For The Defense™

dri
The magazine for defense, insurance and corporate counsel

September 2025

Toxic Torts + Environmental Law, and Medical Liability + Health Care Law

Including . . .

From Transcription to Trap: AI Scribes, Discovery, and Spoliation

Also in This Issue . . .

DRI Election Spotlight

And More!

By Madeleine Pfefferle

Complications and Consents: Admissibility of Informed Consent

Whether evidence establishing the physician complied with this duty is admissible when the validity of consent is not contested is under attack.

Physicians are required to obtain informed consent in treating patients in the absence of few exceptions, such as emergencies or certain mental health crises. Opinion 2.1.1 of the American Medical Association Code of Medical Ethics describes the informed consent process as the communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention. See Opinion 2.1.1, available at *https://code-medical-ethics.ama-assn.org/ethics-opinions/informed-consent*. During the process, it requires the physician to inform the patient of (1) the diagnosis, (2) the nature and purpose of the recommended intervention, and (3) the risks, benefits, and alternatives to the recommended course ("R/B/A"), including forgoing treatment. Id. The process is typically documented both by an entry in the medical record that R/B/As were discussed and memorialized in a written form signed by the patient. Patients have the right to choose which treatment course with which they wish to proceed or refuse medical treatment.

When Informed Consent is Being Litigated

Failure to obtain informed consent can result in disciplinary and/or potential legal action. Different jurisdictions apply different standards to physicians when adjudicating failure to obtain informed consent cases. See Ketchup v. Howard, 543 S.E.2d 371, 377 (Ga. Ct. App. 2000) (collecting cases from all jurisdictions), overruled by Blotner v. Doreika, 678 S.E.2d 80 (Ga. 2009) (declining to extend the application of the duty to obtain informed consent to chiropractors where the Georgia General Assembly specifically codified the duty as applied to specific providers and/or certain procedures, but not extending the duty to chiropractors). Jurisdictions also differ in the weight written and signed consent forms are given—whether they create a conclusive or rebuttable presumption of validity—when consent is challenged.

As to the duty imposed, the majority of jurisdictions require physicians to disclose information a reasonably prudent physician in the same or similar circumstances would disclose. See, e.g., Thompson v. Hall, 191 A.D.3d 1265 (N.Y. App. Div. 2021) ("To succeed in a medical malpractice cause of action premised on lack of informed consent, a plaintiff must demonstrate that (1) the practitioner failed to disclose the risks, benefits and alternatives to the procedure or treatment that a reasonable practitioner would have disclosed and (2) a reasonable person in the plaintiff's position, fully informed, would have elected not to undergo the procedure or treatment."); Rojas v. Barker, 195 P.3d 785, 789 (Kan. App. 2008) ("The duty to disclose information under the informed consent doctrine 'is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances.'"); Tashman v. Gibbs, 556 S.E.2d 772, 777 (Va. 2002) ("A physician's duty of disclosure is defined with reference to the appropriate standard of care…[which is] that degree of skill and diligence exercised by a reasonably prudent practitioner in the same field of practice or specialty in Virginia" and which must be ordinarily be established by expert testimony.); see also N.C. Gen. Stat. § 90-21.13 (2018) ("(a) No recovery shall be allowed against any health care provider upon the grounds that the health care treatment was rendered without the informed consent of the patient …where: (1) The action of the health care provider in obtaining the con-

Madeleine (Maddi) Pfefferle is a North Carolina trial attorney who defends healthcare providers and medical device manufacturers against malpractice and product liability claims. She is well known amongst her colleagues as a positive, passionate, and energetic advocate for her clients. Maddi is an active member of DRI, serving in leadership roles on the Young Lawyers and Medical Liability

sent of the patient or other person authorized to give consent for the patient was in accordance with the standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities; and (2) A reasonable person, from the information provided by the health care provider under the circumstances, would have a general understanding of the procedures or treatments and of the usual and most frequent risks and hazards inherent in the proposed procedures or treatments which are recognized and followed by other health care providers engaged in the same field of practice in the same or similar communities; or (3) A reasonable person, under all the surrounding circumstances, would have undergone such treatment or procedure had he been advised by the health care provider in accordance with the provisions of subdivisions (1) and (2) of this subsection.); Fla. Stat. Ann. § 766.103 (2018) (similar).

Other jurisdictions require a physician to disclose information that a reasonable patient would consider material. See, e.g. Street v. Upper Chesapeake Med. Ctr., Inc., 311 A.3d 321, 337 (Md. 2024) (adopting a "patient-focused" version of informed consent, in which the court analyzes the "data the patient requires in order to make an intelligent decision"; "not what the physician in the exercise of his medical judgment thinks a patient should know before acquiescing in a proposed course of treatment…Consequently, 'the scope of the physician's duty to inform is to be measured by the materiality of the information to the decision of the patient' as 'determined by reference to a general standard of reasonable conduct' rather than professional standard of care.' Information is material when 'a physician knows or ought to know [it] would be significant to a reasonable person in the patient's position in deciding whether or not to submit to a particular medical treatment or procedure.'"); Matthies v. Mastromonaco, 733 A.2d 456, 461–62 (N.J. 1999) (explaining the informed consent standard obligates physicians to disclose information that is material to a reasonable patient's informed decision: "Physicians thus remain obligated to inform patients of medically reasonable treatment alternatives and their attendant probable risks and outcomes. Otherwise, the patient, in selecting one alternative rather than another, cannot make a decision that is informed….The test for measuring the materiality of a risk is whether a reasonable patient in the [plaintiff]'s position would have considered the risk material.").

The scope of the duty to provide informed consent, the burden a plaintiff must meet to prove a failure to obtain informed consent, and the weight given to a written/signed consent form are areas with reasonably well-developed case law in most jurisdictions. A more recent trend, however, challenges the admissibility of informed consent and known risk/complication evidence when plaintiffs stipulate that the defendant physician obtained valid informed.

When Valid Informed Consent is Conceded

When plaintiffs do not challenge the validity of informed consent, they seek to exclude evidence that this fundamental process occurred, which can be particularly detrimental to cases where the plaintiff suffered a known complication of a particular course of treatment of which he or she was advised. Most notably, plaintiffs are seeking to exclude the signed consent forms. However, some plaintiffs are seeking to exclude all evidence related to the informed consent process, including notes in the medical record documenting the informed consent process occurred and testimony elaborating on the same. Even more concerning, some plaintiffs are seeking to exclude evidence of known risks/complications. Where the validity of informed consent is not challenged, plaintiffs argue—and many courts are agreeing—evidence of what the physician told the patient/what the patient knew is not relevant. Plaintiffs further argue that even if such evidence is relevant, the probative value is largely outweighed by the risk of prejudice, confusing the issues, and misleading the jury.

The fact that a known complication can occur in the absence of negligence supports the duty to obtain informed consent and disclose risks, benefits, and alternatives so that the patient can choose his or her

preferred method of treatment. However, in efforts to preclude the jury from hearing that the plaintiff-patient was informed there was a risk that he or she would suffer the very complication upon which the alleged negligence is based, plaintiffs seek to equate informed consent evidence and the doctrine of assumption of risk or some sort of waiver.

Some plaintiffs are seeking to exclude all evidence related to the informed consent process, including notes in the medical record documenting the informed consent process occurred and testimony elaborating on the same.

Even when the validity of informed consent is not at issue, evidence supporting consent was validly obtained is helpful. In countering plaintiffs' arguments and seeking to admit informed consent and known risk/complication evidence, defense counsel must show why it is relevant and not unduly prejudicial. First, exclusion of informed consent evidence presents an unnecessary risk that the jury will improperly infer that the provider did not adequately obtain informed consent based on their own medical experiences participating in informed consent discussions and signing consent forms. Further, juries are capable of understanding that consenting to treatment that carries a risk of certain complications is not the same as consenting to negligent treatment that causes the same alleged injury. Jurors are trusted to follow the law as the judge instructs. If jurors are trusted to understand they cannot infer negligence from the mere occurrence of an adverse outcome; they can be trusted to understand that giving informed consent is not a waiver of a right to sue for negligence. Further, informed consent evidence is relevant to causation and it can potentially be used to support standard of care in diagnosis and evaluation. It also implicates the credibility of witnesses in that it may be used to impeach the plaintiff or bolster the defendant.

Approximately one-quarter of United States jurisdictions have addressed the issue of the admissibility of informed consent evidence and concluded that it is generally irrelevant and inadmissible unless offered for a specific purpose. These jurisdictions include Connecticut, Delaware, Illinois, Indiana, Maryland, Missouri, Nebraska, New Jersy, Ohio, Oregon, Pennsylvania, and Virginia. It is critical, however, that this trend of excluding informed consent does not erode the ability to offer evidence of known complications and educating the jury that such complications can occur in the absence of negligence. The Supreme Court of Pennsylvania explained the difficulty in achieving a fair balance in complex, medical litigation:

> The complex nature of the practice of medicine – requiring, in the litigation realm, expert testimony for virtually all aspects of a plaintiff's burden to prove negligence, as well as in defense to those allegations – is central to our admissibility inquiry. Determining what constitutes the standard of care is complicated, involving considerations of anatomy and medical procedures, and attention to a procedure's risks and benefits. Further, a range of conduct may fall within the standard of care. While evidence that a specific injury is a known risk or complication does not definitively establish or disprove negligence, it is axiomatic that complications may arise even in the absence of negligence. We emphasize that the art of healing frequently calls for a balancing of risks and dangers to a patient. Consequently, if injury results from the course adopted, where no negligence or fault is present, liability should not be imposed upon the institution or agency actually seeking to assist the patient. As a result, risks and complications evidence may clarify the applicable standard of care, and may be essential to prove in this area, a complete picture of that standard, as well as whether such standard was breached. Stated another way, risks and complications evidence may assist the jury in determining whether the harm suffered was more or less likely to be the result of negligence. Therefore, it may aid the jury in determining both the standard of care and whether the physician's conduct deviated from the standard of care…we hold that evidence of the risks and complications of a procedure may be admissible in a medical negligence case for these purposes.

Mitchell v. Shikora, 209 A.3d 207, 318 (Pa. 2019). The Mitchell plaintiff alleged a gynecologist negligently cut her colon during a laparoscopic hysterectomy. See generally, id. The trial court excluded patient-specific informed consent evidence but allowed evidence of the risks and complications of the surgical procedure at issue. Id. The jury returned a verdict for the defense. The plaintiff filed a motion for new trial on the grounds that the court erred in denying her motion in limine to exclude evidence of known risks. Id. The request for relief was denied and plaintiff appealed. The Pennsylvania Supreme Court granted allocatur limited to the issue of admissibility of evidence of general risks and complications after the intermediate appellate court remanded the case for a new trial finding the risks and complications evidence was irrelevant to the standard of care. Id.

Similarly, the Nevada Supreme Court recently analyzed the admissibility of informed consent evidence and risk/complication evidence. See Taylor v. Brill, 539 P.2d 1188 (Nev. 2023). The plaintiff alleged her gynecologist was negligent in perforating her uterus and bowel during a hysterectomy. Id. Pre-trial, the plaintiff sought to exclude any references to known risks or complications, as well as patient education documents and the informed consent evidence. Id. The trial court allowed known complication evidence, including evidence that the plaintiff was aware of the risks and complications associated with the procedure, but excluded the informed consent form. Id. After hearing the evidence, a jury returned a unanimous verdict for the defense. Id. On appeal, the Nevada Supreme Court found that expert

testimony regarding risks and complications of the procedure at issue is admissible in establishing the standard of care and breach. Id. However, the Court parsed that lay witness testimony and hospital literature related to known risks and complications was not suitable for establishing the elements of a malpractice claim and deemed such evidence inadmissible. Id.

Courts that exclude evidence of what the patient knew about risks and complications have reasoned that assumption of risk doctrine is largely inapplicable in the medical malpractice setting. See e.g., Storm v. NSL Rockland Place, LLC, 898 A.2d 874 (Del. Super. Ct. 2005). The Court explained that the common themes in cases where the assumption of risk doctrine may be an appropriate defense rarely present in the context of healthcare. Id. at 883. The assumption of risk defense is appropriate when a plaintiff chooses (1) to engage in an activity out of personal preference, not necessity or (2) to participate in an inherently risky activity during the course of which he or she understands others may not act with ordinary care. Id. The Court rejected that patients choose to be sick or otherwise in need of care, deeming the first theory of assumption of risk inapplicable in the medical context, short of cosmetic care. Id. (concluding "The element of choice is missing."). The Court further held "there is virtually no scenario in which a patient can consent to allow a healthcare provider to exercise less than 'ordinary care' in the provision of services[,]" deeming the second theory inapplicable. Id. at 884.

However, while patients and plaintiffs may not choose to be sick or require care, they certainly are entitled to participate in choosing their treatment based on the available alternatives and risks and benefits associated with the same. Indeed, that is the very foundation of the duty physicians owe to patients in obtaining informed consent. The choice is more complex than the common example of a plaintiff assuming risk of injury by choosing to participate in a sporting event that involves physical contact, but a choice does remain. Patients decline treatment options presented frequently. Some decline life-saving treatment for religious reasons (such as declining blood transfusions) or personal preference, quality of life reasons (such as declining chemotherapy when diagnosed with terminal cancer). Accordingly, defense counsel needs to educate the courts on the complexity to ensure that plaintiffs are not permitted to oversimplify complex medical issues and exclude all evidence of informed consent and known risks/complications.

Practice Pointers:

- Be prepared to argue during motions in limine and/or at the time the evidence is sought to be introduced:
  - Collect orders and be prepared with case law (persuasive authority if no bind authority exists in the jurisdiction);
  - Be prepared to distinguish known risk/complication evidence as an element of the standard of care and potential breach from assumption of risk or wavier;
  - Clearly articulate to the judge the purpose of offering such evidence;
- If a plaintiff's in limine to exclude informed consent evidence is granted, revisit the issue throughout the trial as plaintiff may open the door to the evidence being admitted;
- Know the records:
  - Consider whether a written, signed consent form may or may not be admissible;
  - Consider whether entries that R/B/As were discussed must be redacted;
  - Consider whether discharge instructions will may or may not be admissible;
- When preparing for trial, be mindful of the words counsel, providers, and experts use:
  - Advise providers testify about "known complications"
  - Illicit testimony regarding the risks, benefits, and alternatives considered given the plaintiff's medical condition/comorbidities
  - Direct experts to explain "accepted/tolerated risk" of adverse outcomes in spite of the best of care/in the absence of negligence
  - Avoid the word "consent"
- If informed consent evidence is admitted over plaintiff's objection for any purpose, quality of life reasons (such as declining chemotherapy when diagnosed with terminal cancer). Accordingly, defense counsel needs to educate the courts on the complexity to ensure that plaintiffs are not permitted to oversimplify complex medical issues and exclude all evidence of informed consent and known risks/complications.

Approximately one-quarter of United States jurisdictions have addressed the issue of the admissibility of informed consent evidence and concluded that it is generally irrelevant and inadmissible unless offered for a specific purpose.

examples of jury instructions:

- "The question of whether [the patient] gave consent to the surgery in question is not to be considered by you. Informed consent is not a defense to allegations of medical negligence and does not relieve a physician from the duty to exercise that degree of care of skill ordinarily exercised by the profession generally under similar conditions and surrounding circumstances." Haskins v. Georgia Neurosurgical Institute, PC, 845 S.E.2d 770, 775 (Ga. Ct. App. 2020) (finding no abuse of discretion where the informed consent evidence was admissible to impeach the patient's wife's testimony, though not otherwise relevant or admissible to the issue of liability).
- "A healthcare provider has the duty to possess and use the care, skill, and knowledge ordinarily possessed and used under like circumstances by other healthcare providers engaged in similar practice in the same or similar communities. The fact that a patient goes through with a procedure having been advised of the

risks of such procedure does not change or alter the duty of the health care provider to possess and use the care, skill and knowledge ordinarily possessed and used under like circumstances by other healthcare providers engaged in a similar practice in the same or similar communities." Hillyer v. Midwest Gastrointestinal Associates, PC, 883 N.W.2d 404, 418–19 (Neb. Ct. App 2016) (finding the trial court erred in admitting "risk-of-procedure discussions" but sufficiently mitigated prejudice through the limiting instruction).

- "[S]imply because a particular injury is considered to be a risk of the procedure does not mean that a physician is relieved of the duty of adhering to the appropriate standard of care and does not mean that because the injury was a risk of the procedure injury did not result from the failure to confirm with the standard of care." Hayes v. Camel, 927 A.2d 880, 890–94 (Conn. 2007) (finding the instruction mitigated the prejudice and risk of inappropriate inferences that could be made from improperly admitted evidence that the plaintiff was informed of the risks through both the provider's testimony and office notes).
- See, e.g., "Defendants' exhibits #33 and #35 that are titled 'Operative and Invasive Procedure Informed Consent' have been received into evidence which tend to show consent by the patient [] to the operation/procedure and anesthetic described in the form and tends to show acknowledgement by the patient of her understanding of the stated risks inherent to that operation/ procedure. These documents are not and cannot be considered by you as a release from liability given to a health care provider for any acts of negligence committed by a health care provider in the operation/ procedure described in the consent forms. A patient cannot consent to the negligence of a health care provider. You may consider these exhibits, but only for the limited purposes listed in the informed consent. You may not consider them for any other purpose." (limiting instruction agreed to by plaintiff and given by North Carolina Superior Court in known complication case tried to a defense verdict without appeal).

Conclusion

It is well established that physicians owe a duty to inform their patients of the risks and benefits of each treatment method available, including no treatment at all. However, whether evidence establishing the physician complied with this duty is admissible when the validity of consent is not contested is under attack. If plaintiffs have continued success in eroding the admissibility of informed consent and known risk/complication evidence, healthcare providers will have a difficult time defending known complication cases. Defense counsel must be prepared at all stages to appropriately frame the issues and get this important evidence admitted.

*Discuss these topics and more at next year's Medical Liability and Health Care Law Seminar. **Sign up** to be notified when registration opens for great savings.*