



CLINICAL JURISPRUDENCE COLUMN

Who is liable when a surgical error occurs?

↘ The answer can depend on whether it is a true error and your prevention strategy. These experts discuss how to develop a safety culture that acknowledges fallibility while devising systems for error prevention.

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CASE Surgeon accused of operating outside her scope of expertise

A 38-year-old woman (G2 P2002) presented to the emergency department (ED) with acute pelvic pain involving the right lower quadrant (RLQ). The patient had a history of stage IV endometriosis and chronic pelvic pain, primarily

affecting the RLQ, that was treated by total laparoscopic hysterectomy with bilateral salpingo-oophorectomy 6 months earlier. Pertinent findings on physical examination included hypoactive bowel sounds and rebound tenderness. The ED physician ordered a computed tomography (CT) scan of the abdomen, which showed no evidence of ureteral injury or other abnormality. The gynecologist who performed the surgery 6 months ago evaluated the patient in the ED.

The gynecologist decided to perform operative laparoscopy because of the severity of the patient's pain and duration of symptoms. Informed consent obtained in the ED before the patient received analgesics included a handwritten note that said "and other indicated procedures." The patient signed the document prior to being taken to the operating room (OR). Time out occurred in the OR before anesthesia induction. The gynecologist proceeded with laparoscopic adhesiolysis with planned appendectomy, as she was trained. A normal appendix was noted and left intact. RLQ adhesions involving the colon and abdominal wall were treated with electrosurgical cautery. When the gynecologist found adhesions between the liver and diaphragm in the right upper quadrant (RUQ), she continued adhesiolysis. However, the diaphragm was inadvertently punctured.

As the gynecologist attempted to suture the defect laparoscopically, she encountered

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In this quarterly column, these medical and legal experts and educators present a case-based* discussion and provide clear teaching points and takeaways for your practice.



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*The "facts" of this case are based on actual cases and are a compilation of several cases. The "Verdict" regarding negotiation is for discussion only. The legal discussion that follows is based on the general legal rules in the United States. Medical malpractice liability law varies from state to state; the following discussion does not include individual state law.

difficulty and converted to laparotomy. Adhesions were dense and initially precluded adequate closure of the diaphragmatic defect. The gynecologist persisted and ultimately the closure was adequate; laparotomy concluded. Postoperatively, the patient was given a diagnosis of atelectasis, primarily on the right side; a chest tube was placed by the general surgery team. The patient had an uneventful postoperative period and was discharged on postoperative day 5. One month later she returned to the ED with evidence of pneumonia; she was given a diagnosis of empyema, and antibiotics were administered. She responded well and was discharged after 6 days.

The patient filed a malpractice lawsuit against the gynecologist, the hospital, and associated practitioners. The suit made 3 negligence claims: 1) the surgery was improperly performed, as evidenced by the diaphragmatic perforation; 2) the gynecologist was not adequately trained for RUQ surgery, and 3) the hospital should not have permitted RUQ surgery to proceed. The liability claim cited the lack of qualification of a gynecologic surgeon to proceed with surgical intervention near the diaphragm and the associated consequences of practicing outside the scope of expertise.

Fitz-Hugh Curtis syndrome, a complication of pelvic inflammatory disease that may cause adhesions, was raised as the initial finding at the second surgical procedure and documented as such in the operative report. The plaintiff's counsel questioned whether surgical correction of this syndrome was within the realm of a gynecologic surgeon. The plaintiff's counsel argued that the laparoscopic surgical procedure involved bowel and liver; diaphragmatic adhesiolysis was not indicated, especially with normal abdominal CT scan results and the absence of RUQ symptoms. The claim specified that the surgery and care, as a consequence of the RUQ adhesiolysis, resulted in atelectasis, pneumonia, and empyema, with pain and suffering. The plaintiff sought unspecified monetary damages for these results.

WHAT'S THE VERDICT?

The case is in negotiation prior to trial.

Legal and medical considerations

"To err is not just human but intrinsically biological and no profession is exempt from fallibility."¹

Error and liability

To err may be human, but human error is not necessarily the cause of every suboptimal medical outcome. In fact, the overall surgical complication rate has been reported at 3.4%.² Even when there is an error, it may not have been the kind of error that gives rise to medical malpractice liability. When it comes to surgical errors, the most common are those that actually relate to medications given at surgery that appear to be more common—one recent study found that 1 in 20 perioperative medication administrations resulted in a medication error or an adverse drug event.³

Medical error vs medical malpractice

The fact is that medical error and medical malpractice (or professional negligence) are not the same thing. It is critical to understand the difference.

Medical error is the third leading cause of death in the United States.⁴ It is defined as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim,"⁵ or, in the Canadian literature, "an act of omission or commission in planning or execution that contributes or could contribute to an unintended result."⁶ The gamut of medical errors spans (among others) problems with technique, judgment, medication administration, diagnostic and surgical errors, and incomplete record keeping.⁵

Negligent error, on the other hand, is generally a subset of medical error recognized by the law. It is error that occurs because of carelessness. Technically, to give rise to liability for negligence (or malpractice) there must be duty, breach, causation, and injury. That is, the physician must owe a duty to the patient, the duty must have been breached, and that breach must have caused an injury.⁷

Usually the duty in medical practice is that the physician must have acted as a reasonable and prudent professional would



Negligent error, or malpractice, is error that occurs because of carelessness



have performed under the circumstances. For the most part, malpractice is a level of practice that the profession itself would not view as reasonable practice.⁸ Specialists usually are held to the higher standards of the specialty. It also can be negligent to undertake practice or a procedure for which the physician is not adequately trained, or for failing to refer the patient to another more qualified physician.

The duty in medicine usually arises from the physician-patient relationship (clearly present here). It is reasonably clear in this case that there was an injury, but, in fact, the question is whether the physician acted carelessly in a way that caused that injury. Our facts leave some ambiguity—unfortunately, a common problem in the real world.

It is possible that the gynecologist was negligent in puncturing the diaphragm. It may have been carelessness, for example, in the way the procedure was performed, or in the decision to proceed despite the difficulties encountered. It is also possible that the gynecologist was not appropriately trained and experienced in the surgery that was undertaken, in which case the decision to do the surgery (rather than to refer to another physician) could well have been negligent. In either of those cases, negligence liability (malpractice) is a possibility.

Proving negligence. It is the plaintiff (the patient) who must prove the elements of negligence (including causation).⁹ The plaintiff will have to demonstrate not only carelessness, but that carelessness is what caused the injuries for which she is seeking compensation. In this case, the injuries are the consequence of puncturing the diaphragm. The potential damages would be the money to cover the additional medical costs and other expenses, lost wages, and noneconomic damages such as pain and suffering.

The hospital's role in negligence

The issue of informed consent is also raised in this case, with a handwritten note prior to surgery (but the focus of this article is on medical errors). In addition to the gynecologist, the hospital and other medical personnel

were sued. The hospital is responsible for the acts of its agents, notably its employees. Even if the physicians are not technically hospital employees, the hospital may in some cases be responsible. Among other things, the hospital likely has an obligation to prevent physicians from undertaking inappropriate procedures, including those for which the physician is not appropriately trained. If the gynecologist in this case did not have privileges to perform surgery in this category, the hospital may have an obligation to not schedule the surgery or to intraoperatively question her credentials for such a procedure. In any event, the hospital will have a major role in this case and its interests may, in some instances, be inconsistent with the interests of the physician.

Why settlement discussions?

The case description ends with a note that settlement discussions were underway. If the plaintiff must prove all of the elements of negligence, why have these discussions? First, such discussions are common in almost all negligence cases. This does not mean that the case actually will be settled by the insurance company representing the physician or hospital; many malpractice cases simply fade away because the patient drops the action. Second, there are ambiguities in the facts, and it is sometimes impossible to determine whether or not a jury would find negligence. The hospital may be inclined to settle if there is any realistic chance of a jury ruling against it. Paying a small settlement may be worth avoiding high legal expenses and the risk of an adverse outcome at trial.⁹

Reducing medical/surgical error through a team approach

Recognizing that “human performance can be affected by many factors that include circadian rhythms, state of mind, physical health, attitude, emotions, propensity for certain common mistakes and errors, and cognitive biases,”¹⁰ health care professionals have a commitment to reduce the errors in the interest of patient safety and best practice.



It can be negligent to perform or undertake a procedure for which adequate training has not been received; it is the patient who must prove negligence

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The surgical environment is an opportunity to provide a team approach to patient safety. Surgical risk is a reflection of operative performance, the main factor in the

development of postoperative complications.¹¹ We wish to broaden the perspective that gynecologic surgeons, like all surgeons, must keep in mind a number of concerns

Medical errors: Caring for the second victim (you)

Patrice M. Weiss, MD



We use the term “victim” to refer to the patient and her family following a medical error. The phrase “the second victim” was coined by Dr. Albert Wu in an article in the *British Medical Journal*¹ and describes how a clinician and team of health care professionals also can be affected by medical errors.

What signs and symptoms identify a second victim?

Those suffering as a second victim may show signs of depression, loss of joy in work, and difficulty sleeping. They also may replay the events, question their own ability, and feel fearful about making another error. These reactions can lead to burnout—a serious issue that 46% of physicians report.²

As colleagues of those involved in a medical error, we should be cognizant of changes in behavior such as excessive irritability, showing up late for work, or agitation. It may be easier to recognize these symptoms in others rather than in ourselves because we often do not take time to examine how our experiences may affect us personally. Heightening awareness can help us recognize those suffering as second victims and identify the second victim symptoms in ourselves.

How can we help second victims?

One challenge second victims face is not being allowed to discuss a medical error. Certainly, due to confidentiality requirements during professional liability cases, we should not talk freely about the event. However, silence creates a barrier that prevents a second victim from processing the incident.

Some hospitals offer forums to discuss medical errors, with the goal of preventing reoccurrence: morbidity and mortality conferences, morning report, Quality Assurance and Performance Improvement meetings, and root cause analyses. These forums often are not perceived by institutions’ employees in a positive way. Are they really

meant to improve patient care or do they single out an individual or group in a “name/blame/shame game”? An intimidating process will only worsen a second victim’s symptoms. It is not necessary, however, to create a whole new process; it is possible to restructure, reframe, and change the culture of an existing practice.

Some institutions have developed a formalized program to help second victims. The University of Missouri has a “forYOU team,” an internal, rapid response group that provides emotional first aid to the entire team involved in a medical error case. These responders are not from human resources and do not need to be sought out; they are peers who have been educated about the struggles of the second victim. They will not discuss the case or how care was rendered; they naturally and instinctively provide emotional support to their colleagues.

At my institution, the Carilion Clinic at the Virginia Tech Carilion School of Medicine, “The Trust Program” encourages truth, respectfulness, understanding, support, and transparency. All health care clinicians receive basic training, but many have volunteered for additional instruction to become mentors because they have experienced second-victim symptoms themselves.

Clinicians want assistance when dealing with a medical error. One poll reports that 90% of physicians felt that health care organizations did not adequately help them cope with the stresses associated with a medical error.³ The goal is to have all institutions recognize that clinicians can be affected by a medical error and offer support.

Hear an expanded audiocast from Dr. Weiss on “the second victim” at obgmanagement.com.

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that can be associated with problems related to surgical procedures, including¹²:

- visual perception difficulties
- stress
- loss of haptic perception (feedback using touch), as with robot-assisted procedures
- lack of situational awareness (a term we borrow from the aviation industry)
- long-term (and short-term) memory problems.

Analysis of surgical errors shows that they are related to, in order of frequency¹:

- surgical technique
- judgment
- inattention to detail
- incomplete understanding of the problem or surgical situation.

“Inadequacy” with regard to surgical procedures

Indication for surgery is intrinsic to provision of appropriate care. Surgery inherently poses the possibility of unexpected problems. Adequate training and skill, therefore, must include the ability to deal with a range of problems that arise in the course of surgery. The spectrum related to inadequacy as related to surgical problems includes “failed surgery,” defined as “if despite the utmost care of everyone involved and with the responsible consideration of all knowledge, the designed aim is not achieved, surgery by itself has failed.”⁵ Of paramount importance is the surgeon’s knowledge of technology and the ability to troubleshoot, as well as the OR team’s responsibility for proper maintenance of equipment to ensure optimal functionality.¹

Aviation industry studies indicate that “high performing cockpit crews have been shown to devote one third of their communications to discuss threats and mistakes in their environment, while poor performing teams devoted much less, about 5%, of their time to such.”^{1,13} A well-trained and well-motivated OR nursing team has been equated with reduction in operative time and rate of conversion to laparotomy.¹⁴ Outdated instruments may also contribute to surgical errors.¹

Moving the “learning curve” out of the

OR and into the simulation lab remains valuable, which is also confirmed by the aviation industry.¹⁵ The significance of loss of haptic perception continues to be debated between laparoscopic (straight-stick) surgeons and those performing robotic approaches. Does haptic perception play a major role in surgical intervention? Most surgeons do not view loss of haptic perception, as with minimally invasive procedures, as a major impediment to successful surgery. From the legal perspective, loss of haptic perception has not been well addressed.

The American College of Obstetricians and Gynecologists has focused on patient safety in the surgical environment including concerns for wrong-patient surgery, wrong-side surgery, wrong-level surgery, and wrong-part surgery.¹⁶ The Joint Commission has identified factors that may enhance the risk of wrong-site surgery: multiple surgeons involved in the case, multiple procedures during a single surgical visit, unusual time pressures to start or complete the surgery, and unusual physical characteristics including morbid obesity or physical deformity.¹⁶

10 starting points for medical error prevention

So what are we to do? Consider:

1. Using a preprocedure verification checklist.
2. Marking the operative site.
3. Completing a time out process prior to starting the procedure, according to the Joint Commission protocol.
4. Involving the patient in the identification and procedure definition process. (This is an important part of informed consent.)
5. Providing appropriate proctoring and sign-off for new procedures and technology.
6. Avoiding sleep deprivation situations, especially with regard to emergency procedures.
7. Using only radiopaque-labeled materials placed into the operating cavity.
8. Considering medication effect on a fetus, if applicable.

» For more information on Joint Commission–recommended time out protocols and ways to prevent medical errors, visit https://www.jointcommission.org/standards_information/up.aspx

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9. Reducing distractions from pagers, telephone calls, etc.
10. Maintaining a “sterile cockpit” (or distraction free) environment for everyone in the OR.

Set the stage for best outcomes

A true team approach is an excellent *modus operandi* before, during, and after surgery,

setting the stage for best outcomes for patients.

“As human beings, surgeons will commit errors and for this reason they have to adopt and utilize stringent defense systems to minimize the incidence of these adverse events ... Transparency is the first step on the way to a new safety culture with the acknowledgement of errors when they occur with adoption of systems destined to establish their cause and future prevention.”¹

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