The PO

WER of Informed Consent

Don't overlook these claims, which can provide an edge in medical negligence cases when providers failed to give patients important information.

By || **Peter Mullenix and Patrick Malone**

Informed consent lawsuits often begin the same way. A treatment goes badly wrong, and the patient comes to us. We hire a doctor consultant to review, who says the bad outcome is one that shouldn't normally happen, but it's a recognized complication, and these things can happen without negligence. But the consultant also tells us that the treatment decision doesn't make sense, given the alternatives. The patient says the doctor never mentioned the bad outcome that occurred or any alternative treatments. The doctor discussed the treatment for only a few minutes and assured the patient nothing bad would happen.

Every state varies, but an informed consent claim generally requires proof of four things:[1]

- The doctor omitted information. This is usually either a risk of the doctor's proposed treatment, an alternative treatment, or an option for no treatment that the doctor failed to disclose.
- The information was important. As explained below, states vary about to whom the information must be important: the reasonable doctor or the reasonable patient.
- The patient would not have gotten the treatment in question if adequately

informed. This, again, varies: Some states use a subjective standard (would this specific patient have chosen a different course), and other states use an objective standard (would an objectively reasonable patient have chosen a different course).

- The treatment given proximately caused harm that the alternative (or no treatment) would not have caused.

It's important to remember that informed consent rules apply to *all* treatment decisions, even when the treatment plan is, for example, to send the patient home from an ER with no treatment.

If you have not handled an informed consent claim before, check your state's law for the standard determining what information must be disclosed to a patient. In some states, the case will be judged on a "reasonable doctor" standard: Was the risk or alternative that the doctor failed to disclose something a reasonable doctor would have considered material?[2]

Other states use a "reasonable patient" standard: Would the risk or alternative have been material to an objectively reasonable patient?[3] A few states have subjective patient standards: Would the risk or alternative have been material to this particular patient?[4] And other states have hybrids of these standards.[5] Currently, no clear majority position exists, but the modern trend has moved toward the reasonable patient standard.[6]

Regardless of your jurisdiction's standard, you need to convince a judge and, hopefully, a jury that the undisclosed risk was important. "Important" means two things here: important enough that the risk should have been disclosed, and important enough that the client would have made a different decision if properly informed. For some cases, this is easy. If the proposed procedure is recognized as extremely dangerous, and the alternative that the client never heard about is equally effective but far less dangerous, it won't matter what standard your jurisdiction has.

But proving importance for some consent issues is much harder. For example, what if the surgeon had an extremely low success rate for a given surgery but did not tell your client? The cases go both ways about whether the law should demand disclosure in that situation.[7] What if the doctor didn't disclose a financial conflict that had arguably influenced the doctor to recommend the more dangerous treatment? Again, cases go both ways.[8]

What if your client had a medical device that, unknown to the client, the FDA deemed "experimental or investigational"? Several courts have concluded that this issue is not important enough to patients to support an informed consent claim.[9] Similarly, other courts have decided that a drug's or device's off-label use—a use that the FDA has not approved or cleared—is not "a material issue of fact as to informed consent."[10]

Given this landscape, building evidence to persuade a judge about the materiality of an undisclosed risk and to convince a jury that the client would have cared about the undisclosed information is crucial.

What Do Patients Want to Know?

A study published in July 2019 and designed by a non-physician patient safety advocate aimed to measure the extent to which certain issues matter to patients.[11]

The study's strength lies in its simplicity. The authors first "created a statement of a generic situation in which a hospitalized patient must make choices about their care after being stabilized on entry via the emergency department."[12] The authors then provided a 10-question survey to various groups, including student nurses, health-professions educators, and a group of online participants demographically representative of U.S. patients. The survey asked about specific medical issues. (See the questions on p. 52.) Participants then ranked the intensity with which they would like an answer to the question, from 1 ("definitely no") to 5 ("definitely yes").

The results showed "reasonable patients" place a significant value on information routinely withheld. For

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example, more than two-thirds of the respondents in each group wanted to know if prescribed drugs were being used off label. At least 78% in each group wanted to know more about black-box warnings that accompanied the drugs they would be prescribed. And more than 68% in each group wanted to know the relative skill level of their doctors.

This study helps plaintiff attorneys in several ways. In "reasonable patient" states, it supports your argument that certain types of undisclosed information are important to reasonable patients. This might make the difference between going to trial and losing on summary judgment. Similarly, you can use the study to explain to jurors: "Our client isn't alone in caring about her doctor's experience: It's been shown that almost everybody cares."

The study can be discussed at trial as any medical study would be. This avoids the hearsay rule by having the expert show that this is the type of publication an expert in the field would treat as a "reliable authority."[13] Have the expert lay the foundation for relevance. Then ask: "Doctor, one of the things this jury will need to decide is whether this type of thing is something ordinary patients care about. Could this study be helpful in answering that question? How so?"[14] Look at the 10 issues surveyed in the study to see whether the results can help in your case.

This study is significant because it is an entirely new *kind* of study. There have been essentially no academic attempts to measure what patients actually care about.[15] This study shows that a thoughtful researcher can simply ask patients what they care about and get meaningful results using this method, so we hope patient advocates across the country imitate it. Further studies could create a new body of literature helpful for patients in informed consent cases. More important, doctors and hospital administrators might take notice and improve their informed consent procedures.

Six Tips to Build Your Claim

Until that body of literature develops, here are some battle-tested suggestions for how to better position an informed consent claim.

Consider how any treatment decision can give rise to a good informed consent claim. Plaintiff lawyers often think of informed consent too narrowly—that it applies only to surgical decisions when the patient was harmed by overly aggressive treatment. But patients have the right to be informed and make decisions about any significant medical treatment—that can include decisions not to treat, such as "watchful waiting" with a suspicious lump, sending someone home from an emergency room with a brewing infection, or monitoring an expectant mother rather than immediately delivering a baby in distress.[16]

Use discovery to get concessions that whatever legal standard your state has, it means that patients have a right to know what any reasonable patient would want to hear about. Even in reasonable doctor states, you often can get defendants or their experts to agree that reasonable doctors disclose what reasonable patients want to know. Conversely, no reasonable doctor would withhold information that the doctor knew a reasonable patient would want to know. That's important because it helps focus jurors on facts close to home; after all, they're reasonable people, so what would they want to know if it were them?

Create patient-centered 'rules' concerning disclosure that are clear, inarguable, and important—and have been violated. Consider the difference between the following two proposed rules for an informed consent case:

- "Surgical treatment should not be offered to treat patients without symptoms or disability when what is being treated is unlikely to cause any harm."
- "A doctor must tell the patient how urgent the problem is so the patient can make an intelligent choice."

The first proposed rule does not focus on the patient, and it is harder for jurors to identify with and understand. It is easier for the doctor to quibble with and far harder for you to prove the doctor violated it. The second rule has none of these problems. And it forces the jury to look at the issue from your client's perspective: We all want to make an "intelligent choice." Patient-centered rules that follow the "Rules of the Road" technique (clear, inarguable, violated, and important) will be more successful than doctor-centered rules.[17]

Tell the jury about the meeting that didn't happen. Talking about the informed consent process that your client endured does not give jurors the full picture of the injustice. Go further. Tell the jurors, through your expert and in closing argument, what an appropriate disclosure would have looked and felt like. Let the jurors think about how they expect the health care system to function. Let them imagine your client, in a comfortable chair in a warm room, when the doctor comes in. After pleasantries, the doctor gets very serious. "I want you to think hard about whether this procedure is right for you. It might ruin your hand by damaging nerves. Other doctors do it a different way that is less risky. I've only done this once or twice. And you can put this off indefinitely if you want."

Helping jurors visualize what a serious attempt at disclosure would look like will help them understand why your client experienced a half-hearted, rushed, and ultimately negligent attempt at informed consent.

Watch for stealth issues. Even when you use motions in limine and good jury instructions to try to keep dangerous and unfair arguments out, stealth issues sometimes can tank your case. Smoke these issues out with focus groups, and probe for them in jury selection. Worry less about drawing attention to them than leaving them unaddressed. And in closing, arm your favorable jurors with ways to defeat these arguments. We see these stealth issues often:

- Why didn't the patient get a second opinion? (Or worse, why didn't the patient get a third opinion if the first two disagreed?)
- If they aren't saying the doctor did the surgery wrong, who cares about consent?
- Why didn't the plaintiff do research on the other treatments? Why just rely on the doctor?
- The patient signed the consent form, so doesn't that mean he or she waived any claims?

All these and more can be answered if we listen carefully at trial for any hints of them coming up, and then get appropriate instructions from the court or concessions from witnesses. For example, good case law exists that it is the doctor's duty to disclose, not the patient's duty to ask the right questions.[18] You can make sure this is conveyed to the jurors in the form of the court's instructions, and then use an analogy to explain why this rule makes sense: "No one expects a car owner to ask detailed questions of a mechanic about the repair options available; it's the mechanic's job to disclose that a simple, inexpensive fix is available."

Bring it home in closing. An informed consent case is a request that the jury tell the medical establishment that we, as patients, would like to be treated like adults. We want a say in our care, we want doctors who are candid about risks and alternatives, and we want to make decisions free of unnecessary pressure.

Confront the defense with this throughout trial, and drive it home in closing. If you are in a "reasonable patient" state, show how the jury instructions require doctors to treat patients like adults. If not, make sure you've gotten the defense doctors to admit that treating patients like reasonable adults is one of the fundamental ethical principles they think about as they decide what information to disclose. Emphasize the trust that we, as vulnerable patients, put in our doctors: We are naked, often unconscious, and we let them cut us open and put their hands into our bodies. Explain that your client's only possible misstep in this case was giving this trust too quickly. And again, talk about the meeting that *didn't* happen. The contrast should be stark.

THE 10 QUESTIONS FROM THE SURVEY

1. Would you like to know all your treatment choices, including alternatives and risks and benefits of each choice for a patient like you? Your choices may include invasive procedures (surgery, endoscopic procedures, insertion of a medical device), non-invasive treatments, and what happens if you do nothing.
2. Drugs that have not been approved by the FDA for your condition are off-label for you. Drugs prescribed off-label are about twice as likely to cause serious side-effects as drugs prescribed on-label. Would you like to know if any drugs prescribed to you are off-label, and what their side effects may be?
3. Drugs assigned a "black-box" warning by the FDA pose an especially serious risk of harm. If you are prescribed such a drug, would you want to know the reasons for the black-box warning and if there are alternatives before you take it?
4. Decision aids are created to assist patients with complex medical decisions and to help them understand risks and benefits of treatment options. If there is a decision aid available for your illness, would you like to review it?
5. If you are considering an invasive procedure, would you like to know who will be performing it, their skill level, and how trainee doctors, if any, will be involved?
6. Assuming you have decided on a procedure or treatment, would you like to know what your total, out-of-pocket costs will be?
7. You have a trusted family member that is willing to act as your advocate. Would you like for that person to be present during shared decision-making about your medical care?
8. If you are well enough, would you like to be offered a chance to review and make entries in your medical records each day while you are hospitalized?
9. Before signing any documents that permit invasive, non-emergency procedures, would you like to review these at least one full day in advance of the procedure?
10. If you are considering an invasive procedure, would you like to know your expected difficulties, recovery times, pain management, and restrictions after the procedure while hospitalized and after discharge from the hospital? This includes the risk of infection from the invasive procedure.

Are informed consent cases difficult? Unquestionably. But if patient advocate groups continue to develop studies about what patients really care about, they may become less difficult.

Are these cases worthwhile? Unquestionably. And prevailing on these claims is the only way we will convince the medical establishment that patients deserve to be properly informed about their treatment options.


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Notes

1. Generally, your state's pattern jury instructions will set these elements out. Many states also have statutes specific to informed consent claims.
2. *See, e.g., Potter v. H. Kern Wisner, M.D., P.C.*, 823 P.2d 1339, 1341 (Ariz. Ct. App. 1991) ("'[T]he duty of disclosure of the risks by the physician or surgeon is measured by the usual practices of the medical profession.'" (quoting *Riedisser v. Nelson*, 534 P.2d 1052, 1054 (Ariz. 1975))).
3. *See, e.g., Johnson v. Kokemoor*, 545 N.W.2d 495, 502–03 (Wis. 1996) ("The standard to which a physician is held is determined not by what the particular patient being treated would want to know, but rather by what a reasonable person in the patient's position would want to know.").
4. *See, e.g., Cross v. Trapp*, 294 S.E.2d 446, 455 (W. Va. 1982) ("Under the patient need standard, the disclosure issue is approached from the reasonableness of the physician's disclosure or nondisclosure in terms of what the physician knows or should know to be the patient's informational needs.").
5. *See, e.g., Bloskas v. Murray*, 646 P.2d 907, 913 (Colo. 1982) ("Rather, what is determinative of the physician's duty to warn is the significance of the risk to the patient's informed decision to submit to the medical procedure in question. If the physician, as a reasonable medical practitioner, knew or should have known that an awareness of a particular risk would be a significant factor in the patient's decision to submit to a particular surgical procedure, then the risk is a substantial one which the physician must communicate to the patient.").
6. R. Jason Richards, *How We Got Where We Are: A Look at Informed Consent in Colorado—Past, Present, and Future*, 26 N. Ill. U. L. Rev. 69, 71 (2005).
7. *Compare Wlosinski v. Cohn*, 713 N.W.2d 16, 20 (Mich. Ct. App. 2005) (holding that "a physician's raw success rates do not constitute risk information reasonably related to a patient's medical procedure"), *and Whiteside v. Lukson*, 947 P.2d 1263, 1265 (Wash. Ct. App. 1997) (concluding that "lack of experience in performing a particular surgical procedure is not a material fact for purposes of finding liability predicated on failure to secure an informed consent"), *with Hales v. Pittman*, 576 P.2d 493, 500 (Ariz. 1978) (stating that a patient "is entitled to information concerning the treating physician's experience with the particular procedure"), *and Goldberg v. Boone,* 912 A.2d 698, 717 (Md. 2006) (finding that the elevated complexity of surgery combined with surgeon's relative inexperience gave rise to duty to disclose "that there were other more experienced surgeons in the region that could perform the procedure").
8. *Compare Moore v. Regents of Univ. of Cal.*, 793 P.2d 479, 483 (Cal. 1990) (concluding that "a physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment"), *with Dimmick v. U.S.*, 2006 WL 3741911, at *19 (N.D. Cal. Dec. 15, 2006) (stating that disclosure was not necessarily required because "Dr. Lampiris received fixed compensation for his consultant work, unlike the physician in *Moore* who received compensation in exchange for administering treatment").
9. *See, e.g., Alvarez v. Smith*, 714 So. 2d 652 (Fla. Dist. Ct. App. 1998) (collecting cases).
10. *Klein v. Biscup*, 673 N.E.2d 225, 231 (Ohio Ct. App. 1996).
11. John T. James et al., *Informed Consent, Shared-Decision Making and a Reasonable Patient's Wishes Based on a Cross-Sectional, National Survey in the USA Using a Hypothetical Scenario*, 9 BMJ 1 (2019), https://bmjopen.bmj.com/content/9/7/e028957.
12. *Id.* at 2.
13. *See* Fed. R. Evid. 803(18) or the appropriate state equivalent.
14. In a reasonable doctor state, the question could be reframed as: "Doctor, one of the things this jury will need to decide is whether good doctors know that this type of thing is something ordinary patients care about. Could this study be helpful in answering that question? How so?"
15. The researchers who published the study had found only two examples of research that even approached the same level of specificity on the issue of what *patients* care about, and neither was conducted in the United States. *See* J.L.J. Yek et al., *Defining Reasonable Patient Standard and Preference for Shared Decision Making Among Patients Undergoing Anaesthesia in Singapore,* 18 BMC Med. Ethics 1 (2017); Shamir O. Cawich et al., *From the Patient's Perspective: Is There a Need to Improve the Quality of Informed Consent for Surgery in Training Hospitals?*, 17 Permanente J. 22 (2013).
16. In *McQuitty v. Spangler*, 976 A.2d 1020 (Md. 2009), Maryland's highest court reversed a trial court and intermediate appellate court, reinstating a $13 million verdict for the plaintiffs, who had asserted an informed consent claim arising out of a mother with a partial placental abruption not being given the option of an immediate C-section. The two lower courts had held that an "affirmative violation of the patient's physical integrity" was required to maintain a consent claim. The state's Court of Appeals disagreed and held there was no such requirement when the physician had withheld information that a reasonable patient would have wanted to know.
17. *See* Patrick Malone & Rick Friedman, *Winning Medical Malpractice Cases: With the Rules of the Road Technique* (2012).
18. This was the heart of the court's rationale in the landmark case *Canterbury v. Spence*: "We discard the thought that the patient should ask for information before the physician is required to disclose. Caveat emptor is not the norm for the consumer of medical services. Duty to disclose is more than a call to speak merely on the patient's request, or merely to answer the patient's questions; it is a duty to volunteer, if necessary, the information the patient needs for intelligent decision. The patient may be ignorant, confused, overawed by the physician or frightened by the hospital, or even ashamed to inquire." 464 F.2d 772, 783 (D.C. Cir. 1972).