Reducing Liability Risk through Informed Consent

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A new report by the American Medical Association reveals why medical liability claims are so devastating and costly for America’s doctors: just over 42% of all physicians and an astonishing 57% of physicians in surgical subspecialties have been sued. Nearly 61% of physicians aged 55 or older have faced the ordeal of a lawsuit. But what if the specter of litigation could be reduced through better, more documented patient communication? One Kentucky ophthalmologist believes patient frustration often is rooted in an expectation of clinical results that does not match actual outcomes. To alleviate the disparity, he uses a standardized informed consent process to ensure patients thoroughly understand the procedure and possible outcomes. This article will explain in detail his three-pronged approach, focused on procedure-specific counseling, education, and documentation.

Key words: Medical liability claims; liability risk; informed consent; patient satisfaction; patient education; documentation.

Medical liability claim. These are three devastating and costly words for America’s doctors—and an influential factor in many physicians’ career choices. A new report by the American Medical Association reveals why: just over 42% of all physicians and an astonishing 57% of physicians in surgical subspecialties have been sued. Nearly 61% of physicians aged 55 or older have faced the ordeal of a lawsuit (73% for those physicians in the surgical subspecialties).¹

Even those who have not been sued feel the effects of this litigious environment. There are many procedures that I would like to perform but choose not to because of the risks of litigation. Treating retinopathy of prematurity is a prime example in my own specialty. As an eye surgeon, I have found that I am most comfortable limiting my practice to elective cataract and refractive procedures, although these procedures have their own liability risks. In limiting the scope of my practice, I recognize how liability risk forces many physicians toward more conservative career choices.

But what if the specter of litigation could be reduced through better, more documented patient communication? The idea might sound overly simplistic, but as a colleague once aptly noted, “Frustration is the difference between expectation and reality.”

The level of patient frustration that results in lawsuits often is rooted in an expectation of clinical results that does not match actual outcomes. The concept is supported by the fact that most legal cases are not about medical errors; roughly 90% of those that go to trial are decided in favor of the physician.²

Yet even so, defending against lawsuits takes a tremendous emotional and financial toll. Eliminating miscommunication problems before they start, therefore, is of paramount importance. At Bluegrass Eye Surgery, this is done through a standardized and well-documented informed consent process.

THE INFORMED CONSENT CONVERSATION

The term “informed consent” typically conjures thoughts of a documentation requirement that carries...
Do’s and Don’ts Regarding Informed Consent Documentation

- Don’t execute the consent form on the first visit while the patient is still learning about the procedure.
- Don’t execute the form on the day of surgery.
- Do execute the form in the office setting when the patient is comfortable and has ample time to ask questions.
- Do offer the patient a copy of the form that he or she has signed.
- Do consider a professional source of detailed, easy-to-understand, procedure-specific forms that are continuously updated and reviewed by a reputable vendor.

Three Best Practices for Managing Patient Expectations

1. Use multiple strategies for educating patients.
   - Use personal discussion by the physician.
   - Show a video depicting the procedure.
   - Provide a comprehensive handout.
   - Create a detailed, procedure-specific informed consent form.

2. Ensure that patients are active participants in the informed consent process.
   - Challenge them to pay attention.
   - Confirm understanding.

3. Be very specific about the risks of procedures and possible complications.
   - If a patient appears unwilling to acknowledge those risks, postpone the procedure until he or she is ready to do so, or refer the patient elsewhere.
   - If a patient declines a procedure after understanding risks that he or she deems unacceptable, then you have done an admirable job of informing and considering your patient’s interests.

COUNSELING: OPENING THE DIALOG

As a board-certified ophthalmologist specializing in cataract and refractive surgery, I sometimes see patients who have never worn corrective lenses in their lives. They understand they have cataracts, but think that once those cataracts are removed they automatically will enjoy the same vision they had in their younger years.

Successful cataract surgery involves the uncomplicated removal of the cataract and placement of an intraocular lens that restores the correctable vision back to the patient’s full potential. For many patients to enjoy a full range of clear vision, they will need to wear corrective lenses. However, many patients do not understand the difference between cataract surgery and LASIK refractive surgery and expect to have perfect vision without glasses starting the first day after surgery.

While many patients do experience great results from cataract surgery, including great vision without glasses, it is a mistake to set this as the standard expectation unless you have the tools to deliver on it. The reality is that sometimes patients will need to wear glasses after surgery. A patient who does not fully comprehend this possibility might perceive the outcome as a surgical failure—or even surgical error—should it occur. Thus what I consider a surgical success could be viewed with acrimony and frustration on the part of the patient. That is one reason why the counseling and education process at Bluegrass begins before I ever step into the exam room.

Most patients come to us by referral from other providers who already have made a preliminary cataract diagnosis. Upon arrival, a technician checks the patient’s vision, performs preliminary studies, and dilates the eyes.

Counseling and education begin during the 15 to 20 minutes it takes for eyes to become fully dilated, when the technician plays a 17-minute video (Patient Education Concepts, Houston, Texas) that explains: cataract surgery; intraocular lens technology; and surgical risks, benefits, and alternatives. Patients can take a true/false quiz at the end.

Ideally, every patient would fill in the quiz answer sheet for inclusion in his or her chart; in reality, of course, that does not happen all of the time. Nevertheless, the video
and quiz still prime patients for a meaningful conversation once I have met them and completed their exams.

During the course of that conversation, I always tell patients the great thing about cataract surgery: it is an elective procedure. I am not a surgical salesman. My job is not to talk patients into surgery, but to counsel them about their options and offer them my service if they decide they want it. Putting patients in control of their treatment choice—even if that choice is to do nothing at all—is imperative to the informed consent process.

**EDUCATION: LAYING FACTS ON THE TABLE**

Patients tend to approach informed consent from a different perspective than we do as physicians. They put their trust in a physician expecting a problem-free outcome, so at times it is an uphill battle to get them to take risks seriously. Sometimes they simply do not want to know about potential problems.

In truth, you can only inform patients to the degree they desire. But the informed consent process gives patients the opportunity to know as much as they want to know. That is why, after counseling patients about their treatment options, my conversation turns to a five-point informational discussion. The five key elements of my review:

1. **Describe the surgery.** Discuss what the procedure entails and what the patient should expect. For instance, I explain that cataract surgery is a 10-minute, same-day procedure performed at a surgery center with sedation, but no general anesthesia.

2. **Review the key risks associated with the procedure.** While my success rate for cataract surgery is more than 99%, patients tend to expect a 100% guarantee—which no surgeon can truthfully provide. I let patients know that while small, the risk of a complication that cannot be fixed—including loss of vision or loss of the eye—does exist. Patients must be comfortable with this risk before I will proceed with surgery.
3. Discuss the patient’s post-procedure responsibilities. These are the actions a patient must take to enable an optimal outcome. Whether it is using eye drops on schedule or attending all follow-up visits, patients must assume full responsibility for optimizing their outcomes, too.

4. Explain the patient’s alternatives and surgical options associated with a planned procedure. This is perhaps the most important of the five points at Bluegrass, and where expectation must be aligned with reality. We engage in a lengthy discussion of different artificial lenses and what the lens choice could mean for future vision. Cataract surgery is a modern-day miracle, yet patients must understand the limits of technology. Despite everyone’s best efforts, glasses or contact lenses sometimes are necessary after surgery—even for patients who have never worn them before. Some patients have asked me to provide 100% assurance they would not need glasses. After reiterating that no 100% guarantee is truthful, I tell these patients that it is okay to postpone the surgery until they feel more comfortable with the idea that glasses may be a potential necessity for visual correction after surgery.

5. Review the patient’s long-term prognosis. In the case of an intraocular lens (IOL) implant, I clarify that cataracts do not grow back. It is a common concern, and also one that affects a patient’s treatment decision. Because they do not grow back, the sooner the surgery is performed, the longer a patient can enjoy the results.

Following the discussion, patients are given a 12-page brochure I created that includes a description of my professional experience; a letter from me about cataract surgery; and further information about lenses and options, possible vision outcomes, answers to frequently asked questions, pre- and postoperative surgical instruc-

Figure 2. Consent screenshot showing the risks.
tions, an eye-drop schedule, and an appointment reminder that includes my personal cell phone number.

With information in hand, patients are asked to go home, think through our conversation, read the brochure, consider the available treatment options, and arrive at their treatment choices. They are encouraged to call me with any questions. If they wish, we offer them our informed consent document to take home, but they are never asked to sign it until they come back into the office for their next visit.

**DOCUMENTATION: INDICATING FULL UNDERSTANDING AND CONSENT**

Once patients decide they want to proceed with surgery, they come back into the office, and a technician provides surgery instructions, performs the lens calculation, and walks through the informed consent document. A comprehensive, procedure-specific consent form—available via a software application (Figure 1)—allows me to delegate the task of executing the form to assistive personnel without hesitation.

A thorough, easy-to-understand list of potential complications (Figure 2) is the cornerstone of any solid consent documentation. Everything that could possibly go wrong should be mentioned. In our case, for instance, “droopy eyelid” is a complication commonly forgotten about and left off of consent forms. While rare, the wire speculum used during surgery can cause the eyelid muscle to stretch. This very uncommon—but not unknown—risk is listed on our consent documents.

When Bluegrass first opened, we used some template forms that had been developed by an insurance firm. However, as a resident at the Veterans Administration facility in Lexington, Kentucky, I had become familiar with an automated informed consent and patient education
application (iMedConsent, Dialog Medical, Atlanta, Georgia) with which I was very comfortable because of its professional, in-depth list of potential complications (including the aforementioned droopy eyelid).

Printing out a copy of the consent provides an educational tool for patients—a way to better remember and understand the conversation and their choices (Figure 3). Libraries of procedure-specific educational material can further augment the process. After patients sign the consent documentation, they are always offered a copy.

The well-thought-out, inclusive list of complications on our cataract surgery consent form also makes it difficult for those patients who suffer complications to later claim they did not realize that their particular complication was a possibility. If ever my consent process were questioned, I am comfortable that it would stand up against scrutiny.

**STRENGTHENING OPERATIONS**

At Bluegrass Eye Surgery, I am the sole ophthalmologist working out of three locations that span 140 miles across Kentucky. Last year, I performed more than 1000 cataract procedures. Smooth operations depend on my ability to delegate key tasks to technicians and other staff.

Prompts throughout our informed consent process help make sure technicians consistently discuss all vital risk elements. Without that consistency and the comprehensive nature of the documents themselves, delegation of that task would not be possible. As it is, however, it offers a tremendous “best practices” advantage.

Meanwhile, patients gain a clear perception of both the benefits and risks associated with their care decisions. In the end, some patients have reviewed the documentation, thought about the risks, and decided not to go forward with surgery. That in itself, I believe, speaks to having truly informed patients.

As the *Journal of the American College of Surgeons* study reveals, patients are more likely to understand not only the benefits, but also the risks and choices associated with the procedures we offer if we extend the amount of time spent on informed consent discussions.

The standardized discussion at Bluegrass is only enhanced through comprehensive educational tools—which includes the consent form itself.

“Frustration is the difference between expectation and reality.” It is a profound statement. But it also holds a promise: Patients can be satisfied when their expectations are balanced with the outcomes that are delivered. The potential for dissatisfaction that leads to lawsuits can be diminished.

*Ultimately, using the informed consent process to carefully align hopes with potential outcomes is what keeps patients satisfied with their care—and out of the courtroom.*

The informed consent process can help gain well-educated patients and strengthen the patient/physician relationship. Ultimately, using it to carefully align hopes with potential outcomes is what keeps patients satisfied with their care—and out of the courtroom.

**REFERENCES**

