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Stay Informed About Informed Consent

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On May 24, 2011, a 53-year-old woman presented to a Wisconsin hospital emergency department (ED) with complaints of severe abdominal pain, a rapid heartbeat, and a fever of 101.3°F. During her 9-hour visit, she was treated by a PA and his supervising physician. She was seen by the physician for a total of 6 minutes; the rest of her care was provided by the PA. The patient was discharged around midnight with instructions to contact her gynecologist in the morning for management of uterine fibroids. At the time of discharge, her temperature was 102.9°F.

The following day, May 25, the patient collapsed in her home and was transported to another hospital. She was treated for septic shock from a group A streptococcus infection. Although the infection was halted, the patient sustained ischemic damage to her extremities and a month later required amputation of her 4 limbs.

The plaintiff claimed that the supervising physician was negligent in failing to diagnose the strep A infection, which, left undetected, led to septic shock. She also alleged that the PA should have recognized the potential for her condition's severity to quickly escalate. She maintained that the supervising physician should have been more involved in her case because of its complexity.

Plaintiff's counsel also argued that the PA should have provided "alternative medical diagnoses," which would have prompted consideration of other treatment options. The plaintiff contended that under Wisconsin's informed consent law, both the PA and the physician failed to disclose enough information about her condition and failed to inform her of any choices for treatment.

The defense argued that the plaintiff received proper treatment based on the information available to the providers at the time.

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VERDICT

The jury found for the plaintiff and apportioned 65% liability to the physician and 35% liability to the PA. A total of $25,342,096 was awarded to the plaintiff.

COMMENTARY

This is a huge verdict. Cases involving group A strep or necrotizing fasciitis frequently give rise to large medical malpractice verdicts, because everything about them is difficult to defend: Although there is typically trivial to no trauma involved, the wounds from these infections provide explicit images of damage, intraoperatively and postoperatively. Vasopressors required for hemodynamic support or sepsis itself frequently result in limb ischemia, gangrene, and amputation. In this case, the plaintiff, as a quadruple amputee, was a sympathetic and impressive courtroom presence—the personal toll was evident to anyone in the room.

Two providers—a PA and a physician—saw the patient. We are told only that she complained of severe abdominal pain, rapid heartbeat, and fever, which increased at some point during her ED stay. We aren't given specifics on the rest of the patient's vital signs or examination details. However, we can infer that the exam and lab findings were not impressive, because they weren't mentioned in the case report. But as a result of the failure to catch the group A strep infection, the plaintiff suffered what one judge hearing the case described as a harrowing and unimaginable ordeal: the life-changing amputation of 4 limbs.[1] While the jury did not find the PA or physician negligent, they still found the clinicians liable and awarded a staggering verdict.

How could this happen? The answer is the theory of recovery: The jury found that the physician and the PA failed to provide the patient with informed consent in the form of "alternative medical diagnoses."[2] The plaintiff's attorney argued that the patient was never told a life-threatening bacterial infection was one possible diagnosis and claimed that if she had known, the patient would have pursued other treatment.

As in many malpractice cases, the plaintiff alleged failure to diagnose and failure to provide informed consent. Depending on state law, there are 3 standards for informed consent: *subjective patient*, *reasonable patient,* and *reasonable physician*.[3] About half of the states have a physician-focused standard, while the other half have a patient-focused standard.[3]

Under the subjective patient standard, we would ask, "What would this patient need to know and understand to make an informed decision?"[4] The subjective standard requires the clinician to essentially "get in the head" of a specific patient to determine what he or she would want to know when making a medical decision. This standard is problematic because it requires the clinician to have an intimate familiarity with the patient's belief system and medical decision-making process—a daunting requirement for many clinicians, particularly in the absence of a longstanding clinician-patient relationship, as is the case in most emergency settings. Thankfully, the subjective patient standard is not followed by most states that have a patient-focused standard.

Under the objective reasonable patient standard, we would ask "What would the average patient need to know to be an informed participant in the decision?"[4] One could argue that this standard more adequately allows the patient to be an active participant in shared decision-making. However, the drawback is that what is "reasonable" often falls on a spectrum, which would require the clinician to gauge the volume and type of information a patient cohort would want to have when making a medical decision. Under this standard, the plaintiff must prove that the clinician omitted information that a reasonable patient would want to know. Therefore, these standards are more friendly to the plaintiff, whereas the reasonable physician standard is more defendant friendly.

To meet the standard of care under a reasonable physician standard, information must be provided to the patient that a "reasonably prudent practitioner in the same field of practice or specialty" would provide to a patient.[5] For a plaintiff to successfully sue under this standard, the plaintiff's expert must testify that a reasonably prudent physician would have disclosed the omitted information.[6] The reasonable physician standard is obviously better for malpractice defendants.

While reasonable clinicians can disagree (as can reasonable patients), clinicians are more likely to be closer in opinion. Clinicians are a smaller group whose opinions are underpinned by similar education, training, and experience. By contrast, among the general population, beliefs held by one hypothetical "reasonable person" are much less settled, and in some cases, wildly divergent from another's. For example, vaccine skepticism would probably be considered unreasonable in the majority of jury pools but absolutely reasonable in some. The large size of the general population, coupled with opinions untethered to any definable discipline, make the reasonable patient standard hard to predict.

Additionally, the reasonable physician standard forces the plaintiff to prove his or her case by producing an expert witness (clinician) to specifically testify that the standard of care required the defendant clinician to disclose certain specific information, and that disclosure was lacking. That is an important requirement. Under patient-focused standards, the plaintiff doesn't need a medical expert on this point and can simply argue to the jury that a reasonable patient would require an exhaustive discussion of each possibility in the differential diagnosis. Therefore, I would argue that the reasonable physician standard is more predictable and workable and should be followed.

At the time of this case, Wisconsin's informed consent law was based on the reasonable patient standard. As a result of this case, Wisconsin lawmakers changed the law to a "reasonable physician standard," which states "any physician who treats a patient shall inform the patient about the availability of reasonable alternate medical modes of treatment and about the benefits and risks of these treatments."[7] However, the law stipulates that this duty to inform does *not* require disclosure of (among others):

- Detailed technical information that in all probability a patient would not understand
- Risks apparent or known to the patient
- Extremely remote possibilities that might falsely or detrimentally alarm the patient
- Information about alternate medical modes of treatment for any condition the physician has not included in his or her diagnosis at the time the physician informs the patient.[7]

Finally, this case involved an extremely high verdict of more than $25 million. It may surprise you to learn that many states have caps for medical malpractice awards for noneconomic damages, such as pain and suffering. If you're having a holiday dinner

with friends or family members who are plaintiff's attorneys and you're itching for a good argument, skip current politics and go all-in: *How about liability caps, Uncle Jim?* Get ready for a lively debate.

Of the $25 million verdict, $16.5 million was awarded for pain and suffering—the jury was obviously shocked by the extent of the life-changing nature of the plaintiff's injuries. At the time of this case, Wisconsin had a cap of $750,000 for noneconomic damages.[8] However, plaintiffs may challenge state constitutionality of these caps when they feel they have the right case, which the plaintiff and her attorney felt they did. Two lower courts found the state cap unconstitutional and gave the plaintiff the full award. But the state Supreme Court later reversed that decision, upholding the cap.[1] The court decided that the legislature had a rational basis for making the law and changes to it should occur through the legislature, not the courts. The dissenting justices argued that there was no rational basis for the $750,000 cap, because there was no evidence that clinicians would flee the state fearing malpractice liability, or practice more defensive medicine, or suffer runaway malpractice insurance premiums without the cap. As a result of this case, the cap was upheld, and there was a "lively debate" on this issue at the highest levels of government.

IN SUM

Become familiar with your state's informed consent laws. Involve patients in decision-making, and convey information related to reasonable treatment options and risks. Document all of these discussions. Lastly, state-level political discussions on issues of tort reform, caps, and malpractice matters are ongoing—so take notice. **CR**

REFERENCES

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