Honoring Your Patient’s Right to Informed Decision Making Protects You Against Claims

National data indicates that more than one-third of all malpractice claims and lawsuits allege a failure to obtain informed consent. Actions based solely on issues of informed consent are rare; commonly, informed-consent claims are coupled with allegations of negligence. As an entirely distinct legal theory, failure to obtain informed consent can result in physician liability regardless of whether the standard of care is met.

Case history
A 26-year-old female athlete was hospitalized for a severe staph infection involving her left foot. Her attending physician ordered IV administration of gentamicin (a potent antibiotic), 5 mg/kg every eight hours, with close monitoring of serum levels to avoid toxicity. The physician was aware that the drug had potential serious adverse effects, including nephrotoxicity, otoxicity, and vestibular toxicity—the latter of which can result in ataxia (unsteady gait) and oscillopsia (“bouncing” vision).

On the eleventh day of hospitalization, the patient had improved markedly. Discharge within 24-48 hours was anticipated. However, later that evening, the patient experienced difficulty walking, reporting a sense of “feeling uncoordinated.” A nursing assistant had to assist her back to her bed. The physician was notified.

The following morning, the patient had similar difficulties attempting to walk. Her physician immediately suspected gentamicin-related toxicity, though serum levels had remained within, or very close to, the desired therapeutic range. The physician immediately ordered a change of antibiotic, discontinuing gentamicin.

The patient’s problems with muscle coordination persisted. It was later determined that gentamicin toxicity had resulted in irreversible damage to the vestibular labyrinth. When discharged from the hospital, the patient required a cane to steady her gait. There were no signs of infection, nor any indication of permanent damage to the structures of the foot.

Case evaluation
One year after discharge, the patient named the physician in a lawsuit. On issues of standard of care, the suit alleged that gentamicin dosages were excessive and blood monitoring inadequate. The defense conceded that gentamicin had caused the harm to the plaintiff but vigorously contested the notion that negligence had been involved. Despite the patient outcome, plaintiff experts floundered in their efforts to provide convincing evidence that the defendant had deviated from acceptable standards of practice. The plaintiff’s second legal theory was that the defendant had failed to obtain informed consent. She testified that her physician had told her nothing of the risks of gentamicin therapy, nor had he mentioned any alternatives. She recalled that he had told her that gentamicin was a “heavy-duty” antibiotic, necessary because of the severity and type of the infection. However, “heavy-duty” did not suggest to her that the drug carried any special risks. The plaintiff said she trusted her doctor, and it had never occurred to her to ask questions about the antibiotic. She merely asked the defendant if her foot would be OK and how long she would have to stay in the hospital. Her physician offered general reassurance, which she appreciated at the time, but no specific information. She said he seemed “very caring.” She had felt that if there were something she needed to know, her doctor or the nurses would
have told her. The plaintiff testified that she “devoutly” wished the defendant had told her that there were “less risky” antibiotics that might have worked. She said she would have told her doctor to try something other than gentamicin.

Plaintiff experts agreed, under cross-examination, that gentamicin was not contraindicated or inappropriate—“it worked”—but were firm on the point that it was not the sole antibiotic suitable to combat this infection. “There are other weapons in the arsenal,” they said, and the patient should have been told. These same experts told the jury that, in their opinion, the defendant had a “clear duty” to tell the patient “up front” about the “considerable risks” of kidney damage, hearing loss, and ataxia. If the defendant had done this, a “decent discussion” about alternatives might have followed.

Medical experts on both sides provided testimony concerning the statistical probability of the harm that had befallen the patient and information about the likely severity of such injuries.

The defendant physician recalled mentioning to the patient that he had selected gentamicin because it was a potent antibiotic with a proven record against staph infections. He was uncertain if he had mentioned possible side effects, but “might well have.” He was forced to admit there was nothing in the medical records that indicated the patient was told anything specific about gentamicin. When the questioning turned to therapeutic alternatives, the physician acknowledged that he “probably didn’t go into that …” He would have had a discussion with the patient about other antibiotics had it appeared that gentamicin was proving ineffective, but that was not the case.

After weeks of testimony and lengthy deliberation, the jury returned its verdict: The defendant had not violated the standard of care, but the defendant had failed to obtain the plaintiff’s informed consent. The jury found that:

- Information concerning risks of gentamicin and treatment alternatives was “material” and should have been disclosed.
- If the required disclosure had taken place, a reasonable patient would have, more probably than not, elected one of the options.
- Had one of the testified-to alternative antibiotics been chosen, the plaintiff would have avoided the damage to her vestibular system and would not have suffered from ataxia.

The plaintiff had proven each element of her informed-consent case. That the jury found the standard of care had been met was of little consolation to the physician. The damage award was substantial.

Post-trial, jurors mentioned their sympathy not only for the injured plaintiff, but also for the physician. They agreed he had tried to do what he thought was best for the young woman.

The jurors also said they believed gentamicin was not an unreasonable choice. The problem, however, was that this choice was made solely by the doctor. He did not give the patient a chance to participate in the decision. The jurors agreed that the plaintiff could not be faulted for not asking more questions. She was not a doctor, so she had no way of knowing there were questions to ask.

**Analysis**

This above case did not involve a medical emergency under circumstances where consent is implied by law. Although the patient was dangerously ill upon presentation to the hospital, she was conscious and able to participate in decision making. There was no evidence that the plaintiff exercised her right to refuse informed consent. She did not tell her physician anything along these lines:
Hold on, Doctor, I don’t want to hear anything about those risks—that kind of stuff scares the hell out of me. I want you to make the decision.

A conversation such as this would have relieved the defendant of the obligation to obtain informed consent and possibly avoided a lawsuit—assuming thorough documentation of the patient’s refusal.

The plaintiff verdict resulted from a well-intentioned physician falling into the old snare of medical paternalism, acting in the perceived best interests of the patient, to be sure, but effectively excluding the patient from the decision-making process. The defendant, wholly focused on the challenging clinical issues confronting him, forgot that the paternalistic approach to medicine was discarded decades ago, a casualty of the consumer-oriented informed-consent movement that emerged in the 1960s.

**Guidance**

As always, the devil is in the details: How is the time-deprived physician to know what information must be offered a patient? Recognizing that it is impossible to require that physicians inform patients of every conceivable risk, complication, or treatment alternative, Washington law (fundamentally similar to that of Oregon and Idaho) requires health care providers to disclose only material information. Material is defined as what a reasonably prudent patient would want to know before consenting to the proposed procedure or treatment.

Physicians would be wise to consider: “Would this information, if disclosed, be likely to change a patient’s decision?” If so, the patient should, with few exceptions, be told. When in doubt, it is better to give the patient more information, not less.

**Documenting informed consent**

An adequate informed-consent process includes not only the dialogue with the patient or other decision maker but also the documentation of the discloser and the patient’s understanding of the information imparted. It is advisable to document the informed-consent discussion in hospital and office progress notes as well as employ a procedure-specific, patient-signed consent form.

A properly developed, patient-signed consent form is compelling evidence that a patient was adequately informed before a medical procedure. It can deter litigation or at least help the physician prevail in the courtroom setting. Informed consent also encourages a patient to be more responsive to advice and is associated with a patient’s ability to recuperate more quickly, require fewer analgesics, and feel less anxiety—while experiencing fewer complications and days in the hospital. Expirix offers two informed-consent templates available on expirixllc.com. Both the abbreviated form and the longer, patient-teaching form can facilitate clinicians’ development of procedure-specific forms.

We believe strongly that the specific information called for by the templates, such as risks and complications, is best provided by the clinician. Vendor-provided, procedure-specific forms may not accurately or completely reflect the views of the physician who provides the form to the patient. It is important that the right procedure-specific form—one reflecting the views of the particular clinician—be utilized. Comprehensive documentation often deters potential litigation.

**What’s this about new CMS guidelines?**

In January 2005, the Centers for Medicare and Medicaid Services (CMS) devised new interpretive guidelines for CMS surveyors pertaining to the informed-consent process in the hospital. Though
directed at hospitals, pursuant to Medicare Conditions of Participation, these new hospital informed-consent requirements threatened to place unwelcome new administrative burdens on physicians. Specifically, the 2005 CMS guidelines mandated that hospital informed-consent forms include (in addition to the customary elements) the following:

- In addition to the names of primary physicians or surgeons, the names of other practitioners and the specific, significant surgical tasks to be performed by them. Specific surgical tasks included opening and closing; harvesting grafts; dissecting, removing, or altering tissue; and implanting devices.
- Signature of a “professional person” witnessing the patient’s consent.

Various medical organizations expressed great concern relating to the novel requirements, and uncertainties, inherent in the new form. For example, nowhere did the guidelines define the qualifications of the “professional person,” the required “witness.” Also criticized was the requirement that all persons anticipated to be involved in the procedure be identified on the form by name. Because the identity of “other practitioners” will, as a matter of necessity, sometimes change shortly before surgery or other procedure, this requirement would be difficult or impossible to meet, especially in hospitals with resident training programs. In the face of these and other criticisms, CMS suggested that adjustments and clarification would be released at some point.

Relief: the 2007 CMS revised interpretive guidelines

On April 13, 2007, CMS released substantial revisions to the 2005 guidelines:

- The “professional witness” requirement is abandoned.
- Hospital forms need not list specific risks of a procedure, specific alternative procedures, or specific risks of no treatment.
- The names of all practitioners involved in a procedure—except for the primary surgeon or physician—need not be listed on the consent form.

The new guidelines emphasize well-designed policies, procedures, and forms, citing new minimum requirements for hospital informed-consent forms:

- Name of the hospital
- Name of specific procedure
- Name of physician performing the procedure
- Statement that the procedure, anticipated benefits, material risks, and alternatives were explained
- Signature of patient or legal representative

The date, time, and signature of a person witnessing the patient’s signature on the form is encouraged, but not required, as are other elements of the 2005 requirements.

The reach of the CMS guidelines does not extend to procedures or treatment performed in a non-hospital setting. Nonetheless, we recommend that ambulatory surgery centers and office practices use a form that incorporates the revised CMS requirements to ensure consistency in the informed-consent process for both the patient and the physician. With respect to malpractice liability issues, the fundamental informed-consent responsibilities of physicians are set forth, and consent forms addressed, within the Revised Code of Washington. Oregon and Idaho physicians have similar responsibilities, as set forth in the Oregon revised statutes and in the Idaho statutes. The CMS guidelines are more exacting.
Conclusion
Though physicians’ ultimate legal duty is still controlled by state law, physicians will be required to cooperate as hospitals work to implement the CMS requirements. Our two informed-consent templates will accommodate the 2005 CMS informed-consent guidelines—which, although ultimately rejected as overly ambitious, nonetheless incorporate ideas worthy of your consideration—as well as the more modest April 2007 revised CMS guidelines.