# Health Law: Quality & Liability

Professor Thaddeus M. Pope

Reading Packet for Week 7 (Fall 2018)

## **Weekly Summary**

Last week, we reviewed the basic elements of the informed consent doctrine. This week, we grapple with newer and less settled issues.

*First*, most informed consent cases concern the non-disclosure of a procedure's risks. But some cases concern the nondisclosure of other information such as the physician's own training and experience with the procedure. The *Kokemoor* case is a landmark case on this point. Note that in addition to the malpractice lawsuit, Kokemoor was also disciplined by the state medical board for the same conduct. Wisconsin has since legislatively regressed to a reasonable physician standard. Yet, rather than read *Kokemoor*, we will read a brand-new Supreme Court of Iowa opinion that relies upon *Kokemoor*. Another type of information not typically included in the duty of informed consent is the costs of treatment.

**Second**, the reasonable physician disclosure standard can produce some odd results. The *Canterbury* court anticipated this possibility all the way back in 1972. In these jurisdictions (e.g. Virginia), the information that some relevant populations of reasonably prudent physicians would disclose sets the duty of disclosure. So, if the custom and practice is to disclose nothing, then the duty is to disclose nothing. But as the *Merenstein* case illustrates, that seems wholly inconsistent with the principles of informed consent and patient self-determination.

**Third**, while almost all states measure causation objectively, a small minority do not. For example, Oklahoma does not require the plaintiff to prove that the hypothetical reasonable patient would have acted otherwise had there been no breach. The Oklahoma plaintiff must establish only that, with appropriate disclosures, she herself would not have chosen the procedure that harmed her.

## Reading

All the following materials are collected into a single PDF document:

- Anderson v. Khanna (Iowa 2018) (inexperience)
- Pope, ASCO Post (2017) (costs)
- Merenstein, JAMA (2004)
- Merenstein, JAMA (2014)
- Scott v. Bradford (Okla. 1979)

In addition, please review a patient decision aid of your choice from this website: https://decisionaid.ohri.ca/AZlist.html

### **Objectives**

By the end of this week, you will be able to:

- Analyze and apply all four elements of an informed consent claim (duty, breach, causation, and damages) (3.1).
- Distinguish informed consent from medical battery (3.2).
- Distinguish informed consent from medical malpractice (3.3).
- Distinguish the two leading disclosure standards (measures of duty): reasonable patient and reasonable physician (3.4).
- Distinguish, analyze, and apply three distinct sub-elements of causation (3.5).
- Analyze and apply informed consent principles to information other than the risks and benefits of an intervention, such as physician experience and cost (3.6).
- Assess the impact of certification on patient decision aids (3.7).

#### IN THE SUPREME COURT OF IOWA

No. 14-1682

Filed June 15, 2018

**ALAN ANDERSEN,** Individually and as Injured Parent of **CHELSEA ANDERSEN** and **BRODY ANDERSEN,** and **DIANE ANDERSEN,** Wife of Alan Andersen,

Appellants,

vs.

**SOHIT KHANNA, IOWA HEART CENTER, P.C.,** and CATHOLIC HEALTH INITIATIVES IOWA CORP. d/b/a MERCY HOSPITAL MEDICAL CENTER,

Appellees.

On review from the Iowa Court of Appeals.

Appeal from the Iowa District Court for Polk County, Michael D. Huppert, Judge.

Patient and his family seek further review of a court of appeals decision affirming an adverse jury verdict. **DECISION OF COURT OF APPEALS VACATED**; **DISTRICT COURT JUDGMENT AFFIRMED IN PART, REVERSED IN PART, AND CASE REMANDED**.

Marc S. Harding of Harding Law Office, Des Moines, for appellants.

Nancy J. Penner, Jennifer E. Rinden, and Robert D. Houghton of Shuttleworth & Ingersoll, P.L.C., Cedar Rapids, for appellees.

#### WIGGINS, Justice.

A patient and his family brought a medical negligence action against a physician and the physician's employer. They alleged specific negligence and the failure of the physician to obtain informed consent. The district court granted summary judgment in favor of the defendants on the claim of informed consent based on the physician's failure to disclose his lack of training and experience in performing the particular procedure. During trial, the court refused to allow the plaintiffs to proceed with their informed-consent claim based on the physician's failure to disclose the risk of the surgery considering the patient's bad heart.

The case proceeded to trial on the specific negligence claim. However, the court would not submit a specification of negligence regarding the physician's lack of training or experience. The jury returned a verdict for the defendants, and the court entered judgment for the defendants. The patient and his family appealed. We transferred the case to the court of appeals, and it affirmed the judgment of the district court. The patient and his family sought further review, which we granted.

On further review, we affirm the district court's judgment on the specific negligence claim. However, we find the district court erred when it removed the two informed-consent claims from the case. Accordingly, we remand the case back to the district court to allow the patient and his family to proceed on their two informed-consent claims consistent with this opinion.

#### I. Factual and Procedural Background.

On January 2, 2004, Alan Andersen underwent a Bentall heart procedure performed by Dr. Sohit Khanna, an employee of the Iowa

Heart Center, P.C. Khanna performed the procedure at the Mercy Hospital Medical Center in Des Moines. At the time, Khanna did not have any experience or training in performing the particular Bentall procedure used on Andersen. There were several complications with the procedure that resulted in Andersen being in a coma, undergoing a second heart surgery, and having a heart transplant.

In September 2005, Andersen, his wife, and children<sup>1</sup> filed a petition against Khanna, Iowa Heart, and Mercy. In addition to alleging negligence against Khanna, Iowa Heart, and Mercy, Andersen alleged Khanna and Mercy failed to obtain informed consent from Andersen prior to surgery. The basis of the informed-consent allegation was that Khanna, Iowa Heart, and Mercy failed to properly advise Andersen of the risks and dangers of the procedure.

Andersen filed an amended petition in August 2008. In the amended petition, he alleged Khanna and Iowa Heart did not obtain informed consent because they failed to advise Andersen that Khanna had limited experience in performing a Bentall procedure.

In May 2010, Khanna and Iowa Heart filed a motion for partial summary judgment on the informed-consent allegations in the amended petition, claiming a physician does not have a duty to disclose physician-specific characteristics or experience in obtaining a patient's informed consent. Notably, the motion for partial summary judgment did not explicitly challenge Andersen's informed-consent claim to the extent it was based on Khanna's and Iowa Heart's alleged failure to disclose the risks and dangers of the procedure.

<sup>&</sup>lt;sup>1</sup>We refer to Andersen, his wife, and children as "Andersen."

On June 15, 2010, the district court agreed with Khanna and Iowa Heart that under Iowa law a physician does not have a duty to disclose physician-specific characteristics or experience in obtaining informed consent. Therefore, the court granted Khanna and Iowa Heart's motion for partial summary judgment. The relevant part of the ruling stated,

The first motion the Court considers is Dr. Sohit Khanna and the Iowa Heart Center's Motion for Partial Summary Judgment in regard to the issue of informed consent. The Court having read and reviewed the motion, the memorandum of authorities in support of the motion for partial summary judgment, the resistance filed by the Plaintiffs, the affidavits and the entire court file and otherwise being duly advised in the premises finds that the Motion for Partial Summary Judgment should be, and is, hereby sustained. The Court agrees with the Defendant Khanna and the Iowa Heart Center that the informed consent for patients as defined under Iowa law requires a disclosure to the patient of all known material information concerning the procedure to be performed which includes disclosing the material risks concerning a particular procedure. The Court finds that Iowa law does not include a duty to disclose personal characteristics or the experience of a physician or doctor in obtaining informed consent from a Therefore, pursuant to Iowa law, the Court finds that the motion for summary judgment filed by Dr. Khanna and the Iowa Heart Center regarding informed consent is hereby sustained.

This ruling removed from the case the informed-consent claim based on failure to disclose lack of experience. This ruling did not remove the informed-consent claim based on failure to advise Andersen of the risks and dangers of the procedure due to his bad heart.

In May 2011, Dr. Henri Cuenoud, one of the defendants' experts, was deposed. In that deposition, Dr. Cuenoud opined Andersen's heart valve "was severely stenotic and leaking a lot as well[, which] is the worst valve condition you can get" and described Andersen's heart's presurgery condition as exhausted, "like somebody at the end of a marathon." Dr. Cuenoud also concluded Khanna was aware of the poor condition of

Andersen's heart. When asked, "[G]iven Mr. Andersen's dire condition prior to surgery, were there any special or out-of-the-ordinary steps that Dr. Khanna should have taken to deal with it," Dr. Cuenoud replied, "I would say that I would have quoted a higher risk of surgery of not being able to come off the pump . . . something like 25 percent chance of not making it" and that, retrospectively, Khanna should have been more forthcoming about the risk of surgery.

Based on that information from Dr. Cuenoud's deposition, on June 1, 2011, Andersen filed a motion to reconsider the June 15, 2010 partial summary judgment ruling on informed consent. Andersen asserted Khanna should have informed him of the increased risk of surgery due to Andersen's heart's poor presurgical condition. Andersen requested the court reverse its partial summary judgment grant and "allow[] the parties to adduce evidence regarding the informed consent issue as it has now developed in light of the anticipated testimony of Dr. Henri Cuenoud."

On September 9, 2011, the plaintiffs voluntarily dismissed Mercy from the lawsuit. Therefore, any reference to Khanna will hereinafter also refer to Iowa Heart.

On September 20, 2011, a second judge ruled on the motion to reconsider. The ruling provided in its entirety,

The Court reconsiders its June 15, 2010, ruling and enters the following ruling modifying the same only as follows: The Plaintiffs shall be allowed to present evidence relating to Dr. Cuenoud's awareness of the Plaintiff's increased mortality risk and apprising the Plaintiff of the same.<sup>[2]</sup>

<sup>&</sup>lt;sup>2</sup>While the September 20, 2011 ruling says "Dr. Cuenoud," we think it is clear from the surrounding circumstances that the court meant to say "Khanna."

This ruling allowed Andersen to pursue an informed-consent claim based on Khanna's failure to disclose the increased risk from the heart's presurgery condition.

This ruling also addressed Khanna's second motion in limine, filed June 10, 2011, which requested the court disallow "[a]ny reference to, or evidence concerning, allegations of lack of informed consent, negligent credentialing, and that Dr. Khanna was not qualified." The court ruled that limine request was

**SUSTAINED** as to negligent credentialing. Dr. Khanna's qualifications may be pursued by the Plaintiffs in the context of general negligence claim, along with the issue of informed consent consistent with the Court's ruling on this issue on the Plaintiff's Motion to Reconsider.

Trial began in October 2011 but resulted in a mistrial on October 31, 2011. The court reset the case for trial to begin in April 2013. In anticipation of the second trial, Andersen submitted proposed jury instructions, including an informed-consent instruction based on Khanna's failure to disclose a material risk due to the presurgery condition of Andersen's heart. The second trial also resulted in a mistrial on April 15, 2013. Following the second mistrial, both Andersen and Khanna retained new counsel.

The court reset the case for a third trial to begin in July 2014. On June 30, 2014, Andersen submitted proposed jury instructions, which again included informed consent based on Khanna's failure to disclose a material risk due to the presurgery condition of Andersen's heart.

At the pretrial conference on July 2, 2014, the parties argued whether informed consent was still part of the case. Andersen claimed informed consent based on failure to disclose the increased risk due to

his bad heart remained an issue in the case. Khanna disagreed. Yet another district court judge assigned to preside over the case stated,

Well, here is where I'm still confused, more so from a lack of sustained involvement in this case. There was an informed consent claim that was the subject of a summary judgment motion which was granted. Now, ordinarily that would tell me everything I need to know about the viability of the informed consent claim. Has there been any effort to replead another informed consent claim since Judge Rosenberg's [June 15, 2010] ruling?

Andersen's counsel answered, "Not to my knowledge," and the district court proceeded to the next topic without resolving the informed-consent issue. The court's written order that followed the pretrial conference also did not resolve or conclude whether informed consent based on failure to disclose the increased risk due to Andersen's bad heart remained an issue in the case.

In his case-in-chief at trial, Andersen did not offer evidence to support his informed-consent claim based on failure to disclose the increased risk due to his bad heart. It appears he was waiting for Dr. Cuenoud to testify as an expert witness to present evidence on this claim. Khanna failed to move for a directed verdict on that issue at the close of Andersen's case-in-chief.

This informed-consent issue arose again just before Dr. Cuenoud was to testify. The court held a discussion outside the presence of the jury. Andersen reminded the court of the increased risk claim supported by Dr. Cuenoud's testimony. Khanna again alleged that this issue was out of the case due to the September 20, 2011 ruling.

Following a break for the court to review the September 20, 2011 ruling on Andersen's motion to reconsider, the discussion continued between the court and counsel. Based on the discussion, the court determined the issue of informed consent had been previously closed and

it was not going to reopen the issue at that point in the trial. The court stated,

All right. The parties and the Court have taken this case up to this point we're now in the waning days of trial, after a week and a half of trial, operating under the assumption that informed consent was out of the case. I know that there have been some issues back and forth on this topic, but in general, either in terms of offers of proof or other proffers of evidence, nothing has been presented that would suggest that informed consent was going to be a theory of liability for the jury to resolve or at least to preserve for further review. I'm not going to reopen that issue mid-trial to allow for a discussion of whether or not Dr. Khanna should be found liable or negligent for not discussing any increased risks from the surgery that the doctor may be testifying about today.

So I'm not going to reconsider the prior rulings on informed consent, while acknowledging that it is possible that Judge Stovall may have inserted the wrong doctor's name in his [September 20, 2011] ruling regarding whose awareness of the increased mortality risk in apprising Mr. Andersen of the same may have been intended. I don't know if that reference to the doctor's awareness relates to Dr. Khanna or not. I don't see any way to reasonably read that sentence without concluding that perhaps Dr. Cuenoud was inadvertently inserted when Dr. Khanna may have been intended.

But that being said, the parties under the Court's direction have kept this case from being developed as an informed consent case, and that's not going to change midtrial, with the plaintiffs having rested. And so we'll have to await how that shakes out down the road, but for the remainder of the trial, informed consent is still out.

But the doctor can be examined—Dr. Cuenoud can be examined consistent with his theories on causation regarding the risks that Mr. Andersen posed presurgery and the viability of the decision to be operated on.

Ultimately, the court ruled Dr. Cuenoud could not testify as to the numerical quantification of the increased risk:

To try to bring this back to a state of balance, I'm going to direct counsel and advise the doctor that he is not to testify regarding his knowledge or opinions regarding the quantification of any increased mortality risk posed to this patient, because I think then we do have a slippery slope on apprisement and the potential for rebuttal. I think he can talk about his opinions as developed on causation that the type of failure experience by Mr. Andersen is common or to be expected or at least an issue that is addressed, but the degree it can be developed initially to be quantified in a way that might open the door to an informed consent claim that I think we have all been operating under the assumption is not available will not be allowed.

The court's ruling before Dr. Cuenoud's testimony prevented Andersen from eliciting evidence to support his informed-consent claim based on the failure to disclose the increased risk due to his bad heart. Nevertheless, the court acknowledged, if Khanna elicited testimony opening the door to informed consent, it would allow Andersen to pursue the issue.

Following the testimony of defense expert Dr. Frazier Eales, Andersen argued Khanna opened the door. In his testimony, Dr. Eales was asked if Andersen's heart's presurgery condition would "have an effect on the ventricle's ability to be protected." Dr. Eales responded,

It has a huge effect. It not only has a huge effect on the ability to protect the muscle, but it has an effect on how much reserve, how much reserve strength there is, if you will, following the injury of cardiopulmonary bypass.

When I operate on somebody, I frequently tell them this: I can guarantee that I'll do my best job on the day that we're going to do this operation. And I can guarantee that I'll hurt them. I'll hurt them pretty significantly. It's a big incision. You've got to heal that up. And what we do in our work hurts the heart. It injures the heart. Every time.

The fact we can do this successfully depends on whether the people have reserve capacity in their heart. You know, you don't need to have it working at a hundred percent of possible output in order to do well. And we rely on every patient to have enough reserve there to get through the injury of the heart, the surgery itself, and recover, and recover really well, because we've eliminated the big problem.

Mr. Andersen came to surgery with severe aortic stenosis, severe aortic insufficiency, severe left ventricular hypertrophy, and he had had the bicuspid aortic valve for his entire life. So his heart has been working with an extra workload for a long, long time. There's no question that this was a higher risk operation than the standard elective short procedure.

Andersen argued Dr. Eales's testimony regarding what he tells his patients put the issue back in the case and the court should allow Andersen to present evidence on that issue in rebuttal. The court disagreed, ruling Dr. Eales's testimony did not open the door to informed consent and not allowing the informed-consent claim to be reintroduced.

Like the ruling and limitation on Dr. Cuenoud's testimony, this ruling also prevented Andersen from eliciting evidence in support of the informed-consent claim based on failure to disclose the increased risk due to his bad heart.<sup>3</sup> Additionally, Andersen did not develop any damage claim concerning his informed-consent claims because the court removed the issue from the case. As there was no evidence before the jury on any informed-consent issue, the court did not instruct the jury on informed consent.

The jury concluded Khanna was not negligent in performing the Bentall procedure. Andersen appealed, and we transferred the case to the court of appeals. The court of appeals affirmed the district court. Andersen applied for further review, which we granted. We will discuss additional facts and procedural notes as needed.

#### II. Issues.

Four issues will resolve this appeal. First, we must decide whether the district court erred in granting partial summary judgment when it

<sup>&</sup>lt;sup>3</sup>Andersen made two offers of proof on this claim—one after Dr. Cuenoud's testimony and one after Dr. Eales's testimony—in which Andersen testified Khanna did not inform him of the poor presurgical condition of his heart or the increased mortality risk from surgery because of that condition. Andersen also testified if he had been informed, he would have talked to his primary cardiologist about those issues and sought a second opinion before consenting to the surgery.

decided under Iowa law a physician does not have a duty to disclose information about the physician's inexperience or lack of training. Next is whether the district court erred when it did not allow Andersen to proceed on the informed-consent claim based on Khanna's failure to disclose the risk of the surgery considering the bad condition of Andersen's heart. Third is whether a finding by the jury that Khanna was not negligent precludes Andersen's informed-consent claims. Lastly is whether the district court erred when it denied Andersen's request to amend a jury instruction to include an additional, separate specification of negligence.

#### III. Scope of Review.

Our review of summary judgment rulings is for correction of errors at law. Baker v. City of Iowa City, 867 N.W.2d 44, 51 (Iowa 2015). "[W]e examine the record before the district court to determine whether any material fact is in dispute, and if not, whether the district court correctly applied the law." Roll v. Newhall, 888 N.W.2d 422, 425 (Iowa 2016) (quoting J.A.H. ex rel. R.M.H. v. Wadle & Assocs., P.C., 589 N.W.2d 256, 258 (Iowa 1999)). "A fact is material when its determination might affect the outcome of a suit. A genuine issue of material fact exists when reasonable minds can differ as to how a factual question should be Linn v. Montgomery, 903 N.W.2d 337, 342 (Iowa 2017) resolved." (citation omitted). We view the record in the light most favorable to the nonmoving party. Boelman v. Grinnell Mut. Reins. Co., 826 N.W.2d 494, 501 (Iowa 2013). "We draw all legitimate inferences the evidence bears that will establish a genuine issue of material fact." Linn, 903 N.W.2d at 342.

The court treated its ruling at trial that prevented Andersen from introducing evidence regarding the informed-consent issue involving the failure to disclose the risks of the Bentall procedure considering Andersen's bad heart condition as an evidentiary issue. We review evidentiary rulings for an abuse of discretion. *Stender v. Blessum*, 897 N.W.2d 491, 501 (Iowa 2017); *Giza v. BNSF Ry.*, 843 N.W.2d 713, 718 (Iowa 2014). "A court abuses its discretion when its ruling is based on grounds that are unreasonable or untenable." *Giza*, 843 N.W.2d at 718 (quoting *In re Tr. #T-1 of Trimble*, 826 N.W.2d 474, 482 (Iowa 2013)). A ground is unreasonable or untenable when it is "based on an erroneous application of the law." *Id.* (quoting *Tr. #T-1 of Trimble*, 826 N.W.2d at 718). "Therefore, under our abuse-of-discretion standard, 'we will correct an erroneous application of the law.'" *Id.* (quoting *Rowedder v. Anderson*, 814 N.W.2d 585, 589 (Iowa 2012)).

"Iowa law requires a court to give a requested jury instruction if it correctly states the applicable law and is not embodied in other instructions." *Alcala v. Marriott Int'l, Inc.*, 880 N.W.2d 699, 707 (Iowa 2016) (quoting *Sonnek v. Warren*, 522 N.W.2d 45, 47 (Iowa 1994)). "The verb 'require' is mandatory and leaves no room for trial court discretion." *Id.* Therefore, "we review refusals to give a requested jury instruction for correction of errors at law" when there is no discretionary component. *Id.* 

- IV. Whether the District Court Erred in Granting Partial Summary Judgment Based on Its Conclusion that Under Iowa Law a Physician Does Not Have a Duty to Disclose Information About the Physician's Inexperience or Lack of Training.
- **A.** Informed Consent—Generally. Iowa's current informed-consent law finds it genesis in two cases: Cowman v. Hornaday, 329 N.W.2d 422 (Iowa 1983), and Pauscher v. Iowa Methodist Medical Center, 408 N.W.2d 355 (Iowa 1987). In Cowman we adopted the "patient rule" as the test defining the scope of a physician's disclosure required to

obtain informed consent to an elective procedure. 329 N.W.2d at 427. And in *Pauscher*, we extended the patient rule's applicability to "all informed consent cases, in both elective and nonelective medical procedures." 408 N.W.2d at 359.

[T]he doctrine of informed consent arises out of the unquestioned principle that absent extenuating circumstances a patient has the right to exercise control over his or her body by making an informed decision concerning whether to submit to a particular medical procedure.

Id. at 358 (citing Cowman, 329 N.W.2d at 424–25). "Thus, a doctor recommending a particular procedure generally has, among other obligations, the duty to disclose to the patient all material risks involved in the procedure." Id. (citing Cowman, 329 N.W.2d at 425); accord Doe v. Johnston, 476 N.W.2d 28, 31 (Iowa 1991) ("Under the [patient] rule, the patient's right to make an informed decision about submitting to a particular medical procedure places a duty on the doctor to disclose all material risks involved in the procedure.").

Under the patient rule, "the physician's duty to disclose is measured by the patient's need to have access to all information material to making a truly informed and intelligent decision concerning the proposed medical procedure." *Pauscher*, 408 N.W.2d at 359 (citing *Cowman*, 329 N.W.2d at 425, 427); *accord Doe*, 476 N.W.2d at 31 ("That duty is shaped, not by what the medical community would deem material, but by the patient's need for information sufficient to make a truly informed and intelligent decision."). Several exceptions to the patient rule's disclosure requirement exist that are not applicable to this case.<sup>4</sup>

<sup>&</sup>lt;sup>4</sup>As we acknowledged in *Pauscher* and *Cowman*,

Generally, to succeed on a claim of informed consent, the plaintiff must establish four elements:

- (1) The existence of a material risk [or information] unknown to the patient;
- (2) A failure to disclose that risk [or information] on the part of the physician;
- (3) Disclosure of the risk [or information] would have led a reasonable patient in plaintiff's position to reject the medical procedure or choose a different course of treatment;
  - (4) Injury.

Pauscher, 408 N.W.2d at 360; accord Iowa State Bar Ass'n, Iowa Civil Jury Instruction 1600.10 (2017). The element at issue here is element number one.

**B.** Materiality of a Physician's Experience or Training. The district court granted partial summary judgment because it concluded "that Iowa law does not include a duty to disclose personal characteristics or the experience of a physician or doctor in obtaining

a number of situations may be established by the defendant physician as a defense to an informed consent action, constituting exceptions to the duty to disclo[se]. These include:

<sup>(1)</sup> Situations in which complete and candid disclosure might have a detrimental effect on the physical or psychological wellbeing of the patient;

<sup>(2)</sup> Situations in which a patient is incapable of giving consent by reason of mental disability or infancy;

<sup>(3)</sup> Situations in which an emergency makes it impractical to obtain consent;

<sup>(4)</sup> Situations in which the risk is either known to the patient or is so obvious as to justify a presumption on the part of the physician that the patient has knowledge of the risk;

<sup>(5)</sup> Situations in which the procedure itself is simple and the danger remote and commonly appreciated to be remote;

<sup>(6)</sup> Situations in which the physician does not know of an otherwise material risk and should not have been aware of it in the exercise of ordinary care.

informed consent from a patient." In other words, the district court found, as a matter of law, a physician's lack of experience or training is never material to a patient's decision to submit to a medical procedure. We disagree.

The duty to disclose under Iowa's informed-consent law turns on whether a reasonable person in the patient's position would consider the information at issue to be material to the decision of whether to undergo the proposed treatment. Pauscher, 408 N.W.2d at 359, 361–62. We have never categorically excluded a particular type of information, such as a physician's personal characteristics. Instead, our practice has been to apply the objective reasonable-patient standard to the undisclosed information at issue in a particular case to determine if the failure to disclose that information breached the physician's duty. E.g., Doe, 476 N.W.2d at 31-32; Pauscher, 408 N.W.2d at 360-62; see Bray v. Hill, 517 N.W.2d 223, 225-26 (Iowa Ct. App. 1994) (en banc). We see no reason to change that approach as it applies to information that can be categorized as personal characteristics of the physician. Accordingly, we conclude the district court erred when it found, as a matter of law, there is no duty to disclose personal characteristics, such as experience and training, under Iowa law.

Khanna raises several arguments in support of a blanket, brightline rule against requiring disclosure of personal characteristics when those characteristics are material. We address each in turn.

First, Khanna claims any such holding will impose a duty on physicians to disclose personal information. We agree our holding does impose such a duty, but we emphasize that duty is imposed only when that personal information is material to the decision of a reasonable person in the patient's position to or not to undergo the proposed treatment.

We also note Iowa caselaw already implicitly imposes such a duty. For example, in *Bray*, the court of appeals upheld the exclusion of evidence of the physician's probationary status because that status did not relate to the physician's qualifications as a surgeon or bear on any material risks involved in the procedure. 517 N.W.2d at 226. This reasoning implies the failure to disclose personal information, such as the physician's probationary status, may be the basis for an informed-consent claim in certain circumstances. *See id.* For example, what if the physician was on probation for repeatedly, incorrectly performing the exact same procedure he or she planned to perform on the patient? Would this not be material?

Khanna next contends Iowa Code section 147.137 defines what a physician must disclose.<sup>5</sup> Because this court has acknowledged section

<sup>&</sup>lt;sup>5</sup>Section 147.137 provides,

A consent in writing to any medical or surgical procedure or course of procedures in patient care which meets the requirements of this section shall create a presumption that informed consent was given. A consent in writing meets the requirements of this section if it:

<sup>1.</sup> Sets forth in general terms the nature and purpose of the procedure or procedures, together with the known risks, if any, of death, brain damage, quadriplegia, paraplegia, the loss or loss of function of any organ or limb, or disfiguring scars associated with such procedure or procedures, with the probability of each such risk if reasonably determinable.

<sup>2.</sup> Acknowledges that the disclosure of that information has been made and that all questions asked about the procedure or procedures have been answered in a satisfactory manner.

<sup>3.</sup> Is signed by the patient for whom the procedure is to be performed, or if the patient for any reason lacks legal capacity to consent, is signed by a person who has legal authority to consent on behalf of that patient in those circumstances.

Iowa Code § 147.137 (2018). As a historical side note, the text of section 147.137 has not changed since it was adopted in 1975.

147.137 is "[t]he most definitive statement of public policy on this issue" and "is a plain statement of the requirements of the patient rule," *Pauscher*, 408 N.W.2d at 360, 361, Khanna argues any expansion of the duty to disclose beyond the express language of section 147.137 should come from the legislature.

This argument mischaracterizes the reason *Pauscher* cited section 147.137. In *Pauscher*, we concluded the patient rule, as opposed to the "professional rule," would apply as the test to determine what information a physician must disclose to obtain informed consent. *Id.* at 361. We found support for our rejection of the professional rule, from a public policy perspective, in the language of section 147.137, which we concluded corresponded with the patient rule, not the professional rule. *Id.* at 360–61.

We did not conclude *the scope* of required disclosures under the patient rule is limited to those subjects enumerated in section 147.137. Indeed, we have consistently rejected such a limited, bright-line approach to the scope of disclosure. *See Doe*, 476 N.W.2d at 31 (holding a physician must disclose reasonably available alternative methods of treatment even though such a requirement does not neatly fit within a strict construction of the patient rule language from *Pauscher* and *Cowman*); *Pauscher*, 408 N.W.2d at 362 & n.2 (noting there is no bright-line that denotes when a risk is too remote to be material and "[t]here is no bright line separating the significant from the insignificant; the answer in any case must abide a rule of reason" (quoting *Canterbury v. Spence*, 464 F.2d 772, 788 (D.C. Cir. 1972))).

Additionally, Khanna's interpretation of section 147.137 as an exhaustive list of required disclosures reads too much into the statute. Section 147.137 merely creates a presumption of informed consent when

there is a signed writing addressing the enumerated subjects. Nevertheless, that presumption is rebuttable. In this case, Khanna has not produced or relied upon a written consent. Moreover, our holding in *Doe* indicates information beyond the scope of section 147.137 may be a required disclosure. *Compare* Iowa Code § 147.137 (2018) (requiring written disclosure to include "the nature and purpose of the procedure or procedures, together with the known risks, if any, of death, brain damage, quadriplegia, paraplegia, the loss or loss of function of any organ or limb, or disfiguring scars associated with such procedure or procedures, with the probability of each such risk if reasonably determinable"), *with Doe*, 476 N.W.2d at 31 (holding physician must disclose reasonably available alternative treatments).

Khanna cites to several cases from other jurisdictions where courts have tied the scope of required disclosures to the language of the jurisdictions' informed-consent statutes. However, these cases are unpersuasive because, unlike Iowa's informed-consent statute, the other statutes preempt the common law. See Ditto v. McCurdy, 947 P.2d 952, 958-59 (Haw. 1997) ("Hawaii's statute on informed consent expressly mandates that the board of medical examiners establish standards for physicians or surgeons to follow in disclosing information to a patient 'to ensure that the patient's consent to treatment is an informed consent." (quoting Haw. Rev. Stat. § 671-3(a) (1993)); Abram ex rel. Abram v. Children's Hosp. of Buffalo, 542 N.Y.S.2d 418, 418–19 (App. Div. 1989); Foard v. Jarman, 387 S.E.2d 162, 164 (N.C. 1990). In contrast, Louisiana, a jurisdiction that has an informed-consent statute almost identical to Iowa's, has not interpreted its statute as preempting the common law. See Hidding v. Williams, 578 So. 2d 1192, 1195, 1196-98 (La. Ct. App. 1991) (citing La. Stat. Ann. § 40:1299.40 (now § 40:1157.1))

(holding the physician's failure to disclose his chronic alcohol abuse vitiated the consent to surgery because that condition created a material risk associated with the physician's ability to perform the surgery).

Next, Khanna alleges expanding the duty to disclose to include physician-specific information will lead to several problems. First, Khanna notes "[n]umerical information such as procedure experience and complication values present complex issues." For example, there is no standardization method for gathering or reporting such statistical information. See Jennifer Wolfberg, Comment, Two Kinds of Statistics, the Kind You Look Up and the Kind You Make Up: A Critical Analysis of Comparative Provider Statistics and the Doctrine of Informed Consent, 29 Pepp. L. Rev. 585, 596 (2002). There is, likewise, no standardized rule as to how a physician can present such information to the patient. Second, Khanna alleges requiring disclosure of physician-specific information will force physicians to choose between disclosing protected peer review information and risking an informed-consent lawsuit for failing to disclose that information.

With respect to Khanna's concerns about numerical information, we note that the issue in this case does not involve disclosure of statistical data but rather information as to whether the treating physician has ever performed or received specialized training for the particular procedure. This type of experience and training information does not have the same standardization issues as statistical information. Moreover, a physician can disclose such nonstatistical information without requiring the physician to divulge protected peer review information. Indeed, at trial several experts testified regarding the number of Bentall procedures they had performed and their training to perform the procedure in order to establish their competency to testify as

expert witnesses. It stands to reason that if such information is relevant to establishing a witness's expertise, such information could be material to a reasonable patient's decision to or not to undergo a particular treatment.

Next, Khanna relies on several cases from other jurisdictions to support his argument for a limited interpretation of the informed-consent doctrine. Nevertheless, we find these cases unpersuasive for multiple reasons.

First. several of those jurisdictions base their limited interpretations on adherence to the particular jurisdiction's preference against expansion. See Duffy v. Flagg (Duffy II), 905 A.2d 15, 20-21 (Conn. 2006) (holding physician's experience with the procedure was not relevant to informed consent because that information did not relate to one of Connecticut's four disclosure factors and noting the doctrine of informed consent under Connecticut law is limited); Duttry v. Patterson, 771 A.2d 1255, 1258–59 (Pa. 2001) (holding evidence of physician's qualifications and experience is not relevant to an informed-consent claim because, under Pennsylvania law, the doctrine of informed consent is limited and only five types of information are considered material); cf. Ditto, 947 P.2d at 958-59 (holding there is no duty to affirmatively disclose qualifications or lack thereof because that issue is best left to the legislature and state board of medical examiners). As previously noted, we have not shown a similar predilection for limited interpretation. See, e.g., Doe, 476 N.W.2d at 31.

Second, at least one of the cases Khanna cites has been abrogated in part. Khanna cites to *Whiteside v. Lukson*, wherein the Washington Court of Appeals "conclude[d] that a surgeon's 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." 947 P.2d 1263, 1265 (Wash. Ct. App. 1997). But in *Housel v. James*, the Washington Court of Appeals implicitly limited the effect of its holding in *Whiteside* when it refused to "categorically hold[] that a physician's inexperience is never material to an informed consent claim." 172 P.3d 712, 716 (Wash. Ct. App. 2007). The *Housel* court acknowledged "[t]here may well be situations where evidence of a physician's experience would be a significant factor in a patient's decision to undertake a particular course of treatment." *Id*.

Third, one of the cases rejected arguments that physicians are required to disclose their personal success rates for a particular procedure. Wlosinski v. Cohn, 713 N.W.2d 16, 20 (Mich. Ct. App. 2005). In Wlosinski, the court reasoned a particular physician's success rate was not a risk related to the particular medical procedure, such evidence is irrelevant because the failure of a particular procedure does not mean the physician was negligent in performing the procedure, and requiring disclosure of such would encourage physicians to treat only low-risk patients. Id. at 20–21, 21 n.4.

The concerns that led the Michigan court to reject evidence of a physician's success rate as to a particular procedure support our conclusion that a physician's experience and training can be material. First, a physician's lack of experience or training on a particular procedure can increase the risk of complications. For example, in this case, multiple experts opined that Khanna's lack of experience and training on this Bentall procedure increased the odds of serious complications. Second, like how a physician's success rate is not indicative of whether the physician performed a particular procedure negligently, a physician's experience and training is also irrelevant to the

issue of negligent performance. See id. at 21. But that is not the issue here. A claim for informed consent does not depend on if the physician performed the procedure negligently; rather, it turns on whether the physician failed to obtain consent by failing to disclose material information. Thus, evidence of a physician's training and experience could be relevant because it could indicate the physician failed to disclose material information. Third, to the extent the Michigan court's concern about encouraging physicians to treat only low-risk patients has merit, requiring physicians to disclose their experience and training on the particular procedure at issue will encourage physicians to gain as much training and experience with the procedure as possible.

Finally, we find the reasoning from courts that have interpreted their informed-consent doctrines in a broader fashion more persuasive and in line with the development of our informed-consent doctrine. In *Johnson ex rel. Adler v. Kokemoor*, the Wisconsin Supreme Court concluded information about the physician's lack of experience or training and the difficulty of the procedure was material. 545 N.W.2d 495, 505 (Wis. 1996). In so holding, the court declined to narrowly construe the state's informed-consent statute. *See id.* It also rejected a bright-line rule against such evidence because the materiality of such information is dependent on the facts and circumstances of the particular case. *See id.* at 502, 504–05 (noting what information is material will vary from case to case).

Similarly, in *Goldberg v. Boone*, the Maryland high court held the question of whether a reasonable person would have deemed information about the physician's lack of experience to be material is a question for the jury. 912 A.2d 698, 717 (Md. 2006). The Maryland court also rejected a bright-line rule and declined to adopt an all-inclusive list of

matters to disclose. *Id.* at 716. To support its holding, the court cited to its precedent, which recognized a physician's level of training and experience may be material. *Id.* (citing *Dingle v. Belin*, 749 A.2d 157, 165–66 (Md. 2000)).

In *Moore v. Regents of the University of California*, the California Supreme Court, noting the concept of informed consent is a broad one, held a physician must disclose personal information unrelated to the patient's health that may affect the physician's professional judgment. 793 P.2d 479, 485 (Cal. 1990) (in bank). At issue in the *Moore* case was the physician's failure to disclose that he had a research interest in the procedure conducted on the patient. *Id.* at 483. Khanna cites to *Arato v. Avedon*, a subsequent California Supreme Court case, which refused to endorse mandatory disclosure of life expectancy probabilities, 858 P.2d 598, 607 (Cal. 1993) (in bank), to support his argument. But Khanna ignores *Arato*'s caveat to its refusal: "the better rule is to instruct the jury that a physician is under a legal duty to disclose to the patient all material information . . . needed to make an informed decision regarding a proposed treatment." *Id.* 

In *Hidding*, the Louisiana Court of Appeals held the physician had a duty to disclose his chronic alcohol abuse. 578 So. 2d at 1196. The court reasoned such a "condition creates a material risk associated with the surgeon's ability to perform, which if disclosed would have obliged the patient to have elected another course of treatment." *Id.* 

Like these courts, Iowa courts have consistently comprehended a flexible approach to the doctrine of informed consent. *See, e.g., Doe,* 476 N.W.2d at 31 (requiring disclosure of reasonably available alternative methods of treatment even though the patient rule as expressed in *Pauscher* and *Cowman* did not explicitly require such a disclosure);

Pauscher, 408 N.W.2d at 362 & n.2 (noting there is no bright-line determining when the probability of a risk is too remote to be material). Like the *Hidding* and *Johnson* courts, we find whether a physician's particular characteristics, such as the physician's training and experience with a particular procedure, are material will depend on the facts and circumstances of the case, such as whether those characteristics create or increase the risk to the patient. *See Hidding*, 578 So. 2d at 1196; *Johnson*, 545 N.W.2d at 502, 504–05; *see also Bray*, 517 N.W.2d at 226. Further, like the California and *Goldberg* courts, we believe the question of whether certain information is material is best left to the jury in most cases. *See Arato*, 858 P.2d at 607; *Goldberg*, 912 A.2d at 717.

Accordingly, we hold a physician's experience or training with the proposed treatment can be information material to the decision of a reasonable person in the patient's position to or not to undergo the proposed treatment. Whether such information is material will depend on the facts and circumstances of each case and will be for the jury to decide, unless as a matter of law no reasonable person in the patient's position would find such information material.

The record reveals a Bentall heart procedure is a very complicated procedure. The experts characterized a Bentall heart procedure as being harder to perform than a heart transplant. It is reasonable that anyone undergoing such a procedure would want to know his or her physician's experience and training, or lack thereof, before consenting to such a procedure by that physician. Under these circumstances, we cannot conclude as a matter of law that no reasonable person in Andersen's position would find such information immaterial to his or her decision to have the surgery before consulting another physician.

# V. Whether the District Court Erred When It Did Not Allow Andersen to Proceed on the Informed-Consent Claim Based on Khanna's Failure to Disclose the Risk of the Surgery Considering Andersen's Bad Heart.

When the district court judge made his ruling during trial precluding Andersen from pursuing the informed-consent claim based on Khanna's failure to disclose the risk of the surgery considering Andersen's bad heart, the issue was still part of the case. Andersen pled the issue. Although a prior court order seemed to dismiss all of Andersen's informed-consent claims, a subsequent order allowed an informed-consent claim based on Khanna's failure to disclose the risk of the surgery considering Andersen's bad heart to proceed. The subsequent order was based upon Khanna's expert Dr. Cuenoud's deposition testimony that Khanna should have told Andersen of the risk of the surgery due to Andersen's bad heart prior to performing the surgery.

Pretrial, Andersen submitted requested jury instructions applicable to the informed-consent claim based on Khanna's failure to disclose the risk of the surgery considering Andersen's bad heart. Additionally, the court held a pretrial conference. But neither the discussion at nor the written ruling following the pretrial conference indicates this informed-consent claim was out of the case. At the close of Andersen's case-in-chief, the court did not enter a directed verdict on this claim.

Andersen inquired what he could ask Dr. Cuenoud on crossexamination regarding this informed-consent claim as an attempt to avoid violating a motion-in-limine ruling. Because this informed-consent claim was still part of the case, Dr. Cuenoud's anticipated testimony would have been relevant to that issue and not unduly prejudicial. The court had an extensive colloquy with counsel. From the colloquy, it is apparent everyone at the trial, including the judge, knew the evidence supporting this informed-consent claim was to come from Dr. Cuenoud. It was at that time the court ruled Andersen could not elicit testimony from Dr. Cuenoud to support this informed-consent claim. We find this ruling at that late time to be an abuse of discretion because it was unreasonable or untenable based on its erroneous application of the law.

Although Andersen had rested when Dr. Cuenoud took the stand, our caselaw has long established that parties may rely on opposing parties' evidence to make their cases. See, e.g., Goldapp v. Core, 236 Iowa 548, 553-55, 19 N.W.2d 673, 675-76 (1945) (implicitly accepting one party's reliance on testimony produced by opposing party); Urdangen v. Edwards, 187 Iowa 1005, 1013-14, 174 N.W. 769, 772 (1919) (allowing evidence produced by plaintiff to corroborate defendant's case); Kolb v. Mall, 187 Iowa 193, 197, 174 N.W. 226, 228 (1919) ("The testimony on this point was all put in by the plaintiff. While she was under no duty to prove that Sam Mall was at any time insolvent, and had the right to demand proof that, at stated and material times, he was solvent, yet if, in her volunteer proof, she establishes that solvency, of course the defendants may avail themselves of such proof. It does not matter how the preponderance is created, if it exists." (Emphasis added.)); Buseman v. Schultz, 154 Iowa 493, 495, 132 N.W. 378, 378 (1911) (holding defendant did not need to offer any evidence to support his justification defense to false imprisonment allegation where every element of justification defense was proved by plaintiff's evidence); Ringstad v. Hanson, 150 Iowa 324, 330, 130 N.W. 145, 147 (1911) ("Exception is taken to proof of title by plaintiff in that he failed to introduce in evidence a plat of Callanan. The defect, if any, was cured by

its introduction by defendant."); *Marks v. McGookin*, 127 Iowa 716, 718, 104 N.W. 373, 373 (1905) (acknowledging defendants could prevail by relying solely on plaintiff's evidence but only if plaintiff's evidence was sufficient in itself to prove defendants' case). Therefore, nothing in this record would have prevented Andersen from relying on testimony garnered from Dr. Cuenoud on cross-examination to support the informed-consent claim based on Khanna's failure to disclose the risk of the surgery considering Andersen's bad heart. The district court erred in preventing him from doing so.

Additionally, when the district court refused to allow Andersen to generate evidence from Dr. Cuenoud supporting this informed-consent claim, the court expressly stated it was "not going to reconsider the prior rulings on informed consent." This statement effectively solidified the court's prior rulings as the law of the case because the practical effect of the court's statement was to accept the prior rulings' conclusions, which is essentially acknowledging the prior rulings' conclusions are the law of the case. See Hoefer v. Wis. Educ. Ass'n Ins. Tr., 470 N.W.2d 336, 339 (Iowa 1991) (en banc) (acknowledging the district court's ability to change a prior interlocutory ruling "enhances the court's integrity by refusing to give either party a 'vested right to require the court to perpetuate its mistake,' " and thereby implying the power is for correcting errors, not for changing prior rulings because one party dislikes its effect (emphasis added) (quoting Kuiken v. Garrett, 243 Iowa 785, 793, 51 N.W.2d 149, 154 (1952))).

The prior rulings allowed for Dr. Cuenoud to establish Andersen's informed-consent claim based on Khanna's failure to disclose the risk of the surgery considering Andersen's bad heart. Accordingly, because the court misapplied the law of the case when it precluded Andersen from

adducing evidence from Dr. Cuenoud to support this informed-consent claim, the court abused its discretion. *See, e.g., Lee v. State,* 906 N.W.2d 186, 194 (Iowa 2018) ("A court abuses its discretion when the grounds or reasons for the court's decision are 'clearly untenable' or when the court has exercised its discretion to an extent that is 'clearly unreasonable.'" "A ground or reason is untenable when it is not supported by substantial evidence *or when it is based on an erroneous application of the law.*" (Emphasis added.) (quoting *Equity Control Assocs., Ltd. v. Root,* 638 N.W.2d 664, 674 (Iowa 2001))).

The effect of the court's erroneous refusal to allow Andersen to adduce evidence in support of the informed-consent claim based on Khanna's failure to disclose the risk of the surgery considering Andersen's bad heart was prejudicial to Andersen. Under the evidentiary analysis, Dr. Cuenoud's anticipated testimony that the presurgery condition of Anderson's heart increased the risk of death to twenty-five percent was the only expert testimony quantifying the increased risk. Our caselaw requires the patient "to present expert testimony relating to the nature of the risk and the likelihood of its occurrence" whenever the undisclosed information involves a risk. Pauscher, 408 N.W.2d at 360. Without Dr. Cuenoud's testimony that there was a twenty-five percent chance Andersen would not make it, Andersen would not be able to meet this requirement. Additionally, Dr. Cuenoud's testimony was the only anticipated testimony discussing a physician informing the patient of Dr. Cuenoud's anticipated testimony was such an increase in risk. necessary to Andersen's informed-consent claim based on Khanna's failure to disclose the risk of the surgery considering Andersen's bad heart, and Andersen was prejudiced by the court's ruling.

# VI. Whether a Finding by the Jury that Khanna Was Not Negligent Precludes Andersen's Informed-Consent Claims.

Khanna argues even if the court erred in not submitting Andersen's informed-consent claims, the jury's finding of no negligence defeats Andersen's claims. This argument assumes any damages caused by Khanna's negligent performance are the same damages caused by his failure to obtain informed consent. They are not.

A leading treatise in the area recognizes an informed-consent claim does not depend on whether the physician was negligent in performing the treatment. 2 Dan B. Dobbs et al., The Law of Torts § 308, at 217 (2d ed. 2011) [hereinafter Dobbs et al.] ("The patient who asserts that she was not given appropriate medical information . . . is asserting that, even if the physician was not negligent in performing the procedure, he is liable for harmful results because the patient would have refused consent and avoided the harm had she been appropriately informed."); id. § 308, at 219 ("The negligence in the informed consent claim is not negligence in performing a medical procedure, but rather negligence in failing to explain its risks, alternatives, and other related information."); id. § 308, at 220 ("Under neither [the negligence nor battery approach to informed consent] is the plaintiff required to prove negligence in conducting the operation. . . . The wrong done is not a negligent operation but a failure to respect the patient's right of choice."); id. § 311, at 236 ("The gist of the plaintiff's informed consent claim most commonly is that her consent to a medical procedure was procured by nondisclosure of risks or other information the defendant was required to disclose, that the procedure caused harm even if the procedure was skillfully performed, and that the plaintiff would not have undergone the procedure and suffered the harm had she been properly informed. Such a claim, if proved, would establish but-for causation; but for the tortious nondisclosure, the plaintiff would have escaped the harm suffered." (Emphasis added.)).

Similarly, the cases reaching this issue do not require the physician to be negligent in performing the treatment in order for an informed-consent claim to be available. E.g., Duffy v. Flagg (Duffy 1), 869 A.2d 1270, 1277 (Conn. App. Ct. 2005), rev'd on other grounds, Duffy II, 905 A.2d at 18; Howard v. Univ. of Med. & Dentistry of N.J., 800 A.2d 73, 79 (N.J. 2002) ("The damages analysis in an informed consent case involves a comparison between the condition a plaintiff would have been in had he or she been properly informed and not consented to the risk, with the plaintiff's impaired condition as a result of the risk's occurrence. Our case law does not require a plaintiff to prove that the physician deviated from the standard of care in performing the operation or procedure; the physician's negligence is in the inadequate disclosure and the damages claimed derive from the harm to the patient caused by a procedure that would not have occurred if the disclosure had been adequate." (Citation omitted.)); Parris v. Limes, 277 P.3d 1259, 1263 (Okla. 2012) ("If a physician breaches this duty [to inform the patient of the medical options and their attendant risks], a patient's consent is defective, and the physician is responsible for the consequences. If the physician obtains a patient's consent but has breached this duty to inform, 'the patient has a cause of action sounding in negligence for failure to inform the patient of his options, regardless of due care exercised at treatment, assuming there is injury." (Emphasis added.) (Citation omitted.) (quoting Scott v. Bradford, 606 P.2d 554, 557 (Okla. 1979))); Gouse v. Cassel, 615 A.2d 331, 334 (Pa. 1992); Backlund v. Univ. of Wash., 975 P.2d 950, 954-55 (Wash. 1999) (en banc).

Even those jurisdictions that explicitly reject an informed-consent claim based on failure to disclose experience or training do not require negligent performance as an element of an informed-consent claim. See, e.g., Duffy I, 869 A.2d at 1277 ("[W]e note that the viability of an informed consent claim does not depend on proof of malpractice relating to a particular medical procedure. Consequently, our case law does not require a plaintiff to prove that the physician deviated from the standard of care in performing the particular medical procedure at issue in a claim based on lack of informed consent because the physician's negligence is the inadequate disclosure, and the damages claimed derive from the harm to the patient caused by a procedure that would not have occurred if the disclosure had been adequate. Thus, even though the plaintiff's claim of medical malpractice failed, she, nevertheless, may have prevailed on a separate claim of lack of informed consent." (Footnote omitted.) (Citations omitted.)); Gouse, 615 A.2d at 334 ("|T|he physician or surgeon who operates without his patient's informed consent is liable for damages which occur, notwithstanding the care exercised."); see also Backlund, 975 P.2d at 954-55 ("We note the trial court here made reference to the conduct of Dr. Jackson being in compliance with the standard of care as a factor in its decision on informed consent. The trial court's emphasis on the patient's likely following of the non-negligent recommendation of a physician goes too far in confusing negligence and informed consent claims. Negligence and informed consent are alternative methods of imposing liability on a health care practitioner. Informed consent allows a patient to recover damages from a physician even though the medical diagnosis or treatment was not negligent. . . . The [Washington] Court of Appeals in Holt [v. Nelson] aptly explained that if a doctor breaches the 'duty to obtain an informed consent from the

patient before proceeding with treatment, the patient has a cause of action for damages against the doctor even if the doctor has *performed* the treatment properly within the standard of care of the profession. Thus, the cause of action can arise against a doctor for failing to obtain the patient's knowledgeable permission to the treatment even though the doctor's actions have not been negligent and would not give rise to a cause of action in any other way.'" (First emphasis added.) (Citations omitted.) (quoting *Holt v. Nelson*, 523 P.2d 211, 216–17 (Wash. Ct. App. 1974))).

Some jurisdictions require the undisclosed risk to materialize and cause harm, but that requirement is not the same as the physician performing the treatment negligently. See, e.g., Hales v. Pittman, 576 P.2d 493, 499 (Ariz. 1978) (in banc) (noting the wrong in an informedconsent claim is not the operation itself but rather the failure to disclose, and requiring the unrevealed risk to materialize and cause harm); Howard, 800 A.2d at 79-80 (noting the informed-consent damages analysis involves comparison of the condition the patient would have been in if the patient had been informed and not consented to the risk with the condition the patient is in as a result of the risk's occurrence, but also noting the patient does not have to prove the physician negligently performed the procedure); see also Canterbury, 464 F.2d at 790 (landmark informed-consent case requiring "[a]n unrevealed risk that should have been made known [to] materialize" and "[o]ccurrence of the risk [to] be harmful to the patient," but not requiring negligent performance of the treatment); Kinikin v. Heupel, 305 N.W.2d 589, 591, 594-96 (Minn. 1981) (en banc) (noting informed-consent case plaintiff must prove, inter alia, "the undisclosed risk materialized in harm," and

upholding jury verdict for plaintiff on informed-consent claim even though jury found physician did *not* perform negligently).

In a couple jurisdictions, the plaintiff's "injury" from the physician's failure to obtain informed consent does not have to be physical or a result of the materialization of the undisclosed risk. Lugenbuhl v. Dowling, the Louisiana Supreme Court addressed a situation where an undisclosed risk did not materialize and cause physical harm to the patient. 701 So. 2d 447, 455 (La. 1997). Lugenbuhl, the plaintiff consented in writing to a medical procedure performed with surgical mesh but, during the procedure, the physician decided not to use mesh. Id. at 449, 453. The court determined the physician breached his disclosure duty when he failed to explain the advantages, disadvantages, and risks of using mesh, and "the necessity of reserving the decision on the use of mesh to the surgeon during the course of the operation." Id. at 454. The court noted this was an atypical informed-consent situation because the physician's breach of his duty to disclose "caused plaintiff to undergo a medical procedure to which the plaintiff expressly objected and for which the doctor failed to provide adequate information in response to the patient's request, thereby causing damages to plaintiff's dignity, privacy and emotional wellbeing." Id. at 455 (emphasis added). The court determined the injury in this situation "was to plaintiff's personal dignity and right of privacy," an injury that was compensable. Id. at 455-56. At no point did the court predicate the plaintiff's right to damages on whether the physician negligently performed the procedure. The injury in Lugenbuhl, invasion of the right to make an informed decision, is analogous to the injury in a wrongful-birth claim in Iowa. See Plowman v. Fort Madison Cmty. Hosp., 896 N.W.2d 393, 403 (Iowa 2017) ("The compensable injury in a wrongful-birth claim is the parents' loss of the opportunity to make an informed decision to terminate the pregnancy. This is analogous to a claim for medical negligence based on lack of informed consent.").

In Schiff v. Friberg, the plaintiff was injured when her colon was allegedly perforated during surgery and she subsequently filed an informed-consent claim, alleging the physician failed to warn her of that risk. 771 N.E.2d 517, 521-22 (Ill. App. Ct. 2002). The physician moved for directed verdict, claiming the plaintiff failed to establish that her injury (i.e., the perforated colon) was caused by the undisclosed risk (i.e., the risk of puncture by a surgical instrument). Id. at 526, 529. In other words, the physician claimed the plaintiff failed to present evidence the undisclosed risk materialized. See id. The Illinois appellate court's analysis disregards the physician's materialization-of-risk reasoning. Id. at 529-30. Instead, the appellate court stated the elements of an informed-consent claim, which notably do not include materialization of the undisclosed risk or negligent performance of the procedure, and concluded a directed verdict would be improper. Id. According to The Law of Torts treatise, the effect of this analysis is to permit a "plaintiff" who would have rejected the medical procedure had she been properly informed to recover for failure to disclose significant risks, even when the injury suffered is not a result of the unrevealed risk." 2 Dobbs et al. § 308 & n.30, at 221.

In *Parris*, while discussing the injury element of an informed-consent claim, the Oklahoma Supreme Court acknowledged "the occurrence of an undisclosed risk is important to the determination of injury and absent such occurrence, a physician's failure to reveal the risk is *possibly* not actionable." 277 P.3d at 1263 (emphasis added). But the court stated that focus on the occurrence of an undisclosed risk "is

not relevant to recovery by a patient who contends he would have foregone the treatment altogether, if he had been fully informed of all material facts." *Id.* at 1263–64. The court reasoned "the physician is 'responsible for the consequences' of providing treatment without having obtained informed consent and one of the elements of damage is any injury and expense caused by the treatment." *Id.* at 1264 (quoting *Smith v. Karen S. Reisig, M.D., Inc.*, 686 P.2d 285, 288–89 (Okla. 1984)).

Here, the court removed Andersen's informed-consent claims from the case prior to Andersen developing his damage claims arising from Khanna's failure to obtain informed consent. However, it is clear that in regard to Andersen's informed-consent claim based on Khanna's failure to disclose the risk of the surgery considering Andersen's bad heart, the risk Khanna should have disclosed was the exact injury he suffered regardless of whether Khanna performed the procedure pursuant to the applicable standard of care. As for the informed-consent claim based on Khanna's lack of experience, Andersen should have the opportunity to develop his theory of injury and damages before we summarily dismiss those claims. Accordingly, under this record the appropriate remedy is to remand the case for further proceedings on the informed-consent claims.

# VII. Whether the District Court Erred When It Denied Andersen's Request to Amend a Jury Instruction to Include an Additional, Separate Specification of Negligence.

Generally, lack of qualifications or experience is not by itself an independent basis for negligent performance. *Cf. State v. Davis*, 196 N.W.2d 885, 894 (Iowa 1972) (holding testimony on the failure to have a valid driver's license was irrelevant "in the absence of a showing of a causal relationship between the invalid license and the collision").

Andersen requested a separate specification of negligence that read, in part,

- 1. Sohit Khanna, M.D. was negligent in one or more of the following ways:
- a. In performing the Bentall procedure on Alan Andersen without being properly trained or without the experience to do so.

The district court declined to add the requested specification, concluding "that issue is embedded within all of the specifications." However, as part of its ruling, the court did allow Andersen to argue Khanna's lack of qualifications and experience regarding the Bentall procedure in connection with the submitted specifications of negligence. The specifications actually submitted to the jury included,

- a. In providing inadequate myocardial protection to Alan Andersen's heart during the Bentall procedure; or
- b. In improperly reattaching Alan Andersen's left main coronary artery during the Bentall procedure; or
- c. In taking too much time to perform the left main coronary artery bypass in response to the failure of Alan Andersen's left ventricle following the Bentall procedure.

The jury was also instructed,

Physicians who hold themselves out as specialists must use the degree of skill, care and learning ordinarily possessed and exercised by specialists in similar circumstances, not merely the average skill and care of a general practitioner. A violation of this law is negligence.

When we review the instructions given to the jury to determine whether the instructions properly state the law, we look to the instructions to determine if the instructions taken as a whole accurately reflect the law. *Rivera v. Woodward Res. Ctr.*, 865 N.W.2d 887, 902 (Iowa 2015); *State v. Pelelo*, 247 N.W.2d 221, 225 (Iowa 1976) (en banc). Here, the instructions given require Khanna to exercise the same "degree of

skill, care and learning ordinarily possessed and exercised by specialists in similar circumstances." The failure to do so is negligence.

Thus the court instructed the jury to consider Khanna's training and experience when considering each specification of negligence. In doing so, the jury could use Khanna's lack of training or experience to help it decide if he was negligent as to any one of the specifications of negligence the court submitted to the jury. However, even if Khanna was unqualified to perform the Bentall procedure, as long as he did not actually breach the standard of care of a qualified cardiovascular surgeon performing such a procedure, there is no claim for negligent performance of the operation. This is what the jury found, regardless of his training or experience. In other words, a jury could not find a person posing as a physician negligent as long as that person did not actually breach the standard of care of a qualified cardiovascular surgeon performing such a procedure.

Therefore, the instructions as given incorporate Andersen's claim regarding Khanna's lack of experience or training and the jury's verdict factually found he was not negligent in the performance of the Bentall procedure regardless of his lack of training or experience. Accordingly, the district court did not err in refusing to give Andersen's requested instruction.

# VIII. Disposition.

We vacate the decision of the court of appeals. We affirm the judgment of the district court as to Andersen's specific negligence claims. We reverse the judgment of the district court removing Andersen's informed-consent claims from the case. Accordingly, we remand the case to the district court to allow Andersen to proceed on his two informed-consent claims consistent with this opinion.

DECISION OF COURT OF APPEALS VACATED; DISTRICT COURT JUDGMENT AFFIRRMED IN PART, REVERSED IN PART, AND CASE REMANDED.

All justices concur except Waterman, J., Cady, C.J., and Mansfield, J., who concur in part and dissent in part.

# WATERMAN, Justice (concurring in part and dissenting in part).

I respectfully dissent from parts IV and VI of the majority opinion. I would affirm the district court's summary judgment dismissing the informed-consent claim based on Dr. Khanna's failure to disclose his lack of experience with the Bentall heart procedure. Informed consent is not an open-ended, unlimited theory of liability. Rather, if a physician fails to disclose a known material risk and the risk occurs, the patient can recover for the harm resulting from the risk. But if the physician fails to disclose a risk that never materializes, the patient cannot recover for this nonevent. For example, failure to disclose the possible need for a blood transfusion before a hip replacement surgery does not result in liability if the patient did not need a transfusion.

Alan Andersen's theory is that he should have been told about Dr. Khanna's lack of experience because an inexperienced physician is more likely to make mistakes. That risk never materialized. The jury verdict establishes that Dr. Khanna met the standard of care for this surgery. Thus, even if the number of prior surgeries was something that needed to be disclosed as part of the informed-consent process, the jury verdict precludes recovery on the informed-consent theory. In any event, as most courts recognize, physicians owe no duty under informed-consent statutes to disclose their experiences with particular procedures.

# I. The Jury Verdict of No Negligence Precludes Recovery for Nondisclosure of Dr. Khanna's Inexperience.

Andersen's informed-consent claim fails even if we assume Dr. Khanna was required to disclose his inexperience with the Bentall procedure. It is well-settled that the plaintiff in a medical malpractice informed-consent case cannot recover unless the risk that the physician

failed to disclose in fact materialized and caused harm to the patient. The seminal case is *Canterbury v. Spence*, which adopted this commonsense holding:

No more than breach of any other legal duty does nonfulfillment of the physician's obligation to disclose alone establish liability to the patient. An unrevealed risk that should have been made known must materialize, for otherwise the omission, however unpardonable, is legally without consequence. Occurrence of the risk must be harmful to the patient, for negligence unrelated to injury is nonactionable. And, as in malpractice actions generally, there must be a causal relationship between the physician's failure to adequately divulge and damage to the patient.

464 F.2d 772, 790 (D.C. Cir. 1972) (footnotes omitted).

The majority today acknowledges that *Canterbury* is a "landmark informed-consent case" and quotes the requirement that the unrevealed risk must materialize and harm the patient. Yet the majority fails to apply this rule and, instead, conflates it with a separate rule that the patient need not prove the physician *negligently* performed the surgery to recover under an informed-consent theory. A surgeon who competently performs a procedure may still be liable to the patient under an informed-consent theory, but only if a known risk the surgeon failed to disclose in fact occurs and harms the patient.

State supreme courts began adopting the requirement that the undisclosed risk materialize decades ago.

[A breach of] the physician's obligation to disclose the material risks incidental to a particular treatment . . . does not per se establish liability to the patient. As in the case of any breach of a legal duty, the plaintiff must . . . prove a proximate causal relationship between the physician's failure to adequately inform and injury to the patient.

Proof of proximate cause in such cases requires, initially, a showing that the unrevealed risk which should have been made known has materialized. Absent occurrence

of the undisclosed risk, the doctor's omission is legally inconsequential.

Downer v. Veilleux, 322 A.2d 82, 92 (Me. 1974).

"The view espoused by the courts in *Canterbury* and *Downer* has been uniformly accepted by the high courts of numerous other jurisdictions." Cochran v. Wyeth, Inc., 3 A.3d 673, 680 (Pa. Super. Ct. 2010) (collecting cases). Indeed, "[i]n informed consent cases, it appears to be well-settled and without debate that the non-disclosed risk must manifest itself into actual injury in order for a plaintiff to establish Id.; see also Wachter v. United States, 689 proximate causation." F. Supp. 1420, 1422 (D. Md. 1988) (applying Maryland law, which requires plaintiff to show that the undisclosed risk materialized and caused injuries); Hales v. Pittman, 576 P.2d 493, 499 (Ariz. 1978) (en banc) ("The failure of a physician to disclose a known risk does not, standing alone, constitute sufficient grounds for a malpractice Because the anesthesia dolorosa did not occur in [the patient, the physician's failure to disclose its possibility is not actionable under a malpractice theory."); Davis v. Kraff, 937 N.E.2d 306, 316–17 (Ill. App. Ct. 2010) (rejecting plaintiff's argument "that she was not required to show that the undisclosed risk ever materialized"); LaCaze v. Collier, 434 So. 2d 1039, 1048 (La. 1983) ("[T]he plaintiff [must] show that the undisclosed risk actually occurred."); Aceto v. Dougherty, 615 N.E.2d 188, 192 (Mass. 1993) ("[I]n order to recover for a physician's failure to obtain informed consent, the plaintiff must show not only that the physician failed to disclose material information to the patient, but also that the physician's failure in this regard is causally related to the patient's injury."); Reinhardt v. Colton, 337 N.W.2d 88, 95-96 (Minn. 1983) (en banc) (requiring plaintiff to show that the undisclosed risk

materialized in harm); Smith v. Cotter, 810 P.2d 1204, 1209 (Nev. 1991) (per curiam) ("To establish proximate cause, first there must be a showing that the unrevealed risk which should have been revealed by the doctor actually materialized."); Howard v. Univ. of Med. & Dentistry of N.J., 800 A.2d 73, 79-80 (N.J. 2002) (requiring proof the "undisclosed risk occurred and harmed the plaintiff" (emphasis omitted) (quoting Teilhaber v. Greene, 727 A.2d 518, 524 (N.J. Super. Ct. App. Div. 1999))); White v. Leimbach, 959 N.E.2d 1033, 1035 (Ohio 2011) ("[A] patient bears the burden to present expert medical testimony . . . showing that one or more of those undisclosed risks and dangers materialized and proximately caused injury."); Scott v. Bradford, 606 P.2d 554, 559 (Okla. 1979) ("The risk must actually materialize and plaintiff must have been injured as a result of submitting to the treatment. Absent occurrence of the undisclosed risk, a physician's failure to reveal its possibility is not actionable."); Hook v. Rothstein, 316 S.E.2d 690, 704 (S.C. Ct. App. 1984) ("It is for the plaintiff to show that the undisclosed risk materialized and caused him or her injury . . . . ").

We expressly recognized the requirement that "the risk materialize[]" to recover under an informed-consent theory in *Plowman v. Fort Madison Community Hospital*, 896 N.W.2d 393, 403–04 (Iowa 2017) (quoting *Canesi ex rel. Canesi v. Wilson*, 730 A.2d 805, 813 (N.J. 1999)). We compared informed-consent and wrongful-birth actions. *Id.* at 403. We allowed the parents' wrongful-birth action to proceed against medical defendants who failed to disclose the risk revealed on a fetal ultrasound that the child would be born with severe impairments. *Id.* at 395–96,

<sup>&</sup>lt;sup>6</sup>Plowman was legislatively abrogated on other grounds this year. See S.F. 2418, 87th G.A., 2d Sess. § 118 (Iowa 2018) (2018 Iowa Legis. Serv. S.F. 2418 (West 2018)) (to be codified at Iowa Code § 613.15B).

410. The Plowmans would have had no right of recovery for that nondisclosure if the child had been born healthy—that is, if the undisclosed risk of birth defects never materialized. *See id.* at 399 (reiterating that no recovery is allowed for birth of healthy child).

An illustrative case for this governing rule is K.A.C. v. Benson, in which the Minnesota Supreme Court held that the "plaintiff must demonstrate that a reasonable person knowing of the risk would not have consented to treatment, and that the undisclosed risk actually materialized in harm." 527 N.W.2d 553, 561 (Minn. 1995) (emphasis added). In K.A.C., the defendant-doctor was infected with the human immunodeficiency virus (HIV) and suffered from open sores on his hands and forearms. Id. at 555. While infected, the doctor performed two gynecological procedures on the plaintiff. *Id.* The plaintiff and 335 other patients potentially exposed to the AIDS virus were advised to undergo testing; all who did so, including the plaintiff, tested negative for the HIV antibody. Id. at 557. The Minnesota Supreme Court affirmed summary judgment for the medical defendant because "the undisclosed, minuscule 'risk' of HIV exposure did not materialize in harm to [the] plaintiff because [she] tested negative for the HIV antibody." *Id.* at 561–62 (emphasis added). Similarly, here, the risks of mistakes from inexperience never materialized, precluding recovery under an informedconsent theory.

We have never upheld a recovery under an informed-consent theory when the undisclosed risk did not occur and cause harm to the patient. The risk presented by Dr. Khanna's inexperience was that he might fall below the standard of care performing the surgery. The jury, which the majority acknowledges was instructed properly, found Dr. Khanna not negligent. This verdict establishes that the undisclosed

risk of mistakes due to inexperience in fact never materialized. The verdict is the death knell for Andersen's informed-consent claim. The majority errs by holding otherwise.

# II. Dr. Khanna Owed No Duty to Disclose His Inexperience with the Specific Procedure.

There is a second, independent reason why Andersen's informed-consent claim was properly taken from the jury. The district court correctly ruled that Dr. Khanna had no duty to disclose that he had never previously performed the Bentall procedure. Dr. Khanna is a board-certified cardiothoracic surgeon who has performed numerous heart surgeries. One can often define a medical procedure narrowly enough to say that this particular procedure has not been done by this particular physician.

The majority creates a new, ill-defined duty to volunteer information regarding the physician's experience. I would not go there. The legislature detailed the disclosure requirements for informed consent in Iowa Code section 147.137 (2018). Section 147.137 provides,

A consent in writing to any medical or surgical procedure or course of procedures in patient care which meets the requirements of this section shall create a presumption that informed consent was given. A consent in writing meets the requirements of this section if it:

1. Sets forth in general terms the nature and purpose of the procedure or procedures, together with the known risks, if any, of death, brain damage, quadriplegia, paraplegia, the loss or loss of function of any organ or limb, or disfiguring scars associated with such procedure or procedures, with the probability of each such risk if reasonably determinable.

Iowa Code § 147.137. In *Pauscher v. Iowa Methodist Medical Center*, we described section 147.137 as "[t]he most definitive statement of public policy" on informed consent and as "a plain statement of the [disclosure]

requirements." 408 N.W.2d 355, 360–61 (Iowa 1987). The statute does not require disclosure of physician-specific information such as the doctor's success rate or number of times he or she has performed the procedure. I would not add disclosure requirements that the legislature chose to omit.

In Doe v. Johnston, we said that "truly informed consent must be based on knowledge of reasonably available treatment alternatives." 476 N.W.2d 28, 31 (Iowa 1991). The plaintiff contracted "the dread disease AIDS" from a blood transfusion during hip replacement surgery. Id. at 30. The fighting issue at trial was whether the surgeon "breached the standard of medical care by failing to warn Doe of the risk of acquiring AIDS through a blood transfusion or . . . [by] failing to advise him of the possibility of self-donating the necessary units of blood." Id. The jury found the surgeon not negligent, and we affirmed the trial court's denial of Doe's motion for a directed verdict or JNOV because he failed to prove such disclosures were required as a matter of law. Id. at 31-32. We did not mention section 147.137, but the availability of ways to reduce the risk of the hip replacement surgery by securing safer blood for transfusion fits comfortably within the statutorily required disclosure of the "known risks . . . of the procedures." That is different from the physician's personal experience.

We have never previously held the physician must disclose his or her personal experience or lack thereof in an informed-consent case. Most courts reject such a requirement. *See, e.g., Duffy v. Flagg,* 905 A.2d 15, 20–21 (Conn. 2006) (rejecting argument that a physician's prior experience with vaginal birth after cesarean section was relevant to an informed-consent claim because the only required disclosures are the nature of the procedure, its risks and anticipated benefits, and

alternatives to the procedure); Ditto v. McCurdy, 947 P.2d 952, 958 (Haw. 1997) ("declin[ing] to hold that a physician has a duty to affirmatively disclose his or her qualifications or the lack thereof to a patient" and noting that "this is a matter best left to the legislature, and . . . the board of medical examiners"); Włosinski v. Cohn, 713 N.W.2d 16, 20 (Mich. Ct. App. 2005) ("As a matter of law, we hold that a physician's raw success rates do not constitute risk information reasonably related to a patient's medical procedure" that a physician must disclose to a patient.); Abram v. Children's Hosp. of Buffalo, 542 N.Y.S.2d 418, 419 (App. Div. 1989) (noting that the cause of action for lack of informed consent has been statutorily defined and concluding it does not "require disclosure of qualifications of personnel providing . . . treatment"); Foard v. Jarman, 387 S.E.2d 162, 167 (N.C. 1990) (acknowledging that "[t]he statute imposes no affirmative duty on the health care provider to discuss his or her experience" and declining to impose such a duty); Duttry v. Patterson, 771 A.2d 1255, 1259 (Pa. 2001) ("[W]e hold that information personal to the physician, whether solicited by the patient or not, is irrelevant to the doctrine of informed consent."). I would follow this well-developed body of precedent.

The majority instead relies on *Johnson ex rel. Adler v. Kokemoor*, 545 N.W.2d 495 (Wis. 1996), which is readily distinguishable. That court affirmed evidentiary rulings allowing evidence of the surgeon's lack of experience with the specific procedure (which he had never performed previously) only *after* he had misled the patient by telling her falsely that he had performed the surgery she required dozens of times. *Id.* at 499.

Regardless, today's decision should be limited to its facts—requiring disclosure of the physician's inexperience only when the procedure is extraordinarily complicated and the physician has never

performed it.<sup>7</sup> The problem will be drawing the line on when and what physicians now must disclose about their personal experience. Is disclosure required if the physician has only performed the procedure twice previously? Ten times? Is the physician required to disclose that other specialists in his or her group have greater experience? What about similar procedures? Do the outcomes matter? What if the outcomes depend on variables unrelated to surgical skill, such as the age or health of the other patients? Who decides what must be disclosed? Today's decision raises many more questions than it answers. See Jennifer Wolfberg, Comment, Two Kinds of Statistics, the Kind You Look Up and the Kind You Make Up: A Critical Analysis of Comparative Provider Statistics and the Doctrine of Informed Consent, 29 Pepp. L. Rev. 585, 596 (2002) (criticizing Kokemoor for raising "[c]ountless questions").

And how would the physician disclose to a new patient the outcomes of his or her other patients' surgeries without violating statutes requiring confidentiality? See Iowa Code § 622.10 (physician-patient privilege); Willard v. State, 893 N.W.2d 52, 63–64 (Iowa 2017) (holding patient safety net records were nondiscoverable and inadmissible under the morbidity and mortality privilege codified in Iowa Code §§ 135.40–.42); Carolan v. Hill, 553 N.W.2d 882, 886–87 (Iowa 1996) (discussing broad peer review privilege in Iowa Code section 147.135(2)); see also 45 C.F.R. § 164.502 (2013) (Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule establishing protections for confidentiality of health information). Will physicians face a Hobson's

<sup>&</sup>lt;sup>7</sup>The majority notes that "[t]he record reveals a Bentall heart procedure is a very complicated procedure. The experts characterized a Bentall heart procedure as being harder to perform than a heart transplant."

choice between disclosing confidential information or risking an informed-consent claim for failing to do so?

I foresee that any patient with a bad outcome will now bring informed-consent claims that must go to the jury whenever the physician failed to disclose his or her specific experience and success rate on the procedure. This will further increase costs of healthcare burdening Iowans. The legislature can have the last word and should overrule this ill-advised decision.

For these reasons, I respectfully dissent from sections IV and VI of the majority opinion.

Cady, C.J., and Mansfield, J., join this concurrence in part and dissent in part.

# Informed Consent and the Oncologist: Legal Duties to Discuss Costs of Treatment

By Thaddeus Mason Pope, JD, PhD November 25, 2017 Tweet this page

ADVERTISEMENT				





For 50 years, clinicians in the United States have had a legal duty to disclose to patients with cancer the risks, benefits, and alternatives to a proposed cancer treatment. Until recently, however, it has been unclear whether clinicians have a similar duty to discuss the costs of that treatment. Today, to mitigate the risks of civil liability and disciplinary sanctions, the ethical and, arguably, legal consensus is that the prudent clinician should discuss the costs of treatment with his or her patients. Here is a brief history of how this consensus evolved.

## **Changing Standards**

"To mitigate the risks of civil liability and disciplinary sanctions, the ethical and, arguably, legal consensus is that the prudent clinician should discuss the costs of

— Thaddeus Mason Pope, JD, PhD

treatment with his or her

patients."

THE TRADITIONAL RULE: For decades, legal commentators maintained that clinicians had no legal duty to discuss costs with their patients. Many pointed to a 1993 decision from the Supreme Court of California to support their position. The patient in that case, Miklos Arato, sued his oncologists for negligent nondisclosure, claiming that his near futile pursuit of pancreatic cancer treatments resulted in the "failure of his contracting business and to substantial real estate and tax losses." The court rejected Mr. Arato's claim, holding that physicians have no duty to disclose risks that might affect the patient's "nonmedical rights and interests."

**The New Rule:** The law is different today. Subsequent legal developments have eclipsed the holding in the Arato case. Over the past 25 years, appellate courts in many states have expanded the scope of required disclosure beyond information pertaining solely to medical treatment. For example, clinicians now also often have legal duties to disclose information about themselves, such as their experience, <sup>2,3</sup> their substance abuse and health conditions that might affect treatment, <sup>4,5</sup> and their financial conflicts of interest. <sup>6–8</sup> In short, informed consent duties are no longer limited to purely clinical risks, benefits, and alternatives. <sup>9</sup>

Moreover, even if some courts were to continue the "therapeutic limitation" in the Arato case, overwhelming evidence now shows that financial toxicity has a direct and substantial impact on a patient's health. Obviously, a patient's finances are impacted by the high cost of cancer treatment, such as medications costing over \$100,000, combined with higher deductibles of \$6,000 or more, 20% copays, and lower income earnings. But "financial toxicity" also negatively impacts treatment and medical outcomes because patients frequently skip or adjust chemotherapy doses and appointments to reduce their oncology care costs. O

The way courts measure the scope and extent of informed consent duties varies from state to state. Most states follow one of two dominant disclosure standards. About 25 states follow the malpractice (also known as "physician-based," "professional," or "custom-based") standard. The other 25 states follow the material risk (also known as "patient-based" or "lay") standard. There is probably now a duty to discuss costs under both standards for the following reasons.

# Legal Difference Between the Two Standards

MEDICAL MALPRACTICE STANDARD: The medical malpractice standard requires physicians to provide only the information to patients that a hypothetical reasonably prudent physician would disclose in the same circumstances. The custom and practice of the medical profession set the standard. While a minority of states set geographic limitations, in most states a physician must disclose the same information that a reasonable physician in the United States would disclose under the same circumstances.<sup>11</sup>

Duty is based on professional custom. Traditionally, physicians did not discuss costs of treatment with their patients. Consequently, there was no duty to have such discussions. Today, however, professional standards have changed. Therefore, so, too, have physician disclosure duties.

First, a significant percentage of oncologists discuss costs of treatment with their patients. Second, recognizing the clear consequences of financial toxicity, leading professional oncology societies, such as ASCO, have published guidance statements encouraging clinicians to discuss costs of treatment with their patients, as has the Institute of Medicine.

Because of these two developments, physicians in malpractice standard states probably have a legal duty to discuss the costs of cancer treatment with their patients, since that is what the reasonably prudent physician already does or would do. Indeed, survey evidence shows that nearly a majority of physicians are discussing treatment costs with their patients. <sup>15,16</sup> Because the professional custom is to discuss costs, physicians have a legal duty to discuss costs.



"Just as clinicians have a legal duty to warn patients about physical side effects like vomiting, neutropenia, and hair loss, they also have a duty to warn patients about the financial side effects of treatment."

— Thaddeus Mason Pope, JD, PhD Material Risk Standard: While the medical malpractice standard is physician-defined, the material risk standard is patient-defined. It requires physicians to provide all the information that a hypothetical reasonable patient would consider important or significant in making a treatment decision.<sup>11</sup> This disclosure duty is broader than the malpractice standard and increases the burden on physicians.<sup>17,18</sup> After all, a reasonable patient may deem information important even if the medical profession does not customarily discuss that information.

Indeed, significant survey evidence shows that with substantial increases in health-care cost sharing, most patients deem financial information important. One study reports that 59% to 80% of patients want to discuss health-care costs with their physicians. Another shows that more than 80% of patients report it is "extremely important" or "quite important" to know what they will personally be responsible to pay. Because the reasonable patient wants to discuss costs, physicians in material risk standard states probably have a legal duty to discuss costs.

## Legal Obligation to Discuss Costs

MEDICAL BOARD DISCIPLINE: Informed consent duties are not solely a matter of medical malpractice liability. That is only one form of legal sanction. The state medical licensing boards also impose discipline when physicians provide inadequate informed consent.<sup>21</sup> Increasingly, health-licensing boards have amended their informed consent regulations to include an explanation of "financial obligations." Notably, some state medical boards have recently brought charges against physicians for failing to disclose the costs of cancer treatment.<sup>22</sup>

Implementation: A key objection to imposing a duty on clinicians to discuss costs of treatment is that clinicians do not know the actual costs. But clinicians can provide patients with useful information without calculating either specific prices or out-of-pocket costs for individual patients. There are already tools and resources for oncologists to start these difficult conversations with patients, including the National Comprehensive Cancer Network's® Evidence Blocks<sup>™23</sup> and ASCO's Value Framework.<sup>24</sup> Moreover, feasibility is amply demonstrated by the fact that many physicians are also already reducing the cost of oncology care for their patients. Two common approaches include using lower-cost drugs when appropriate that have the same efficacy as newer, more expensive ones and helping patients secure drug copayment assistance through drug manufacturer patient programs.<sup>25</sup> Notably, medical malpractice insurance companies are recommending such measure as "risk mitigation strategies."<sup>26</sup>

#### Conclusion

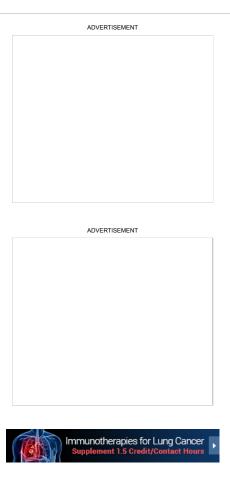
TODAY'S CANCER TREATMENTS are more effective and less toxic. But just as clinicians have a legal duty to warn patients about physical side effects like vomiting, neutropenia, and hair loss, they also have a duty to warn patients about the financial side effects of treatment.

DISCLOSURE: Dr. Pope reported no conflicts of interest.

#### REFERENCES

- 1. Arato v Avedon, 858 P2d 598 (Cal 1993).
- 2. Howard v University of Medicine & Dentistry of New Jersey, 800 A2d 73 (NJ 2002).
- 3. Johnson v Kokemoor, 545 NW2d 495 (Wis 1996).
- 4. Hidding v Williams, 578 So2d 1192 (La Ct App 1991).
- 5. Faya v Almaraz, 620 A2d 327 (Md 1993).
- 6. DAB v Brown, 570 NW2d 168 (Minn Ct App 1997).
- 7. Moore v Regents of the University of California, 793 P2d 479 (Cal 1990).
- 8. Shea v Esensten, 208 F3d 712 (8th Cir 2000).
- 9. Silva v Baptist Health South Florida, 856 F3d 824 (11th Cir 2017).
- 10. de Souza JA, Yap BJ, Wroblewski K, et al: Measuring financial toxicity as a clinically relevant patient-reported outcome: The validation of the comprehensive score for financial toxicity (COST). Cancer 123:476-484, 2017.
- 11. Pope TM: Certified patient decision aids: Solving persistent problems with informed consent law. J Law Med Ethics 45:12-40, 2017.
- 12. Wollins DS, Zafar SY: A touchy subject: Can physicians improve value by discussing costs and clinical benefits with patients? Oncologist 21:1557–1600, 2016.
- 13. Meropol NJ, Schrag D, Smith TK, et al: American Society of Clinical Oncology guidance statement: The cost of cancer care. J Clin Oncol 27:3868-3874, 2009.
- 14. Levit LA, Balogh EP, Nass SJ, et al (eds): Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis. Washington, DC; National Academies Press; 2013. Available at www.nap.edu/read/18359/chapter/1. Accessed November 7, 2017.
- 15. Glode AE, May MB: Rising cost of cancer pharmaceuticals: Cost issues and interventions to control costs. Pharmacotherapy 37:85-93, 2017.
- 16. Schmittdiel JA, Steers N, Duru OK, et al: Patient-provider communication regarding drug costs in Medicare Part D beneficiaries with diabetes: A TRIAD study. BMC Health Serv Res 10:164, 2010.

- 17. Canterbury v Spence, 464 F2d 772 (DC Cir 1972).
- 18. Wisconsin Medical Examining Board, Clearinghouse Rule 14-040, Admin Reg (April 26, 2015).
- 19. Hunter WG, Zhang CZ, Hesson A, et al: What strategies do physicians and patients discuss to reduce out-of-pocket costs? Analysis of cost-savings strategies in 1,755 outpatient clinic visits. Med Decis Making 36:900-910, 2016.
- 20. Kelly RJ, Forde PM, Elnahal SM, et al: Patients and physicians can discuss costs of cancer treatment in the clinic. J Oncol Pract 11:308-312, 2015.
- 21. Miller T: Informed consent: A medical board analysis. J Med Regul 96:16-22, 2011.
- 22. Texas State Office of Administrative Hearings, SOAH Docket No. 503-14-1342 MD. Available at www4.burzynskimovie. com/images/burzynsk/Responsdents%20Answers%20 to%20the%20Second%20Amended%20Complaint-2.pdf. Accessed November 7, 2017.
- 23. National Comprehensive Cancer Network: NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) with NCCN Evidence Blocks™. Available at www.nccn.org/evidenceblocks. Accessed November 7, 2017.
- 24. Schnipper L, Davidson NE, Wollins DS, et al: Updating the American Society of Clinical Oncology value framework: Revisions and reflections in response to comments received. J Clin Oncol 34:2925–2934, 2016.
- 25. Hunter WG, Zafar SY, Hesson A, et al: Discussing health care expenses in the oncology clinic: Analysis of cost conversations in outpatient encounters. J Oncol Pract. August 23, 2017 (early release online).
- 26. Diamond R: Internal medicine closed claims: What can we learn? Doctor's Advocate 3rd Quarter 2016. Available at http://www.thedoctors.com/KnowledgeCenter/ Publications/TheDoctorsAdvocate/Internal-Medicine- Closed-Claims-What-Can-We-Learn. Accessed November 8, 2017.



# NOV TODAY IN ONCOLOGY

ACKC Secures \$10 Million for Kidney Cancer Research

Long-Term Risk of Breast Cancer Recurrence After 5 Years of Endocrine Therapy

Constructing a Risk Stratification Model for Pediatric Acute Lymphoblastic Leukemia

Seattle Children's Opens Trial for Children and Young Adults With Leukemia That Targets CD22 and CD19 Proteins Simultaneously

#### Winners and Losers

Daniel Merenstein. JAMA. Chicago: Jan 7, 2004. Vol. 291, Iss. 1; pg. 15

THERE ARE MANY LOSERS IN THIS STORY: THE MAN WITH incurable prostate cancer, me, my family, family practice residency programs, national guidelines, the shared decision-making model, and anyone who believes in evidence-based medicine (EBM). There were also a few winners: the man with prostate cancer's lawyer, to some extent his family, and anyone who wants to continue to practice outdated medicine or doesn't believe in continuing medical education.

The date was July 19, 1999, when as a third-year resident I saw a highly educated 53-year-old patient. In June 2002, my residency and I were served with court papers. June 2003, the trial.

On that day in July 1999 I saw the 53-year-old man for a physical examination. I discussed with him, and documented in his chart, the importance of colon cancer screening, seat belts, dental care, exercise, improved diet, and sunscreen use. I also presented the risks and benefits of screening for prostate cancer and documented the discussion. I never saw the patient again, and after I graduated, he went to another office. His new doctor ordered prostate-specific antigen (PSA) testing without discussing the risks and benefits of screening with him. Unfortunately for the patient, his PSA level was very high and he was subsequently diagnosed with incurable advanced prostate cancer. This patient lost on many accounts. For starters, he had a horrible cancer (Gleason 8), a cancer that is very difficult to treat in any stage and even harder to find early in its course. The literature does not support that early detection would have changed his outcome, although society and many physicians do believe so, thus making the patient live with the false belief that if something had been done differently, he would have survived longer. Clearly, this patient lost the most in this story.

When the trial started on June 23, 2003, I was nervous but confident. I realized that the patient was going to say we had never discussed prostate cancer screening hut since I always do and had documented it, I didn't think this would be a very strong plaintiff argument. What I didn't anticipate was that the plaintiff's attorney was going to argue that I should have never discussed the risks and benefits and should have just ordered the PSA. But he did. In fact, a major part of his argument was that there is little risk involved in performing a PSA and that the standard of care is to order the test. Although we had the recommendations from every nationally recognized group supporting my approach and the literature is clear that screening for prostate cancer is controversial, the plaintiff's attorney argued otherwise.

In the medical world it is well accepted that screening for prostate cancer is a risky proposition, in which there is the potential for more harm than good. Nearly all of the national guidelines-including those of the American Academy of Family Physicians, the American Urological Association, and the American Cancer Society-recommend nearly identical approaches a physician should take when it comes to prostate cancer screening. This approach is discussing with the patient the risks and benefits, providing thorough informed consent, and coming to a shared decision. Family medicine has begun to stress the shared decision-making model because of the uncertainty in the literature with regard to such practices as hormone therapy, screening mammography, and many other medical procedures. The shared decision-making model and national guidelines are both losers in this story.

As the trial progressed we presented national experts who discussed the controversy surrounding prostate cancer screening and explained some of the potential dangers of PSA. We discussed such things as false positives, indolent vs aggressive cancers, sensitivity and specificity. Our experts explained that because of the questionable benefit vs associated risks of PSA screening, a shared decision by the physician and the patient was recommended by all of the national health associations. The science was clearly in our favor.

As a family physician I have reveled in keeping up-to-date and providing my patients with the best possible medicine. I have discussed with both patients and colleagues that simply ordering more tests because we have them is not always the best medicine. We have discussed false positives and their implications. The active practitioners who keep up-to-date and stay informed are the losers in this story. During that year before the trial, my patients became possible plaintiffs to me and I no longer discussed the risks and benefits of prostate cancer screening. I ordered more laboratory and radiological tests and simply referred more. My patients and I were the losers.

A major part of the plaintiff's case was that I did not practice the standard of care in the Commonwealth of Virginia. Four physicians testified that when they see male patients older than 50 years, they have no discussion with the patient about prostate cancer screening: they simply do the test. This was a very cogent argument, since in all likelihood more than 50% of physicians do practice this way. One may have argued that we were practicing above the standard of care, but there is no legal precedent for such an argument.

As is well documented in the literature, physicians take quite a long time to change their patients' protocols. Thus, we know that many practicing physicians are not using well-proven interventions or implementing well-publicized national guidelines. The legal definition of standard of care protects these physicians and encourages them to change slowly, if at all. It is often claimed that malpractice is a mechanism for holding physicians accountable and improving the quality of care. This case illustrates quite the opposite: punishing the translation of evidence into practice, impeding improvements to care, and ensconcing practices that hurt patients. In our legal system, the physicians who are slow to change are the winners.

During closing arguments the plaintiff's lawyer put evidence-based medicine on trial. He threw EBM around like a dirty word and named the residency and me as believers in EBM, and our experts as the founders of EBM. He defined EBM as a cost-saving method and stated his belief that the few lives saved were not worth the money. He urged the jury to return a verdict to teach residencies not to send any more residents on the street believing in EBM.

Before this case, I believed that following the current literature and evidence-based medicine was well accepted in medicine and throughout the country. Neither my lawyers nor the judge ever questioned if the plaintiff's attorney could argue against EBM or the national guidelines; the argument was clearly admissible. Sackett and colleagues have generally been given credit for reviving the idea of EBM, which is generally defined as the "conscientious, explicit, and judicious use of current best evidence in making clinical decisions about the care of individual patients."1 Evidence-based medicine was a loser.

On June 30, 7 days after the trial started, I was exonerated. My residency was found liable for \$1 million.

The plaintiff's lawyer was convincing. The jury sent a message to the residency that they didn't believe in evidence-based medicine. They also sent a message that they didn't believe in the national guidelines and they didn't trust the shared decision-making model. The plaintiff's lawyer won.

As I see it, the only way to practice medicine is to keep up with the best available evidence and bring it to my patients. As I see it, the only way to see patients is by using the shared decision-making model. As I see it, the only way to step into an examination room is to look at a patient as a whole person, not as a potential plaintiff. As I see it, I'm not sure I'll ever want to practice medicine again.

No one can walk backward into the future. -Joseph Hergesheimer (1880-1954)

#### [Sidebar]

A Piece of My Mind Section Editor: Roxanne K. Young, Associate Editor.

# [Reference]

REFERENCE

1. Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ. 1996;312:71-72.

# PERSPECTIVE

Dan Merenstein, MD
Department of Family
Medicine, Georgetown
University Medical
Center, Washington,
DC.

# PSA Screening—I Finally Won!

I must have won. That is what everyone tells me. At the beginning there were a few telephone calls, followed by e-mails, and now every talk I give someone brings up how happy I must feel for winning. What I purportedly won was the new recommendations against routine checking for prostate-specific antigen (PSA). The new recommendations acknowledge the limitations of PSA after years of heated debate. I had written an essay about our malpractice system and evidence-based medicine (EBM) after being sued, but the take-home point for many was that I did not order a PSA test after discussing the options with a patient. The new recommendations are consistent with how I practiced. I "won."

This all started in 1999, when I was barely 30 and a third-year resident in Family Practice. I understood data and followed evidence-based guidelines. So I discussed PSA testing with my patients before ordering it. One summer day I saw a well-educated 50-plus individual for a full physical and discussed the pluses and minuses of checking his PSA. He declined and I documented such. Unfortunately, the man was diagnosed as having advanced prostate cancer a few years later. He sued my residency and me and won the maximum amount. He "won" the court case because everyone knows the earlier you diagnose cancer the better. It just sounds like it must be true. Stakeholder groups consistently expound this, celebrities do commercials talking about the importance of early detection, and it appears many physicians believe in the holy grail of early detection. He also "won" his court case because the standard of care in Virginia was to check PSA on all men older than 50 years, even if that was not based on evidencebased guidelines. The plaintiff's lawyer won.

After publishing an article about this in JAMA, <sup>1</sup> I was inundated with support. People usually do not write about getting sued, especially when they lose. My essay hit a nerve as EBM was just beginning to take off and there was a lot of backlash. Many practicing physicians were worried that medicine would become computer driven and experience would cease to exist. Fifteen years later, we have trained physicians who understand and have matured with EBM, having practiced it their whole lives. Unfortunately, we still do not have a better test to diagnose the sixth leading cause of cancer death in men. Physicians practicing EBM have no better test to offer a man interested in screening for prostate cancer than I did 15 years ago. Practitioners have not won.

What we do have are new studies that have clearly shined the light on the limitations of PSA. Now nearly all organizations, including the American Urological Association (AUA) and American Cancer Association, have changed their recommendations. The AUA states, "For men age[d] 55 to 69 years the Panel recognizes that the decision to undergo PSA screening involves weighing the

benefits of preventing prostate cancer mortality in 1 man for every 1000 men screened over a decade against the known potential harms associated with screening and treatment. For this reason, the Panel strongly recommends shared decision-making for men age 55 to 69 years."<sup>2(p1)</sup> The AUA state that because we now know that if a positive PSA test leads a man to having a biopsy, there is a 1 in 50 chance that he will be spared death in the next 10 years; however, there is a 49 in 50 chance that he was treated unnecessarily for a cancer that would have no impact on his life. This is the new information we can give to patients. But how does one talk about this? How much time does one really think they would need to truly discuss this in the detail it requires? This information is not intuitive and requires a lot more information, give and take, and understanding of a patient's values. None of this is typical for most primary care visits. From what I witness, these discussions are the exception and most physicians are still ordering PSA tests without any patient input. I believe this is primarily the case because it is 2014 and physicians have nothing better to offer and not enough time to discuss what goes against the simplistic message that early detection is always best. Patients have not won.

Data and guidelines are still being attacked. No oncologists on committees. The equipment they used was old. We do it better in our center. You can't compare those doctors to ours. You don't care about men. Government death panels. For many years I have wondered what better test we may have had for prostate cancer if we had not spent so many years pretending PSA was a good test. I am not the only one. Richard Albin, generally credited with developing the PSA test, stated in the NY Times, "As I've been trying to make clear for many years now, P.S.A. testing can't detect prostate cancer and, more important, it can't distinguish between the two types of prostate cancer—the one that will kill you and the one that won't."3 I still see mass group screenings, advertisements aimed to get men tested, and counseling among health care professionals about the importance of getting the PSA test. As Michael Milken, the founder of the Milken Institute and the renamed George Washington School of public health, the Milken Institute School of Public Health, states, "The USPSTF [US Preventive Services Task Force] recommendation could produce a cruel form of rationing in which the well-off and well-informed would get PSA tests while many of the poor wouldn't. That could disproportionately affect African Americans, who have higher prostate cancer risk and death rates."4 The debate about PSA has never been about the data. The problem with the debate has always been this type of for-or-against approach, which such statements seek to promote; it is those who care about men vs those who are out to harm men. I did not win because I had nothing against

Corresponding Author: Dan Merenstein, MD, Director of Research Programs, Department of Family Medicine, Georgetown University Medical Center, 4000 Reservoir Rd NW, Building D 240, Washington, DC 20007 (Djm23@georgetown edu).

jamainternalmedicine.com JAMA Internal Medicine Published online November 3, 2014

testing for prostate cancer. As a primary care physician, as a father of 4 boys, and as a patient I strongly believe in prevention. I would love nothing more than a test that helps prevent prostate cancer. No one is seeking to increase death or marginalize certain groups. The goal of prevention is to improve care for all, and unfortunately the PSA test does not do that. Evidence-based medicine has not won.

Recently there have been some similar questions about the validity of mammography. It reminds me of the same debates we have had about PSA screening. First the USPSTF lowered the grade for women younger than 50 years and more recently a Canadian study questioned the efficacy for mammography for women younger than 59 years. <sup>5,6</sup> Discussing with a 40-year-old women the pluses and minuses of mammography is as difficult as

the PSA discussion because of the recent recommendations and data. The public debate, however, is the same; one is either for mammograms or against them. We still believe that early diagnosis of breast and prostate cancer is beneficial, but the evidence for PSA and mammography screening has *not* shown that to be true. Society is not winning.

The man with prostate cancer died.

Practitioners are not winning.

Patients are not winning.

Evidence-based medicine is not winning.

Society is not winning.

I appreciate the calls and the congratulations, but for some reason I do not feel like a winner.

**Published Online:** November 3, 2014. doi:10.1001/jamainternmed.2014.5441.

Conflict of Interest Disclosures: None reported.

- 1. Merenstein D. Winners and losers. *JAMA*. 2004; 291(1):15-16.
- 2. Carter HB, Albertsen PC, Barry MJ, et al. Early Detection of Prostate Cancer: AUA Guideline. 2013. http://www.auanet.org/education/guidelines/prostate-cancer-detection.cfm. Accessed September 23, 2014.
- 3. Albin R. The great prostate mistake. *New York Times*. March 9, 2010. http://www.nytimes.com/2010/03/10/opinion/10Ablin.html?\_r=0. Accessed September 23, 2014.
- 4. Milken M. Why block a cancer test that saves lives? Washington Post. 2011. http://www.washingtonpost.com/opinions/why-block-a-cancer-test-that-saves-lives/2011/10/10/gIQAzybedL\_story.html. Accessed September 23, 2014.
- **5**. Miller AB, Wall C, Baines CJ, Sun P, To T, Narod SA. Twenty five year follow-up for breast cancer incidence and mortality of the Canadian National Breast Screening Study: randomised screening trial. *BMJ*. 2014;348:g366.
- **6**. US Preventive Services Task Force. Screening for breast cancer. http://www .uspreventiveservicestaskforce.org/uspstf /uspsbrca.htm. Accessed September 23, 2014.

den of proof, to identify which of the two dogs involved in the attack actually bit her.

For the above stated reasons, we reverse the judgment of the trial court and remand the case for new trial, in which the issue of common law liability is to be submitted to the jury, along with the question of lack of provocation, damages, and ownership of the dogs. In so ruling, we hold that if the jury accepts Ms. Hood's identification of the dogs involved in the attack, as the defendants' dogs, such identification shall be sufficient to establish identification under the statute and under the common law, despite the fact that Ms. Hood is unable to identify which of the two dogs bit her.

REVERSED AND REMANDED WITH INSTRUCTIONS.

LAVENDER, C. J., IRWIN, V. C. J., and WILLIAMS, HODGES, SIMMS, HAR-GRAVE and OPALA, JJ., concur.

DOOLIN, J., dissents in part.



Norma Jo SCOTT and Dale M. Scott, Appellants,

v.

Vance A. BRADFORD, Appellee. No. 51208.

Supreme Court of Oklahoma.

Nov. 28, 1979.

Rehearing Denied Feb. 25, 1980.

In a malpractice action against a surgeon, a jury in the District Court, Oklahoma County, William S. Myers, Jr., J., returned a verdict in favor of the surgeon. The plaintiffs appealed. The Supreme Court, Doolin, J., held that: (1) a cause of action against a physician or surgeon, based on lack of informed consent, consists of a

duty to inform, causation and injury, and the element of causation requires that the patient would have chosen no treatment, or different course of treatment, as an alternative had material risks of each been made known to him; (2) the reasonable man standard is not applicable in determining whether the patient would have consented; and (3) the instant decision, imposing a new duty on physicians with respect to disclosure of risk of treatment, would be applied prospectively only, affecting those causes of action arising after date of promulgation of opinion.

# Affirmed.

Barnes, J., filed an opinion concurring in part and dissenting in part, in which Irwin, V. C. J., Simms, J., and Reynolds, Special Justice, joined.

## 1. Appeal and Error €=1067

In malpractice action against surgeon, absent evidence which would show willful abandonment by defendant after surgery, and in view of fact that abandonment as an indicia of negligence was covered by court's general instructions on negligence and proximate cause, there was no reversible error in refusing requested instructions on issue of abandonment. Supreme Court Rules, rule 15, 12 O.S.A. c. 15 Appendix 1.

# 2. Physicians and Surgeons = 15(8)

Law does not permit physician to substitute his judgment for that of patient by any form of artifice.

# 3. Physicians and Surgeons ← 15(8)

The "informed consent" requirement imposes duty on physician or surgeon to inform patient of his options and their attendant risks, and if physician breaches this duty, patient's consent is defective and physician is responsible for consequences.

# 4. Assault and Battery ←2 Physicians and Surgeons ←15(8)

If medical or surgical treatment is completely unauthorized and performed without any consent at all, there has been battery, but if physician obtains patient's conYon, Yon & Brooks, Oklahoma City, for appellants.

George F. Short, Robert C. Margo, Oklahoma City, for appellee.

#### **DOOLIN**, Justice:

This appeal is taken by plaintiffs in trial below, from a judgment in favor of defendant rendered on a jury verdict in a medical malpractice action.

Mrs. Scott's physician advised her she had several fibroid tumors on her uterus. He referred her to defendant surgeon. Defendant admitted her to the hospital where she signed a routine consent form prior to defendant's performing a hysterectomy. After surgery, Mrs. Scott experienced problems with incontinence. She visited another physician who discovered she had a vesico-vaginal fistula which permitted urine to leak from her bladder into the vagina. This physician referred her to an urologist who, after three surgeries, succeeded in correcting her problems.

Mrs. Scott, joined by her husband, filed the present action alleging medical malpractice, claiming defendant failed to advise her of the risks involved or of available alternatives to surgery. She further maintained had she been properly informed she would have refused the surgery.

The case was submitted to the jury with instructions to which plaintiffs objected. The jury found for defendant and plaintiffs appeal.

[1] In plaintiffs' amended appeal brief it is suggested that the trial court erred in failing to instruct the jury on the issue of defendant's abandonment of plaintiff post surgery. Although plaintiffs did offer two requested instructions on this issue, not given, they did not set them out in their brief as required by the rules of this Court, 12 O.S. 1971, Ch. 15, App. 1, Rule 15. Neither do plaintiffs offer any authority to suggest a cause of action based solely on abandonment exists. In reviewing the evidence we do not find any willful abandonment such

as would warrant a separate instruction. Abandonment, an indicia of negligence, is covered by court's general instructions on negligence and proximate cause. We find no reversible error in this area.

Plaintiffs complain of three instructions and submit the following instruction should have been given:

"The law requires physician to disclose to his patient the material risks of a proposed treatment, the material risks of foregoing any treatment, the existence of any alternatives and the material risks of choosing these alternatives. The failure to disclose these things is negligence.

"A risk is 'material' when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy.

"If you find from the evidence in this case that the defendant failed to make disclosures to the plaintiff, NORMA JO SCOTT, as required by law, then your verdict would be for the plaintiffs, for the amount of their damages proximately caused thereby."

This instruction refers to the doctrine of "informed consent".

The issue involved is whether Oklahoma adheres to the doctrine of informed consent as the basis of an action for medical malpractice, and if so did the present instructions adequately advise the jury of defendant's duty.

- [2] Anglo-American law starts with the premise of thoroughgoing self-determination, each man considered to be his own master. This law does not permit a physician to substitute his judgment for that of the patient by any form of artifice. The doctrine of informed consent arises out of this premise.
- [3] Consent to medical treatment, to be effective, should stem from an under-

(1960). Also see Rolater v. Strain, 390 Okl. 572, 137 P. 96 (1913).

See Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093, reh. den. 187 Kan. 186, 354 P.2d 670

standing decision based on adequate information about the treatment, the available alternatives, and the collateral risks. This requirement, labeled "informed consent," is, legally speaking, as essential as a physician's care and skill in the performance of the therapy. The doctrine imposes a duty on a physician or surgeon to inform a patient of his options and their attendant risks. If a physician breaches this duty, patient's consent is defective, and physician is responsible for the consequences.<sup>2</sup>

[4] If treatment is completely unauthorized and performed without any consent at all, there has been a battery.<sup>3</sup> However, if the physician obtains a patient's consent but has breached his duty to inform, the patient has a cause of action sounding in negligence for failure to inform the patient of his options, regardless of the due care exercised at treatment, assuming there is injury.<sup>4</sup>

Until today, Oklahoma has not officially adopted this doctrine. In Martin v. Stratton, 515 P.2d 1366 (Okl.1973), this Court discussed a physician's duty in this area but reversed the trial court on other grounds. It impliedly approved the doctrine and stated its basic principles but left its adoption until a later time.

The first buds of court decisions heralding this new medical duty are found in Salgo v. Leland Stanford, Jr., University Board of Trustees, 154 Cal.App.2d 560, 317 P.2d 170 (1957). That court grounded the disclosure requirement in negligence law holding a physician violates a duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment. The court strongly suggested a physician is obligated not only to disclose what he in-

- 2. Martin v. Stratton, 515 P.2d 1366 (Okl.1973).
- See Rolater v. Strain, supra, n. 1; Wilkinson v. Vesey, 110 R.I. 606, 295 A.2d 676 (1972).
- 4. Wilkinson v. Vesey, supra, n. 3.
- See Katz, Informed Consent—A Fairy Tale? 39 U.Pitt.L.Rev. 137, 143 (1977).

tends to do, but to supply information which addresses the question of whether he should do it. This view was a marked divergence from the general rule of "professional standard of care" in determining what must be disclosed. Under that standard, earlier decisions seemed to perpetuate medical paternalism by giving the profession sweeping authority to decide unilaterally what is in the patient's best interests. Under the "professional standard of care" a physician needed only to inform a patient in conformance with the prevailing medical practice in the community.

More recently, in perhaps one of the most influential informed consent decisions, Canterbury v. Spence. 150 U.S.App.D.C. 263. 464 F.2d 772 (D.C.Cir.1972), cert. den. 409 U.S. 1064, 93 S.Ct. 560, 34 L.Ed.2d 518, the doctrine received perdurable impetus. Judge Robinson observed that suits charging failure by a physician adequately to disclose risks and alternatives of proposed treatment were not innovative in American law. He emphasized the fundamental concept in American jurisprudence that every human being of adult years and sound mind has a right to determine what shall be done with his own body. True consent to what happens to one's self is the informed exercise of a choice. This entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. It is the prerogative of every patient to chart his own course and determine which direction he will take.

- [5,6] The decision in Canterbury recognized the tendency of some jurisdictions to turn this duty on whether it is the custom of physicians practicing in the community to make the particular disclosure to the patient. That court rejected this standard and held the standard measuring performance of the duty of disclosure is conduct
- See list of jurisdictions still maintaining this standard of care as of 1976, found in an excellent discussion of the problem, Seidelson, Medical Malpractice; Informed consent cases in "Full-Disclosure" Jurisdictions, 14 Duq.L.Rev. 309 (1976).

which is reasonable under the circumstances: "[We can not] ignore the fact that to bind disclosure obligations to medical usage is to arrogate the decision on revelation to the physician alone." We agree. A patient's right to make up his mind whether to undergo treatment should not be delegated to the local medical group. What is reasonable disclosure in one instance may not be reasonable in another.7 We decline to adopt a standard based on the professional standard. We, therefore, hold the scope of a physician's communications must be measured by his patient's need to know enough to enable him to make an intelligent choice. In other words, full disclosure of all material risks incident to treatment must be made. There is no bright line separating the material from the immaterial; it is a question of fact. A risk is material if it would be likely to affect patient's decision. When non-disclosure of a particular risk is open to debate, the issue is for the finder of facts.8

[7,8] This duty to disclose is the first element of the cause of action in negligence based on lack of informed consent. However, there are exceptions creating a privilege of a physician not to disclose. There is no need to disclose risks that either ought to be known by everyone or are already known to the patient.9 Further, the primary duty of a physician is to do what is best for his patient and where full disclosure would be detrimental to a patient's total care and best interests a physician may withhold such disclosure,10 for example, where disclosure would alarm an emotionally upset or apprehensive patient. Certainly too, where there is an emergency and the patient is in no condition to determine for himself whether treatment should be administered, the privilege may be invoked.11

- 7. Wilkinson v. Vesey, supra, n. 3.
- Woods v. Brumlop, 71 N.M. 221, 377 P.2d 520 (1962); Canterbury v. Spence, 150 U.S.App. D.C. 263, 464 F.2d 772 (D.C.Cir.1972); Natanson v. Kline, 187 Kan. 186, 354 P.2d 670 (1960).
- Yeates v. Harms, 193 Kan. 320, 393 P.2d 982 (1964).

- [9] The patient has the burden of going forward with evidence tending to establish prima facie the essential elements of the cause of action. The burden of proving an exception to his duty and thus a privilege not to disclose, rests upon the physician as an affirmative defense.
- [10] The cause of action, based on lack of informed consent, is divided into three elements: the duty to inform being the first, the second is causation, and the third is injury. The second element, that of causation, requires that plaintiff patient would have chosen no treatment or a different course of treatment had the alternatives and material risks of each been made known to him. If the patient would have elected to proceed with treatment had he been duly informed of its risks, then the element of causation is missing. In other words, a causal connection exists between physician's breach of the duty to disclose and patient's injury when and only when disclosure of material risks incidental to treatment would have resulted in a decision against it.12 A patient obviously has no complaint if he would have submitted to the treatment if the physician had complied with his duty and informed him of the risks. This fact decision raises the difficult question of the correct standard on which to instruct the jury.

[11] The court in Canterbury v. Spence, supra, although emphasizing principles of self-determination permits liability only if non-disclosure would have affected the decision of a fictitious "reasonable patient," even though actual patient testifies he would have elected to forego therapy had he been fully informed.

Decisions discussing informed consent have emphasized the disclosure element but

- 10. Nishi v. Hartwell, 52 Haw. 188, 473 P.2d 116 (1970).
- 11. Woods v. Brumlop, supra, n. 8.
- Martin v. Stratton, supra, n. 2; also see Holt
   Nelson, 11 Wash.App. 230, 523 P.2d 211 (1974).

Cite as, Okl., 606 P.2d 554

paid scant attention to the consent element of the concept, although this is the root of causation. Language in some decisions suggest the standard to be applied is a subjective one, i. e., whether that particular patient would still have consented to the treatment, reasonable choice or otherwise. See Woods v. Brumlop, supra, n. 8; Wilkinson v. Vesey, supra, n. 3; Gray v. Grunnogle, 423 Pa. 144, 223 A.2d 663 (1966); Poulin v. Zartman, 542 P.2d 251 (Alaska 1975), reh. den. 548 P.2d 1299 (Alaska 1976).

Although the Canterbury rule is probably that of the majority,13 its "reasonable man" approach has been criticized by some commentators 14 as backtracking on its own theory of self-determination. The Canterbury view certainly severely limits the protection granted an injured patient. To the extent the plaintiff, given an adequate disclosure. would have declined the proposed treatment, and a reasonable person in similar circumstances would have consented, a patient's right of self-determination is irrevocably lost. This basic right to know and decide is the reason for the full-disclosure rule. Accordingly, we decline to jeopardize this right by the imposition of the "reasonable man" standard.

If a plaintiff testifies he would have continued with the proposed treatment had he been adequately informed, the trial is over under either the subjective or objective approach. If he testifies he would not, then the causation problem must be resolved by examining the credibility of plaintiff's testimony. The jury must be instructed that it must find plaintiff would have refused the treatment if he is to prevail.

Although it might be said this approach places a physician at the mercy of a patient's hindsight, a careful practitioner can

always protect himself by insuring that he has adequately informed each patient he treats. If he does not breach this duty, a causation problem will not arise.

The final element of this cause of action is that of injury. The risk must actually materialize and plaintiff must have been injured as a result of submitting to the treatment. Absent occurrence of the undisclosed risk, a physician's failure to reveal its possibility is not actionable. 15

In summary, in a medical malpractice action a patient suing under the theory of informed consent must allege and prove:

- defendant physician failed to inform him adequately of a material risk before securing his consent to the proposed treatment;
- if he had been informed of the risks he would not have consented to the treatment;
- the adverse consequences that were not made known did in fact occur and he was injured as a result of submitting to the treatment.

As a defense, a physician may plead and prove plaintiff knew of the risks, full disclosure would be detrimental to patient's best interests or that an emergency existed requiring prompt treatment and patient was in no condition to decide for himself.<sup>16</sup>

[12] Because we are imposing a new duty on physicians, we hereby make this opinion prospective only, affecting those causes of action arising after the date this opinion is promulgated.<sup>17</sup>

The trial court in the case at bar gave rather broad instructions upon the duty of a physician to disclose. The instructions objected to did instruct that defendant should

- Downer v. Veilleux, 322 A.2d 82 (Me.1974);
   Hales v. Pittman, 576 P.2d 493 (Ariz.1978).
- 16. We do not hold these to be the sole defenses, as others may be presented in the future.
- 17. See First National Bank of Porter v. Howard, 550 P.2d 561 (Okl.1976).

See Archer v. Galbraith, 18 Wash.App. 369, 567 P.2d 1155 (1977); Funke v. Fieldman, 212 Kan. 524, 512 P.2d 539 (1973); Cobbs v. Grant, 8 Cal.3d 229, 104 Cal.Rptr. 505, 502 P.2d 1 (1972).

Seidelson, Medical Malpractice: Informed Consent Cases in "Full-Disclosure" Jurisdictions, 14 Duq.L.Rev. 309 (1976); Katz, Informed Consent—A Fairy Tale? Laws Vision, 39 U.Pitt.L.Rev. 137 (1977).

have disclosed material risks of the hysterectomy and feasibility of alternatives. Instructions are sufficient when considered as a whole they present the law applicable to the issues.<sup>18</sup> Jury found for defendant. We find no basis for reversal.

AFFIRMED.

LAVENDER, C. J., and HODGES, HAR-GRAVE and OPALA, JJ., concur.

BARNES, Justice, concurring in part, dissenting in part:

I concur with the majority opinion in all respects except I would adopt the reasonable man test set out in Canterbury v. Spence, 150 U.S.App.D.C. 263, 464 F.2d 772 (D.C.Cir.1972), cert. den. 409 U.S. 1064, 93 S.Ct. 560, 34 L.Ed.2d 518.

I am authorized to state that IRWIN, V. C. J., SIMMS, J., and REYNOLDS, Special Justice, join in the views expressed in this opinion.



Willis J. HOYT, Appellee,

v.

CONTINENTAL OIL COMPANY, King Resources Company and Aladdin Petroleum Corporation, Appellants.

No. 53860.

Supreme Court of Oklahoma.

Jan. 8, 1980.

Rehearings Denied March 3, 1980.

Action was brought praying for cancellation of oil and gas lease as well as damages for failure to release, preventing plaintiff's releasing the premises and receiving a bonus therefor in addition to acquiring a

commercial oil and gas well. The District Court for Dewey County, Joe Young, J., granted plaintiff's motion for partial summary judgment on cancellation issue and petition for certiorari to review the interlocutory order was granted. The Supreme Court, Hargrave, J., held that: (1) period following filing of petition did not constitute nonproductive time; (2) since primary term had expired and cessation of production clause modified habendum clause and their was no production in paying quantities, there had been a cessation of production for purpose of 60-day savings provision of cessation clause; and (3) shut-in gas well doctrine had no application where there has not been completion of a gas well capable of production in paying quantities.

Affirmed and remanded for further proceedings.

Opala, J., dissented.

## 1. Mines and Minerals \$\infty 78.1(1)

Two-month period following filing of petition praying for cancellation of oil and gas lease for failure to obtain production in paying quantities did not constitute nonproductive time since filing of proceedings put defendants' title at issue and relieved him of production covenants until determination was made that title to the lease indeed rested with him.

# 2. Mines and Minerals € 78.1(8)

"Production" means production in paying quantities in Oklahoma when the term appears in the habendum clause of an oil and gas lease.

See publication Words and Phrases for other judicial constructions and definitions.

# 3. Mines and Minerals ← 78.1(9)

Where cessation of production clause of oil and gas lease stated, "If, after the expiration of the primary term \* \* \* production \* \* \* shall cease from any cause," effect thereof was that after the primary term the production clause modified the habendum clause, which specified

18. Fields v. Volkswagen, 555 P.2d 48 (Okl. 1976).