OBG MANAGEMENT

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Malpractice risk management

Be thorough—and involved—in obtaining informed consent

The seminal event is a focused discussion between you and your patient. There's no substitute for "you."

You the physician—not a medical assistant, not a clerk, not a nurse—must initiate and complete the process of informed consent. You must personally obtain the patient's consent before performing any operation, minor or major, in the office, surgical center, or operating room.

The setting should be an examining room or hospital room, not a waiting room, nursing station counter, or gurney in the operating room holding area. Exceptions occur, but considering how litigious society is today, these criteria represent the ideal.

Does the patient understand?

You must feel assured that the patient is capable of participating in the discussion, both receptively and expressively, and that she can make a sound and reasoned decision. Exceptions can apply in emergencies and for minors or adults who are otherwise not competent to grant informed consent.

If the patient wants to have a loved one or close friend join the discussion, invite that person into the room. However, he or she should play a peripheral role only.

You initiate the informed consent process, but the patient must conclude it by granting or refusing consent.

Focus the discussion

The preeminent case law on informed consent is Cobbs v. Grant, which the California Supreme Court handed down in 1972. Even today, many states follow

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This article is the final one of 4 derived from a symposium on malpractice risk management at the 91st Clinical Congress of the American College of Surgeons, San Francisco, Calif., in October 2005. Mr. Nelson updated his comments in February 2007.

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CASE Informed consent—then 8 months elapse before surgery

A situation that I recently confronted was a lapse of 8 months between the time the patient gave informed consent and the actual surgery. Here's how that case unfolded:

- A couple of months after the surgeon obtained informed consent from the patient, and just before the day of the scheduled surgery, the patient called the surgeon and said: "I feel better. I don't want to have the surgery."
- A couple of months after that, the patient again called: "I've changed my mind," she said. "I don't feel well. I want the surgery." So the surgeon performed the operation that the patient had consented to more than 8 months earlier.

Was the surgeon obligated to conduct another history, physical examination, and informed-consent discussion with the patient—long before the patient is on the gurney under preanesthesia and ready to go into the operating room? In this case, the surgeon should have—and did—talk briefly with the patient, reminding her of their earlier discussion. The patient confirmed her intent to have the surgery.

But the patient later alleged: "I lost the documents I was given and I wasn't really prepared for the surgery." She sued for negligence, claiming the surgery resulted in continuing severe pain. Informed consent was an issue at trial because:

- the surgeon did not document the final informed-consent discussion
- the patient denied that the discussion took place.

This situation doesn't happen often, but it had significant consequences for my client.

this law. The California justices held that a patient's "right of self-decision" was a measure of the doctor's "duty to reveal."

In other words, presenting information to the patient and receiving her consent requires both the physician and patient to participate. The process may require a few office contacts and perhaps 1 or 2 office visits or hospital calls. The seminal event is a focused discussion between you and the patient.

The physician describes the proposed treatment or procedure in language the patient can understand. That is, the information must be conveyed in a way that a reasonable person in the patient's position would expect to hear it.

Explain the likely outcome

Express the likelihood of success in general terms, not as a percentage. Courts have frowned on such statements as, "The failure rate for this procedure is 1% to 2%." They've preferred that the physician simply state that a successful outcome is likely.

Another mandatory point of communication is the expected benefit and outcome. This includes a discussion of potential risks or complications that a reasonable person would consider important: any risk of death, serious injury, or significant complication—but not necessarily minor or trivial side effects.

Lay out any alternatives

You must tell the patient about any reasonable alternatives to the planned treatment or procedure, along with their potential risks, complications, and outcomes. We've found that physicians who satisfied their responsibility to discuss alternative treatments or operations sometimes failed to explain the risks, benefits, and complications.

Do not draw conclusions or speak cryptically. Never make assumptions about the patient's knowledge or understanding of a proposed operation or its alternatives. Instead, invite the patient to ask questions. Be receptive and thoughtful when those questions are posed.

The patient should receive a clear, concise explanation of his or her condition or diagnosis and how that might affect the outcome. For example, discuss proposed surgery for pelvic prolapse in the context of the patient's presentation.

There's more to do afterward

The process does not necessarily end after you've answered all the patient's questions and she has given informed consent (or has declined to consent). For selected treatments or operations, some states require a presentation of risks, benefits, and alternatives more specific than the

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"reasonable person" communication.

In many states, for example, a patient who grants consent for a hysterectomy or sterilization must be told specific points or complete a form. Some states apply similar protocols for breast cancer surgery or chemotherapy.

Handouts and videos are no substitute!

More and more, physicians are using videotapes, CDs, Web-based sources, and handouts to help patients understand procedures. But these resources cannot supplant the role of even a very busy physician. Such materials can supplement a focused discussion between physician and patient, but do not legally serve the purpose of obtaining informed consent.

A nurse or other nonphysician provider can convey some information or provide materials to the patient about the treatment or procedure toward the goal of obtaining informed consent, but, again, it is you who must then come in and complete the discussion. Whether a court accepts this system depends on the quality of the materials.

An informative handout (or video, etc.) can have a big impact on a jury's impression of whether the patient was informed adequately. However, sometimes a busy physician relies too heavily on nonmedical staff and fails to participate sufficiently in deciding what the staff hands out. Furthermore, the physician is responsible for any information that a staff member provides to a patient.

Full disclosure needed

Often, in a university hospital or large medical center, a surgeon who discusses a procedure with the patient is not the one who is scheduled to perform it. That situation should be included in the informed consent: "I will be the second assistant surgeon, but it's Dr. Smith who will perform your operation."

When a proposed therapy or procedure will involve off-label use of a drug or medical device, tell that to the patient, too, and document the discussion in the chart.

At the end of the informed-consent process, you must be satisfied that you've complied with the court's mandate to meet the patient's protected interest in autonomous decision making. ■

Must you disclose a lack of experience?

You don't need to volunteer information that you've done a certain procedure only a few times. If the patient or a family member asks this question, however, answer honestly. Even the most aggressive plaintiff's experts acknowledge that physicians do not have to provide a tabulation of procedures they've performed.

***FAST** TRACK*

There's no need to volunteer the fact that you've performed a procedure only a few times

Highlights from this series on malpractice risk management

"If a patient is reluctant or noncompliant, you may not be doing enough if you simply document that she refused your treatment."

—James M. Goodman, JD, on informed refusal, March 2007

"We've often found postoperative progress notes to be thin on detail: *Wound looks good*, *Patient happy with results*… Be specific in these notes!"

—Claudia Dobbs, MA, on proper documentation, April 2007

"A surgeon who wants a test done but anticipates a roadblock from a managed-care company can't say, weeks later, *The insurance carrier didn't approve it*."

—Thomas J. Donnelly, JD, on patient safety, May 2007

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