implications for Surgeons

Notwithstanding the court's decision, the jury found in favor of Dr. Dingle. This does not, however, diminish the court's indication that a cause of action for breach of contract may be valid in this type of situation.

The *Dingle* case has important implications for physicians and residents. Patients, as health care consumers, are increasingly "savvy" regarding medical decision making. Their greater access to information about medical procedures and physician credentials may lead to an increase in requests for allocations or specifications of duties as alleged in this case. Opinion 8.08, Informed Consent, in the AMA *Code of Ethics* indicates that "[t]he patient should make his or her own determination on treatment." Furthermore, "[t]he physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice" [9].

The patient has an interest in the medical procedure, and there is a need for disclosure and agreement if there is likely to be significant participation by other persons. The lack of a clear understanding prior to the procedure may prompt a later finding that a true informed consent was not obtained. Accordingly, specific allocations of duties, if any, should be accounted for realistically and discussed with the patient. When a patient makes demands, the physician can choose to accommodate when possible or desired, or he or she can refer the patient if the demands compromise his or her ability to effectively perform the procedure. The underlying obligation of veracity is expressed in Opinion 8.12, Patient Information, stating that "it is a fundamental ethical requirement that a physician should at all times deal honestly and openly with patients" [10]. In addition to an honest discussion with the patient, it would be prudent for patient and surgeon to document any agreements or allocations of duties on the informed consent form.

Resident involvement in the informed consent process has potential advantages and disadvantages. If residents participate in the informed consent process and, therefore, are aware of any specific allocations or demands made by the patient, the resident is then informed of those specifications and any deviation thereof may result in his or her liability. However, if the resident does not participate in the informed consent process, he or she might not be aware of any allocations or demands made by the patient regarding the procedure. Regardless of the level of involvement in the informed consent, the resident should be made aware of any discussions or allocations of duties expressed and agreed upon by the patient and the surgeon.

References

1. *Dingle v Belin*, 749 A2d 157 (Md 2000).
2. *Ibid.*,164.
3. *Ibid.*,161.
4. *Ibid.*,166.
5. *Ibid.*,163.
6. *Ibid.*,160
7. *Ibid.*,166.
8. *Ibid.*,169.
9. American Medical Association. Opinion 8.08 Informed consent. *Code of Medical Ethics*. Accessed August 19, 2004.
10. American Medical Association. Opinion 8.12 Patient information. *Code of Medical Ethics*. Accessed August 19, 2004.

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the AMA.

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Policy Forum

The Universal Protocol

The Joint Commission on Accreditation of Healthcare Organizations has implemented patient safety initiatives to help decrease the number of medical errors in surgery.

Dennis O'Leary, MD

This past July, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) formally implemented a Universal Protocol for the Prevention of Wrong Site, Wrong Procedure, and Wrong Person Surgery[1]. This occurred amidst the fanfare of a National Time-Out Day sponsored by the Association of Operating Room Nurses and with the formal endorsement and backing of more than 50 professional organizations, including almost all of the major surgical professional societies. How could a problem that required so much professional investment have arisen?

In the fast-paced, high-tech, and increasingly complex health care delivery environment, human errors—and the adverse events that all too often ensue—are seemingly inevitable. Indeed, there appears to be a certain fatalism about the occurrence of medication errors, surgical complications, and health care-associated infections, even where the most stringent error-prevention procedures are in place. Certain adverse events, however, simply should never happen. The performance of a surgical procedure on the wrong part of a patient's body, the performance of the wrong procedure on a patient, and the performance of surgery on the wrong patient rank at the top of such a list.

It is unlikely that the admonition of the Hippocratic Oath, "First do no harm," anticipated the potential occurrence of wrong site, wrong procedure, or wrong patient surgery. Indeed, available epidemiological patient safety data—whether sought in the refereed clinical literature or elsewhere—suggests that this problem arose *de novo* in the 1990s. Such an interpretation is simply not tenable. The absence of earlier data suggests a high level of professional and organizational denial in our health care system and reflects the ability of the delivery system and its participants to hide seemingly obvious mistakes.

The first highly visible case of wrong site surgery—involving the amputation of the wrong leg of a patient at a Florida hospital—was a major 1995 news media event and became the initial case in what would become the Joint Commission's Sentinel Event Database. Over the next 3 years, several additional cases of wrong site surgery became known to the Joint Commission and led to the issuance of one of its first Sentinel Event Alerts. This initial Sentinel Event Alert on wrong site surgery emphasized the need for pre-operative verification of the intended performance of a specific procedure on a specific patient; the desirability of marking the planned site of the surgery on the patient's body; and the conduct of a "time out" in the operating room to assure agreement among the surgeon and the other members of the operating room team as to patient, procedure, and surgical site.

What happened next surprised all of us. Following the issuance of the alert, the numbers of reported cases of wrong site surgery grew and then grew some more. By 2001, when the Joint Commission decided to issue a second Sentinel Event Alert on this subject, the number of these cases in the database was well over 100 and included 14 instances of surgery on the wrong patient, resulting in the death of 2 patients. Despite a concurrent initiative to encourage patient involvement in surgical site marking, the second alert seemingly also had little impact on surgical preparations: the number of reported cases continued to rise.

With concern about this problem beginning to grow in the surgery community, the Joint Commission—in

promulgating its 2003 National Patient Safety Goals—codified the performance expectations first suggested in the 1998 alert. A year later, the Joint Commission convened a national summit of professional leadership organizations which recommended the creation of the Universal Protocol. Adopted by the Joint Commission's Board of Commissioners and endorsed by virtually all of the key professional organizations that have an interest in surgery, the Universal Protocol is unambiguous in its expectations. In step-wise fashion, it outlines requirements for the pre-operative verification process, surgical site marking, and the conduct of an operating room team "time-out" immediately before the actual surgery is to commence. Compliance with the Universal Protocol is an accreditation requirement—any identifiable pattern of non-compliance can lead to loss of Joint Commission accreditation.

We might think this is the end of the story, but it is only the beginning of another chapter. We now have over 300 cases of wrong site, wrong procedure, or wrong person surgery in our database, and more continue to be reported. We do not know the frequency of these occurrences because the increased reporting could reflect either increased frequency of incidents or a higher rate of reporting. We do know, however, that we are dealing with a stubborn problem.

No surgeon willfully performs surgery on the wrong body site or wrong patient. Most surgeons believe they are careful, conscientious, and technically competent; have the results to back up those suppositions; and are certain that they themselves will never perform the wrong procedure on a patient or perform the intended procedure on the wrong body site or patient…until it actually happens. This is not a matter of maleficence, but it is a matter of denial and lack of awareness.

Why aren't they aware of the risks? As noted, the actual frequency of wrong site, wrong procedure, and wrong person surgery is not known, but it is certainly greater than the frequency with which it is reported to the Joint Commission. Although these are rare events, each year there are individual hospitals which report 4-6 new cases of wrong site surgery, often in the same surgical specialty. While occurrences have been reported in all surgical specialties, some have inherently greater risk exposure than others. In orthopaedic surgery for example, where the potential for right/left confusion is almost an occupational hazard, the American Academy of Orthopaedic Surgeons has estimated that the typical orthopaedic surgeon has a 25 percent risk of performing wrong site surgery during his or her career [2]. Other risk factors are also known. The rapid sequential performance of similar procedures in multiple patients, eg, cataract surgery, is a known risk factor. So too are complex procedures, patients with deformities or morbid obesity, and procedures that require special positioning of the patient on the operating room table. Any or all of the above considerations should provide ample basis to create at least a yellow alert mindset (to borrow from the terrorism alert warning system) for the typical surgeon.

The need for increased awareness is not limited to the frequency of and risk factors for surgical error. Most physicians also have little knowledge about organizational systems and the critical links between system integrity and patient safety. Nor have most surgeons been trained as team players with individuals from other disciplines or made aware of the rich knowledge base identifying the circumstances in which human error is more likely to occur. These are just a couple of the most dramatic examples of areas in which our medical education and post-graduate training programs are failing us.

The Universal Protocol describes a series of organizational systems. These systems are, like all good health care systems, designed to prevent human error from reaching and affecting the patient. The salutory potential effect of system design, however, is a function of the actual execution of system requirements. Effectively executing the system requires the surgeon and the rest of the operating room team—not the Joint Commission—to own the system, to own the Universal Protocol. It also means that the surgeon, as the "captain of the ship," must be aware of the capabilities and potential foibles of each team member and work with them to achieve successful outcomes.

Today, there are more hospitals and ambulatory surgery centers and surgeons who reflect the professional values embodied in the Universal Protocol than ever before. Further, by endorsing the Universal Protocol and affirming the professional expectation of their members, the leaders of the American College of Surgeons and the surgery specialty societies, have reinforced the importance of this message. Nonetheless, serious challenges remain, including the need for change in the organizational culture, the alignment of behavioral incentives, and health professions education and training reform. We simply have more to do before this "scourge" can be eliminated from health care.

References

1. Universal Protocol for the Prevention of Wrong Site, Wrong Procedure, Wrong Person Surgery. *Joint Commission Perspectives*. 2004;24:3-4.
2. Tipton W. Personal Communication.

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Policy Forum

Should Surgery Have an FDA?

There are many challenges that need to be overcome before a regulating body can be established to oversee surgical procedures and devices.

Robert S. Rhodes, MD

The FDA ensures the safety and efficacy (when used properly) of the drugs that have its approval. To ask whether surgery should have an FDA is to ask whether surgery needs a *means* for dealing with a problem(s) or problems; the answer depends on the presence and nature of the problem(s) and the desired *ends*. This essay looks at the ethical implications of the current lack of a regulating body, like the FDA, for new techniques in surgery. I begin by considering the role the FDA now plays in regulating medical devices.

The FDA's Center for Devices and Radiological Health (CDRH) has responsibility for ensuring the safety and effectiveness of medical devices and for eliminating unnecessary exposure to man-made radiation from such devices [1]. The CDRH seeks to accomplish this mission by:

- Reviewing requests to research or market medical devices;
- Collecting, analyzing, and acting on information about injuries and other experiences in the use of medical devices and radiation-emitting electronic products;
- Setting and enforcing good manufacturing practice regulations and performance standards for electronic products and medical devices;
- Monitoring compliance and surveillance programs for medical devices and radiation-emitting electronic products; and
- Providing technical and other nonfinancial assistance to small manufacturers of medical devices.

The CDRH tests thousands of new products annually, each tested under "ideal" conditions. As a result, FDA approval attests to the *efficacy* of the device. But once approved, the device enters the realm of more general use, which often involves conditions less favorable than those of initial testing. The less-than-ideal circumstances include use in ways for which the devices were not intended; use in combination with other devices with which it had not been initially evaluated; and use by individuals who are inadequately familiar with its use. Moreover, many new devices replace older models, and the individuals who use them may confuse the functions and readouts of the new device with those of its predecessor. This is particularly true when an institution does not replace all older models with the new model. Thus, a device may be substantially less safe or effective than initially demonstrated under ideal conditions. The results of use under these general circumstances define the *effectiveness* of a device.

The key to improving the safety and effectiveness of medical devices is collecting, analyzing, and acting on data about injuries and other experiences once the devices are in use. This type of analysis could have the same important benefit in medical care as the reporting system used to improve aviation safety. However, the aviation reporting system works in large part because reporting is anonymous and confidential. Unfortunately, the current legal system does little to protect the reporting of adverse medical information from discovery and its subsequent use in law suits. Since it is natural for people or institutions to be reluctant to participate in any reporting system that might increase their legal risk, adverse experiences are underreported. The lack of an effective reporting system precludes identifying the root causes of problems with medical devices and this, in turn, precludes specific solutions.

Other significant limitations in FDA approval of medical devices are that the CDRH does not review advertisements before use, it does not assess cost-effectiveness, and it does not compare competing devices [2]. A striking example of a problem caused by failure to compare competing devices occurred when the regulator knobs on anesthesia machines of one manufacturer increased gas flow when turned in one direction while turning the knobs on machines from another manufacturer in that direction would decrease gas flow. Confusion resulting from this difference contributed to many unnecessary anesthetic deaths. There are also concerns that the FDA is pressured for speedy approvals and that members of FDA Advisory Committees may have substantial conflicts of interest [2].

Other problems arise from conflicts among the CDRH missions. One recent example is the controversy over the publication of data on endovascular devices. In this case, a specialty journal set the precedent of cooperating with the FDA and manufacturers to ensure publication of new data on device trials simultaneously with the initial public release of the data by the FDA [3]. When data on mortality rates with endovascular grafts was included, the graft manufacturer alleged that the article's FDA authors used confidential and proprietary data without its permission. The manufacturer claimed that the public release of such data constituted criminal and civil violation of the Federal Food, Drug, and Cosmetic Act and the Freedom of Information Act even though the alleged confidential data was already in the public domain. The journal editors concluded that the manufacturer's concerns were not with the data but the author's interpretation and discussion of the data and argued that such interpretations should be regarded as appropriate scientific discourse. Nonetheless, the FDA requested that the article be withdrawn from the journal's pre-publication Web site.

An FDA for surgery is not likely to be able to address other important aspects of the practice of surgery that lie outside the current CDRH mission, eg, geographic variations in the frequency of surgical procedures and the failure to adopt surgical practices in the face of substantial evidence of their effectiveness. Examples of the latter are breast conservation therapy in breast cancer [4], beta-blockers to reduce the frequency of perioperative cardiac events [5], and the prevention of complications that occur when central lines are in place [5].

The human penchant for adopting new technology necessitates many of the current functions of the CDRH. Yet the safe and effective use of new technology requires substantial training in the use of that technology. Such training is not currently emphasized sufficiently, and the investment in training relative to the cost of the new technology is disturbingly small. A recent approach by the Centers for Medicare and Medicaid Services (CMS) recognizes the important role of training. CMS conducted a town hall meeting among relevant specialists on the use of percutaneous transluminal angioplasty for carotid stenting in order to address "the degree of facility experience required, types of provider training programs to be developed and the rigor of these programs…to ensure the correct use of this procedure in the appropriate patient population" [6]. Another means of emphasizing the importance of training may be linking levels of reimbursement to training (ie, pay for performance).

If a policy requiring demonstrated proficiency had existed when laparoscopic cholecystectomy was introduced, fewer bile duct injuries might have occurred during surgeons' learning curves. But even here it must be recalled that this procedure was the application of existing gynecologic techniques to an existing surgical procedure. Again, the issue was training in the technique and not the technique per se. Most areas of complex endeavor such as aviation or nuclear power plant operation provide opportunities to practice in non-game situations. In contrast, medical education often occurs in live situations where education is compromised by demands of efficiency. This is not unique to surgery but occurs across all specialties.

In summary, substantial barriers hamper the current CDRH mission. These barriers are primarily legal rather than ethical, and their elimination might enable improvements in quality and safety. Further, to be effective, CDRH evaluations must be coupled with adequate training programs for new devices and techniques.

One final concern is that a surgery FDA might become subject to political issues masquerading as ethical dilemmas. For example, new techniques for performing what have been politically termed "partial birth abortions" might not receive CDRH approval.

References

1. FDA. Overview of what we do. Accessed September 3, 2004.
   Google Scholar
2. Deyo RA: Gaps, tensions, and conflicts in the FDA approval process: implications for clinical practice. *J Am Board Fam Pract*. 2004;17:142-149.
   PubMed Google Scholar
3. Cronenwett JL, Seeger JM: Withdrawal of an article by the FDA after objection by Medtronic. *J Vasc Surg*. 2004;40: 209-210.
   PubMed Google Scholar
4. White J, Morrow M, Moughan J, et al. American College of Surgeons Commission on Cancer, American College of Radiology Patterns of Care Study. *Cancer*. 2003;97:893-904.
   Google Scholar
5. Making Health Care Safer: A critical analysis of patient safety practices. Wachter RM, (Project Director), Evidence Report/Technology Assessment #43, Agency for Healthcare Research and Quality, Publication 01-E058, Washington, DC, July 2001.
6. 69 *Federal Register* 35650-35651 (2004).
7. McNeil BJ. Shattuck Lecture – Hidden barriers to the improvement of the quality of care. *N Eng J Med*. 2001;345:1612-1620.
   View Article PubMed Google Scholar

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Medicine and Society

Television on the Cutting Edge: Cosmetic Surgery Goes Prime-Time

Reality television programs that focus on cosmetic surgery show misguided viewers that such procedures are the key to emotional health and well-being.

Leigh Turner, PhD

Let's say you are 20 years old. You are embarrassed by what you call your "Roman nose." You look in the mirror and see a "weak chin." You want more prominent cheekbones. You are tired of having acne. You wish you were more popular. You like your current friends but wouldn't mind finding more attractive replacements for them. What would you do? Well, if you are Mike and Matt Schlepp, 2 brothers from Arizona, you decide to undergo rhinoplasty, get chin implants, and obtain porcelain veneers in order to resemble Brad Pitt. One brother prefers the look of Pitt in *Meet Joe Black*. The other brother wants his look from *Legends of the Fall*.

Mike and Matt are 2 participants on the MTV series, "I Want a Famous Face." The program features individuals undergoing cosmetic surgery because they hope to acquire the face and physique of particular celebrities. Five other individuals join the brothers in their quest for celebrity bodies, from Elvis to Jennifer Lopez and Kate Winslet. "I Want a Famous Face" takes fantasies about beauty and stardom and inscribes them on flesh. Call it cosmetic surgery karaoke.

"I Want a Famous Face" premiered last March. "The Swan″ began one month later on Fox. In "The Swan," 16 contestants, all women, subject themselves to cosmetic surgery in a competition to see who will win the beauty pageant held at the end of the series. The show selects women characterized by the program as "ugly ducklings" and offers them cosmetic surgery to determine who will emerge as the victorious "swan." Though participants work with a therapist, trainer, cosmetic dentist, and "life coach," the series focuses upon the multiple surgeries each woman undergoes. The list of procedures for one woman, Cindy, includes: endobrow lift, mid-face lift, cheek fat removal, fat removal under eyes, lip augmentation, liposuction of face, chin refinement, fotofacial, laser hair removal, collagen, Lasik surgery, breast augmentation, tummy tuck, and liposuction of inner thighs. Other contestants undergo similar procedures.

In 2002, ABC's "Extreme Makeover″ initiated the trend in television series featuring cosmetic surgery procedures. "Extreme Makeover″ documents men and women undergoing multiple surgeries before revealing their new features to family members and friends. A typical list of procedures for someone appearing on "Extreme Makeover″ includes liposuction of the abdomen, medial thighs, and arms, breast augmentation, brow lift, rhinoplasty, upper eyelid lift, fotofacials, chemical peels, laser treatment for acne, scalp treatment, porcelain veneers, and teeth whitening. Compared to this list of procedures, the surgery performed on "I Want a Famous Face″ seems almost minimalist.

The dominant message conveyed by each of these 3 programs is remarkably similar. Each series suggests that to undergo an "extreme makeover" is to experience a rite of passage requiring a death and resulting in a rebirth. The old and inadequate face, body, and self are surgically excised and a new, more attractive, sophisticated, and engaging "personality" emerges. The ugly duckling of the old body and self must succumb to the blade for the swan to take flight. Promotional material for these programs draws upon the rhetoric of psychological growth, personal

transformation, and spiritual fulfillment. The new bodies do not just have bigger breasts, more pronounced cheekbones, and whiter teeth. Rather, the programs suggest that individuals undergoing multiple cosmetic surgery procedures become livelier, more outgoing, and psychologically content individuals. Personal growth or spiritual development used to be connected to taking a pilgrimage to Thailand, watching Oprah, or training for marathon runs. Now, apparently, you need buttock implants or breast augmentation to let your authentic self emerge.

Feminist critiques of cosmetic surgery typically draw attention to the sexism and outright misogyny of many forms of cosmetic surgery. All 3 programs suggest that the beautiful female body has large, gravity defying breasts jutting from an impossibly lithe body. All signs of aging and maturity must be excised; the attractive, sexual body has a permanently youthful look. "The Swan," with its competition amongst women, its characterization of women as "ugly ducklings" prior to their surgeries, and its shudder-inducing beauty pageant is the most overtly misogynistic of the 3 programs. The primary responsibility of women, this program suggests, is to look attractive. Problems at home, a troubled marriage, inattentiveness from a spouse or partner, and lack of opportunities in the workplace can all be fixed through cosmetic surgery, regimented dieting, and visits to a "life coach."

Though a wide misogynistic streak runs through all three programs, ″Extreme Makeover″ and "I Want a Famous Face″ include male participants. Accordingly, they illustrate important features of this new "genre" of television programming that go beyond female bodies, the "male gaze," and women as the primary objects of cosmetic surgery.

″Extreme Makeover″ demonstrates that both men and women can become convinced of the notion that psychological and spiritual rebirth will result from surgical modification of the body. The series reveals that both men and women are influenced by particular social stereotypes of what constitutes "beautiful" bodies. To lead a truly fulfilling, rewarding life, this program suggests, you need sparkling white teeth, a full head of hair, a svelte body, smooth skin, sparkling eyes, an unfurrowed brow, full lips, firm buttocks, and tight thighs. To deviate from this standard is to reveal physical failings, spiritual torpor, and psychological flaws.

"I Want a Famous Face" offers the most literalistic reading of how ideal bodies are defined. The individuals featured on this show do not have vague notions of beauty, attractiveness, or bodily "perfection." Rather, they want Pamela Anderson's breasts, Brad Pitt's chin, and Jennifer Lopez's buttocks. "I Want a Famous Face″ reveals one pervasive source of images of the beautiful body. If the fantasies of the participants on the series provide a window onto broader trends in popular culture, movie idols and pop stars are playing iconic functions in shaping public perceptions of beauty, youthfulness, and attractiveness. Music videos, television programs, and Hollywood films send powerful messages about what constitutes ideal body types. Of course, simply to blame "Hollywood" for the current appeal of multiple cosmetic surgery procedures is to oversimplify. When movie stars and pop stars have breast implants, face lifts, Botox injections, liposuction, and collagen infusions they both shape and are shaped by popular notions of beautiful bodies.

Perhaps the most intriguing aspect of the 3 series is the near total absence of discussion of moral considerations. Family members' reservations about the benefits of cosmetic surgery are largely dismissed. Participants on the series are viewed as autonomous decision makers; they know what they want, and the role of cosmetic surgeons is to fulfill their wishes. "I Want a Famous Face″ is the one program that directly addresses the influence of coercive forces upon the decision making of participants. The website for the program notes that the show did not pay for any of the surgeries. All 3 programs neglect other moral issues. Questions of risks and long-term consequences are minimized even though many of the operations involve invasive procedures and require general anesthesia. The cosmetic surgeons on these programs are willing and eager to provide the multiple cosmetic surgeries requested by program participants. The programs do not attend to the individual and communal harms associated with promoting particular social norms about what constitutes "beautiful" bodies. Cosmetic surgery is simply offered as a panacea for what are clearly complex social and emotional problems. The programs ignore the consequences of characterizing surgeons as amoral technicians guided only by aesthetic preferences and the desires of their patients. There is no examination of whether the provision of multiple cosmetic surgery procedures in a televised context violates professional norms, poses a challenge to notions of professional integrity, and makes cosmetic surgeons complicit in promoting narrow, damaging notions of beauty.

Finally, "Extreme Makeover," "The Swan," and "I Want a Famous Face″ all contribute to the widespread social

normalization of cosmetic surgery. They place cosmetic surgery on a continuum with taking yoga classes, dieting, psychological counseling, and visiting the gym. Complicit in promoting highly circumscribed notions of beauty and attractiveness, the programs routinely ignore the question of whether there might be aspects of life more important than having a particular physique. As I scrolled through the post-surgery faces on the websites for these programs, the contestants all seemed oddly alike: the women have large breasts and thin bodies, and the men have firm chins and chiseled cheekbones.

Medical parentalism—the notion that to be a physician means to promote and defend particular moral norms regardless of the individual preferences of the patient—has fallen into disrepute. Every first year medical student is introduced to the notion of respect for patient autonomy. However, situated within market constraints, advertising, and attenuated notions of "ideal" body types, the ethic of personal autonomy leads to the strangest of outcomes. You are free to decide whether you would prefer to resemble J. Lo or Kate Winslet, Elvis Presley or Brad Pitt. Fortunately, life coaches are available to help with these difficult decisions.

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Op-Ed

Evidence-Based Surgery: a Growing Need for a Limited Enterprise

The gap between surgeons' professional idealism and clinical reality is widening because surgeons fail to keep up with the growing demand for evidence-based surgery.

Angelique M. Reitsma, MD, MA

The call for rigorous scientific testing of surgical therapies is not new[1, 2], but has seen a steady increase in volume. About a decade ago a surgery textbook observed that:

> When large numbers of innovative treatments are being continuously introduced into clinical practice, rigorous testing is mandatory for the protection of individual patients and the just use of limited resources. This holds true with even greater force in light of the evidence that many innovations show no advantage over existing treatments when they are subjected to properly controlled study [3].

The latter observation came painfully true for cardiac ventriculotomy and arthroscopic knee surgery[4,5].

Concurrently, the push to innovate is greater than ever. Surgery professional meetings encourage the presentation of "new approaches" specifically selected by their program committees, and most surgery journals have a section especially reserved for innovations and new techniques. New is hot, old is not. Academic and private surgeons alike feel this unrelenting push to innovate, not only for the sake of their patients, but also to safeguard their status, their reputation and, ultimately, their income. Yesterday's procedures are old news, and surgeons may be reluctant to continue using old-fashioned techniques, regardless of the fact that these may have been proven safe and effective unlike their innovative counterparts. While ideally these "new and improved" procedures should have been scientifically tested for safety and efficacy, this is not often the case. Though most surgeons' awareness of the importance of evidence-based therapy is deepening, as a profession, surgeons fail to keep up with the growing demand for evidence-based surgery (EBS) [6-14]. The gap between surgeons' professional idealism and clinical reality is widening.

It needs to be stated up front that surgeons are not alone in using therapies that are essentially untried and unproven. Other physicians are at liberty to employ medical therapies at their discretion, may opt for off-label use of drugs, and can choose dosages, medication combinations, and strategies as they see fit. But unlike innovative surgeries, (conventional) drugs have generally been tested before entering the market and have been determined to be safe and effective (for specific conditions) in FDA-monitored trials and studies. Surgeons have, in essence, carte blanche to introduce untested new procedures. In the absence of any overseeing entity [15-19], it currently is the sole responsibility of the surgical profession to ensure the use of evidence-based techniques [20]. Individual surgeons have brought this point to light, and have sought ways to stimulate others to innovate responsibly [19, 21-36], and the American College of Surgeons has made it its goal to improve the use of EBS [37].

Regardless, it remains a formidable challenge for surgeons to embrace EBS. Within evidence-based therapy, there is a hierarchy of evidence according to strength [38,39]. The best evidence is ranked Level 1: (meta-analysis of) prospective randomized clinical trials and Level 2: cohort studies or outcomes research. Evidence of lesser strength is

ranked Level 3 (case-control studies), 4 (case series) or 5 (expert opinion and bench research). Modern-day surgical literature still consists mainly of reported Level 4 and 5 evidence, sometimes Level 3, and rarely Level 2 or 1 [34]. The reported declining engagement of surgeons in research adds to this troublesome situation [40]. Moreover, as Rangler et al. reported recently, surgeons are less likely to receive federal funding for research, they often receive smaller awards when they do, fewer surgeons participate in the National Institutes of Health (NIH) reviewing process, and, most surprisingly, surgeons were in the minority in the Surgery Study Sections [41].

Why is the occurrence of evidence-based therapy so limited in surgery? Several explanations that are more or less related have been given for this apparent discrepancy between surgery and the rest of medicine. First, the very definition of surgical innovation and, related to that, clinical surgical research, is vague. The boundaries between clinical care and clinical experimentation are not always clear in the surgical situation. It is difficult for surgeons to determine when routine modifications in operations become extensive enough to warrant formal study and a patient's informed consent for participation in research. This elusive definition of surgical research is the very core of this problem [34, 42].

Second, and related to this, is the notion of surgical exceptionalism [43]. This is the view that the somewhat exceptional ethical or regulatory status of surgery and surgical research is justified by the exceptional differences between surgeries and pharmaceutical interventions [44-46]. Comparing 2 pills appears more straightforward than comparing 2 surgical procedures. Whether this comes down to substantial differences between the 2 forms of therapy or is due, perhaps, to psychological differences between physicians and surgeons is not wholly understood.

Third, and indirectly flowing from the above notion; to produce Level 1 evidence, one has to conduct randomized controlled clinical trials (RCTs) or meta-analyze existing RCTs. Implementing RCTs can be problematic for the surgical situation, and incorporating sham surgery as a placebo into such trials even more so. Sham surgery is ethically contentious at best [47], and although it has proven effective in certain scenarios [5] and its ethical permissibility has been defended effectively [48], it has not gained wide acceptance yet. It deserves attention that while the RCT is widely regarded as the gold standard of evidence-based therapy, it is not always necessary, feasible, or appropriate in the surgical situation [11, 49-52].

Finally, and perhaps the most worrisome reason why EBS has not taken off, is the alleged insufficiency of knowledge and research skills among surgeons [18, 53]. In his 2004 American College of Surgeons presidential address, surgeon R. Scott Jones paints a dismal picture of the current research climate in surgery [40]. Most alarmingly, Jones stipulates that the mainstream surgery community actually devalues research, and is neither well-informed about nor respectful of the scientific method. Jones goes on to state that it is enormously difficult to incorporate research into a surgeon's professional life, not in the least because other demands are increasingly taking away time and energy from potential research efforts. Understandably, Jones urges his professional community to address this problem and dedicate more time and attention towards EBS and to the education of future surgeons about this matter. Indeed, it appears necessary and timely for surgeons to realize they are lagging behind in the quest for evidence-based therapy, and to increase their efforts to embrace, produce, and implement EBS into their professional lives and in every day clinical practice, for the protection of themselves, their patients, and the public interest [54].

References

1. Lombardo PA. The history of ethics in innovative surgery: a few stories, many questions. Commissioned paper for the Committee on Development of Ethical Guidelines for Innovative Surgery. March 2004. Charlottesville: University of Virginia Press (In press).
   Google Scholar
2. McCullough LB. Standard of care, innovation and research in surgery: a problem in research ethics or professional medical ethics? Commissioned paper for the Committee on Development of Ethical Guidelines for Innovative Surgery. March 2004. Charlottesville: University of Virginia Press. (In press).
   Google Scholar

3. Roy DL, Black P, McPeek B, "Ethical Principles in Research" In: Troidl H, Spitzer WO, McPeek B, Mulder DS, McKneally MF, Wechsler AS, et al, eds. *Principles and Practice of Research: Strategies for Surgical Investigation*. New York: Springer-Verlag, 1991:92.
Google Scholar
4. Starling RC, McCarthy PM, Buda T, et al. Results of partial left ventriculectomy for dilated cardiomyopathy: hemodynamic, clinical and echocardiographic observations. *J Am Coll Cardiol*. 2000;36:2098-2103.
View Article PubMed Google Scholar
5. Moseley JB, O'Malley K, Petersen NJ, et al. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. *N Engl J Med*. 2002;347:81-88.
View Article PubMed Google Scholar
6. Law S, Wong J. Use of controlled randomized trials to evaluate new technologies and new operative procedures in surgery. *J Gastrointest Surg*. 1998;2:494-495.
View Article PubMed Google Scholar
7. McLeod RS. Issues in surgical randomized controlled trials. *World J Surg.* 1999;23:1210-1214.
View Article PubMed Google Scholar
8. Carey TS. Randomized controlled trials in surgery: an essential component of scientific progress. *Spine.* 1999;24:2553-2555.
PubMed Google Scholar
9. Moss RL. The CONSORT Statement: progress in clinical research in pediatric surgery. *J Ped Surg.* 2001;36:1739-1742.
View Article PubMed Google Scholar
10. Maddem GJ. Evidence-based medicine in practice—surgery. *Med J Aust.* 2001;174:528-529.
View Article PubMed Google Scholar
11. Meakins JL. Innovation in surgery: the rules of evidence. *Am J Surg*. 2002;183:399-405.
View Article PubMed Google Scholar
12. Arya J, Wolford H, Harken AH. Evidence-based science. Arch Surg. 2002;137:1301-1303.
Google Scholar
13. Cook RC, Alscher KT, Hsiang YN. A debate on the value and necessity of clinical trials in surgery. Am J Surg. 2003;185:305-310.
PubMed Google Scholar
14. Jimenez RE, Guitierrez AR, Benitez IM. Methodological requirements for assessing surgical procedures in current medical literature. *World J Surg.* 2003;27:229-233.
Google Scholar
15. Spodick DH. Numerators without denominators. There is no FDA for the surgeon. *JAMA.* 1975;232:35-36.
View Article PubMed Google Scholar
16. Frader JE, Caniano DA. Research and innovation in surgery. In: McCullough LB, Jones JW, Brody BA, eds. *Surgical Ethics*. New York: Oxford University Press;1998:216-241.
Google Scholar
17. Siegler M. Ethical issues in innovative surgery: should we attempt a cadaveric hand transplantation in a human subject? *Transplant Proc*. 1998;30:2779-2782.
PubMed Google Scholar
18. Reitsma AM, Moreno JD. Ethical regulations for innovative surgery: the last frontier? *J Am Coll Surg*. 2002;194:792-801.
View Article PubMed Google Scholar
19. Strasberg SM, Ludbrook PA. Who oversees innovative practice? Is there a structure that meets the monitoring needs of new techniques? *J Am Coll Surg*. 2003;196:938-948.
View Article PubMed Google Scholar
20. Jones JW. The surgeon's autonomy: defining limits in therapeutic decision-making. Commissioned paper for the Committee on Development of Ethical Guidelines for Innovative Surgery. March 2004. Charlottesville: University of Virginia Press. (In press).
Google Scholar
21. Love JW. Drugs and operations. some important differences. *JAMA.* 1975;232:37-38.
View Article PubMed Google Scholar
22. Bunker JP, Hinkley D, McDermott WV. Surgical innovation and its evaluation. *Science*. 1978;200:937-941.

View Article PubMed Google Scholar
23. Shinebourne EA. Ethics of innovative cardiac surgery. *Br Heart J*. 1984;52:597-601.
PubMed Google Scholar
24. Qualms about innovative surgery. *Lancet*. 1985;1:149.
PubMed Google Scholar
25. Gross M. Innovations in surgery. *J Bone Joint Surg Br*. 1993;75:351-354.
PubMed Google Scholar
26. Ward CM. Surgical research, experimentation and innovation. *Br J Plast Surg*. 1994;47:90-94.
PubMed Google Scholar
27. Waring GO, III. A cautionary tale of innovation in refractive surgery. *Arch Ophthalmol*. 1999;117:1069-1073.
View Article PubMed Google Scholar
28. McKneally MF. Ethical problems in surgery: innovation leading to unforeseen complications. *World J Surg*. 1999;23:786-788.
View Article PubMed Google Scholar
29. Jones JW. Ethics of rapid surgical technological advancement. *Ann Thorac Surg*. 2000;69:676-677.
PubMed Google Scholar
30. Josefson D. University must tell patients that they were research "guinea pigs." *BMJ*. 2000;321:1487A.
View Article PubMed Google Scholar
31. Moore FD. Ethical problems special to surgery: surgical teaching, surgical innovation, and the surgeon in managed care. *Arch Surg*. 2000;135:14-16.
View Article PubMed Google Scholar
32. Bunch WH, Dvonch VM. Moral decisions regarding innovation. The case method. *Clin Orthop*. 2000;378:44-49.
PubMed Google Scholar
33. Frader JE, Flanagan-Klygis E. Innovation and research in pediatric surgery. *Semin Pediatr Surg*. 2001;10:198-203.
View Article PubMed Google Scholar
34. Margo CE. When is surgery research? Towards an operational definition of human research. *J Med Ethics*. 2001;27:40-43.
View Article PubMed Google Scholar
35. Cronin DC, II, Millis JM, Siegler M. Transplantation of liver grafts from living donors into adults--too much, too soon. *N Engl J Med*. 2001;344:1633-1637.
View Article PubMed Google Scholar
36. Casler JD. Clinical use of new technologies without scientific studies. *Arch Otolaryngol Head Neck Surg*. 2003;129:674-677.
View Article PubMed Google Scholar
37. Jones RS, Richards K. Office of Evidence-Based Surgery Charts Course for Improved System of Care. *Bull Amer Coll Surg*. 88;4:11-21.
PubMed Google Scholar
38. Centre for Evidence Based Medicine. Levels of evidence and grades of recommendation. Available at http://www.cebm.net/levels_of_evidence.asp. Accessed September 27, 2004.
39. Guyatt G, Haynes RB, Jaeschke RZ, et al. User's guide to the medical literature XXV. Evidence-based medicine: principles for applying the user's guides for patient care. *JAMA*. 2000;284:1290-1296.
View Article Google Scholar
40. Jones RS. Requiem and renewal. presidential address. *Ann Surg*. 2004;240:395-404.
PubMed Google Scholar
41. Rangel S, Efron B, Moss RL. Recent trends in National Institutes of Health funding of surgical research. *Ann Surg*. 2002;236:277-287.
View Article PubMed Google Scholar
42. Reitsma AM, Moreno JD. Surgical research, an elusive entity. *AJOB*. 2003:3:49-50.
View Article PubMed Google Scholar
43. London AJ. Cutting surgical research at the joints: individuating and assessing surgical procedures. Commissioned paper for the Committee on Development of Ethical Guidelines for Innovative Surgery. March 2004. Charlottesville: University of Virginia Press. (In press).

Google Scholar
44. Agich GJ. Ethics and innovation in medicine. *J Med Ethics*. 2001;27:295-296.
View Article PubMed Google Scholar
45. McKneally MF. A bypass for the Institutional Review Board: reflections on the Cleveland Clinic study of the Batista operation. *J Thorac Cardiovasc Surg*. 2001;121:837-839.
View Article PubMed Google Scholar
46. McKneally MF. Surgical innovation. Panel presentation at American Society for Bioethics and Humanities. November 2003; Montreal, Canada.
Google Scholar
47. London AJ, Kadane JB. Placebos that harm: sham surgery controls in clinical trials. *Stat Methods Med Res*. 2002;11:413-427.
View Article PubMed Google Scholar
48. Miller FG. Sham surgery: an ethical analysis. *AJOB.* 2003;3:41-48.
View Article PubMed Google Scholar
49. McCulloch P, Taylor I, Sasako M, Lovett B, Griffin D. Randomized controlled trials in surgery: problems and possible solutions. *BMJ*. 2002;324:1448-1451.
Google Scholar
50. Reeves B. Health-technology assessment in surgery. *Lancet*. 1999;353 Suppl 1: SI 3-5.
View Article PubMed Google Scholar
51. Baum M. Reflections on randomized controlled trials in surgery. *Lancet.* 1999;353 Suppl 1: SI6-8.
View Article PubMed Google Scholar
52. Lilford RJ, Braunholz D, Harris J, Gill T: Trials in surgery. *Br J Surg.* 2004;91:6-16.
View Article PubMed Google Scholar
53. Rutan RL, Deitch EA, Waymack JP. Academic surgeons' knowledge of food and drug administration regulations for clinical trials. *Arch Surg*. 1997;132:94-98.
View Article PubMed Google Scholar
54. Reitsma AM, Moreno JD, Bosk CL, et al. Ethical guidelines for innovative surgery: recommendations for national policy. Position statement. Submitted for publication. 2004. *J Am Coll of Surg*.

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Medical Humanities

Writing as Surgery: Words and Swords

A retired surgeon explains how keeping a journal helped him deal with difficult professional situations and led him to stronger relationships with his patients.

Bernie S. Siegel, MD

Years ago what started me writing was the total avoidance of all issues related to feelings during my medical school years and surgical training. I was not taught to take care of myself or treat my patients as human beings. I was turned into a wonderful technician who was not supposed to feel. When I wrote to the people who trained me, telling them this and asking them to change the way they did things, they never wrote back. Try standing up at Grand Rounds or Morbidity and Mortality Conferences and discussing how you feel about the death of your patient due to an error in care—like transplanting the wrong organs—and watch the reaction you get. The discussion is all about what you think and not how you feel. When surgeons at Yale were asked, "How does it feel to be a surgeon?" They all started their answers with, "I think it's like . . . ."

How many surgeons are trained to talk to patients? As I have written, a scalpel can kill or cure and so can words, because wordswordswords can become swordswordswords. Scalpels and words are instruments which can cure or kill. What most often trains physicians is their own, or their loved one's disaster or illness. Then they write books, because the tourist has become a native and now understands the experience and no longer just treats the diagnosis and illness. I became a much better surgeon after a week in the hospital. All medical students should have to spend time in a hospital bed before graduation.

I spontaneously started to keep a journal when I found it very hard to remain a surgeon because of all the things I couldn't cure and the complications related to my being human and not God or a Medical Deity. Why was this painful? Because if you cannot bring forth your feelings they will destroy you. Physicians develop PTSD but never have it treated. By journaling I could get what was within me out. One evening I realized the extent to which what was stored within had not been dealt with; I looked at the journal notes I had written during the day and couldn't remember what they were about. To look at the words "Boy in ER" and not remember the disaster the words referred to revealed to me what I was not dealing with. My wife also helped me when she found my hidden journal and remarked there was nothing funny in it. I told her my life wasn't funny and she then went on to recount funny stories about the hospital that I had shared with her and our 5 children, none of whom is a physician, at the dinner table. She helped me to remember the joyful moments which occurred each day and record them in my journal too.

I became a pediatric and general surgeon for healthy reasons, an issue that is not dealt with by medical schools. I loved people, found science fascinating, liked fixing things, and was an artist so I wanted to use my skilled hands in some profession (not knowing you could earn a living as an artist). So it hurt when children told me they hated me every morning while I debrided their burns. If you became a doctor because you are fascinated by the human body you will have a problem because people come in the body.

So words and swords became my tools when a patient of mine, sitting beside me at a workshop she was attending because of cancer and I was attending because of My Disease (MD), turned to me and said, "You're a nice guy and I feel better in the office with you but I can't take you home with me. So I need to know how to live between office visits." That sentence led me to change my life. I offered support groups to all our patients, through letters from our

office, to help them live longer, better lives and less than 20 percent of patients had any interest in attending. That was my wake-up call, revealing to me that I didn't know my patients as people. I put my desk against the wall so I was not separated from the people I cared for and learned to share their experience and speak to them in ways that could help them survive.

By becoming more aware of the effect of my words as well as my scalpel, I was better able to care for myself and my patients. I returned to painting every evening to help me to heal the pain of the day and realized one evening I was painting portraits and not natural scenes. When you lose track of time, you are in a healing trance; painting and operating have always done that for me. I awakened to the fact I that needed to see the people I was treating and not just their afflictions, which I often could not cure. I learned when the sword cannot cure, the word can heal.

The sickest portrait I have done was a self portrait. When our pets and my family were tired of sitting for me, I put up a mirror and painted a self portrait wearing cap, mask, and gown. I was covering up even in a painting. When I wrote an article for the American College of Surgeons entitled, "Surgery; Mechanical or Healing Art", the title of the course I taught at Yale, they refused to publish the painting. My smiling face was okay but not the portrait.

One last bit of advice. If you are unhappy as a surgeon you are the problem. You can quit surgery or change your attitude, either one works. I worked at a Subway franchise for one of our sons and had a knife, gloves, and a uniform. It was great. If people wanted a sandwich they had to answer a question. I asked things like, "What can I pray for you? What's the best day of your life? How would you introduce yourself to God?" and therapy started over a sandwich.

The other way to be therapeutic is to wear a bandage or make rounds using a cane. I shaved my head 30 years ago and people knew I was troubled. I uncovered skin not feelings. When patients see you are wounded they will share things with you they have never told you before because now you are a wounded healer and will understand. Thornton Wilder wrote about an angel who refuses to heal a doctor of his emotional pain, "Without your wound where would your power be….In love's service only the wounded soldier can serve." After I shaved my head people lined up to talk to me at the hospital.

By the way, the burned child who hated me called years later called to tell me her father had died and ask me to be her father at her wedding. Why? Because I taught her that when you are giving love you are beautiful and no one notices your scars. Madeline is a nurse today and one of my CDs, that is, a Chosen Daughter, and I am her CD, Chosen Dad. That is why words are what surgery is about, and not just making incisions. So learn to use them correctly as you do your other instruments.

A patient being discharged told me he was not giving me a gift as he was everyone else who cared for him.

"Why not?"

"You're always angry."

"I didn't like what I had to do to you."

"But you took it out on me."

"I'm sorry."

"Okay, here's a bottle of liquor."

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