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Medicolegal Sidebar: (Mis)Informed Consent in Medical Negligence Lawsuits

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Introduction

In civil litigation, such as medical malpractice trials, evidence is admitted or excluded by a court, depending, in part, on its probative value. Probative value refers to the ability of a piece of evidence to make a relevant, disputed point in litigation either more or less true.

In recent years, several jurisdictions have grappled with the probative value

of informed consent, and patient-physician discussions related to it. Briefly, under the legal doctrine of informed consent, a doctor must provide enough information to help the patient make rational healthcare choices [1]. In trial practice, medical malpractice defense attorneys almost always introduce the informed consent into evidence. Thus, jurors are introduced to informed consent documents that usually list all the possible complications and risks of a procedure, and a patient signature attesting to an understanding and acceptance of those risks. Should informed consent documents be routinely admissible in medical malpractice trials, where the underlying issues are unrelated to

informed consent? The concern, of course, is that a signed document might confuse or prejudice jurors into a belief that the plaintiff was more aware of the potential risks of the intervention than might have been the case. Such juror confusion would be prejudicial against the plaintiff, whose consent would only reflect a genuine understanding of the risks of the procedure only if the consent process was fully and thoughtfully performed. And in any case, such consent—even fully and thoughtfully performed—does not acknowledge the acceptance of risk of negligent treatment. Some recent judicial rulings have confronted this issue, and these rulings are instructive to clinicians.

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Illustrative Legal Case

In the 2012 ruling for *Brady v Urbas* [2], the Pennsylvania Supreme Court ruled that evidence of informed consent by patients should be excluded from medical malpractice lawsuits against doctors. In *Brady*, the plaintiff had hammertoes, and underwent several corrective operations by a podiatrist, including resection arthroplasty of the

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affected toe joints. The patient was left with disfigured, shortened toes and continuing pain. She consulted a second podiatrist who performed an interpositional bone graft procedure, thereby restoring proper toe length. Following this intervention, the patient had a successful result, obtaining pain relief, and a return to activity. She sued the first podiatrist alleging that he was negligent in performing the operations, and in giving her false assurances about the success of surgery.

During pretrial court hearings, the plaintiff sought to exclude the surgical consent forms that she had signed before each procedure by the first podiatrist. She argued that these consent forms were irrelevant to whether or not the podiatrist had complied with the standard of care. The defendant podiatrist countered that the risks and complications of surgery, and discussions with the patient were relevant to the plaintiff's credibility and to her state of mind in forming the decision to proceed with the operations. The trial court agreed with the defendant, and permitted admission of the consent-related evidence. Accordingly, during trial, the jury was presented with the informed consent documents, and ultimately returned a verdict in favor of the podiatrist.

The plaintiff's attorneys appealed, and the matter ultimately reached the Pennsylvania Supreme Court, which reversed the trial court's ruling.

Specifically, the court noted that "no assumption-of-the-risk defense is available to a defendant physician which would vitiate his duty to provide treatment according to the ordinary standard of care. The patient's actual, affirmative consent, therefore, is irrelevant to the question of negligence" [2].

In overturning the trial court verdict, the appellate court in *Brady* cited a 2004 Virginia ruling, *Wright versus Kaye* [3]. In this medical malpractice trial, the patient had undergone pelvic laparoscopic surgery to diagnose the source of chronic pelvic pain. Complications in that case led to bladder dysfunction from retained staples placed in bladder tissue. In ruling on the relevance of informed consent documents in the *Wright* litigation, the Supreme Court of Virginia said "... the admission of evidence concerning a plaintiff's consent could only serve to confuse the jury because the jury could conclude that consent to the surgery was tantamount to consent to the injury which resulted from that surgery. In effect, the jury could conclude that consent amounted to waiver, which is plainly wrong" [3].

Analysis of Ruling

Brady and *Wright* reflect emerging trends in medical negligence law in the

United States, and we expect additional state jurisdictions to adopt the reasoning that a surgeon cannot compel a patient to accept as a risk that the patient will be injured by a negligent act. Courts are questioning whether or not informed consent forms are probative in a case where the plaintiff only raises the issue of medical negligence, but does not assert that the patient was inadequately informed.

Excluding informed consent as a defense to medical malpractice allegations may be discouraging to physicians and surgeons who have been taught these documents are an important legal tool. Physicians invest considerable time and effort in patient communication about the risks of an operation. Even so, in our view, the *Brady* and *Wright* courts articulated an enlightened and accurate view of informed consent documentation in medical malpractice litigation. Furthermore, if properly applied to the clinical setting, the judicial reasoning in these rulings can help improve the informed consent process, and clinical practice.

First, the courts are correct in ruling that informed consent is not a blanket defense against the occurrence of complication that is listed on the consent form. Consider the following example: If a total knee replacement results in a peroneal nerve palsy, and all work-up at identifying a cause for

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the nerve injury proves negative, and late surgical exploration of the peroneal nerve during a separate operation identifies an intact, normal-appearing nerve in its expected anatomic location, then reliance on the informed consent to prove that the patient was aware of this particular risk of surgery is appropriate. If on the other hand, under identical circumstances, exploration of the nerve showed a laceration of the peroneal nerve, the informed consent should not be used to imply that the patient consented to the risk of cutting the peroneal nerve during knee replacement. The danger of introducing informed consent into the second scenario is that a jury may wrongly infer that the patient agreed to a risk of peroneal nerve injury, regardless of what caused the injury.

Second, the judicial reasoning in the *Brady* and *Wright* cases is important in liberating clinicians from the misconception that informed consent is a legal compliance issue, rather than an opportunity to build physician-patient trust and understanding. Instead of viewing informed consent as a legal exercise—or worse, a piece of paper rather than a thoughtful process that takes place in the office—crafted by institutional counsel and committees to protect the system, physicians should focus on the true value of informed consent as an

educational resource. Conveying uncertainty is one of the most-difficult tasks in practicing medicine, and informed consent is one tool by which a physician not only conveys uncertainty, but also reassures the patient that no matter what the outcome, the physician will be there for the patient. Trust and communication are likely to be more effective in insulating a physician against medical negligence claims, than complex legal documents with expected complication jargon designed to confuse jurors.

Beyond Informed Consent

Today, cases such as *Brady* and *Wright* are being litigated in other US jurisdictions, and in the future, it is likely that most, if not all such jurisdictions will exclude routine admission of the informed consent and the familiar “known risks and benefits of surgery” component of the presurgical discussion, from medical malpractice trials. Going forward, it is of interest to ask if courts will view other evidentiary matters related to medical malpractice litigation in light of the probative value of such evidence.

For example, in addition to the informed consent and listed complications, medical malpractice defense attorneys also routinely introduce complication rates of surgery, to

persuade juries that such complications occur at finite rates, and are simply unavoidable. Left unanswered is the question that raw complication rate data do not differentiate unavoidable complications versus those caused by medical negligence. In the absence of scientific evidence, it is impossible to determine if a 2%–3% incidence of dural tears during spinal surgery, for example, truly reflects an unavoidable phenomenon, or if some dural tears are the result of medical negligence. Thus, the introduction of complication rate data may not be probative on the issue of whether or not the surgery was performed negligently. Also, complication data may be prejudicial against a surgeon whose individual complication rates may be higher, simply because he/she is treating sicker patients at a tertiary care facility. Surgeon awareness of the foreseeable and material risks of a procedure can help differentiate negligent from non-negligent complications. From a practical standpoint, this awareness is best documented in the operative record, along with appropriate steps taken to reduce risk.

Courts have yet to address the probative value of raw complication rate from surgical procedures in medical-negligence litigation. However, as the *Brady* and *Wright* rulings aptly demonstrate, the legal system is scrutinizing evidence that in the past was

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routinely introduced by defense counsel, to see whether or not its probative value outweighs the risk of juror confusion and prejudice against the injured patient.

References

1. Bal BS, Brenner LH. Medicolegal sidebar: Informed consent in the information age. *Clin Orthop Relat Res.* 2015;473:2757–2761.
2. *Brady v Urbas*, 80 A.3d 480; Pa. Super. Ct. 2013.
3. *Wright v Kaye*, 267 Va. 510, 593 S.E.2d 307, 2004.