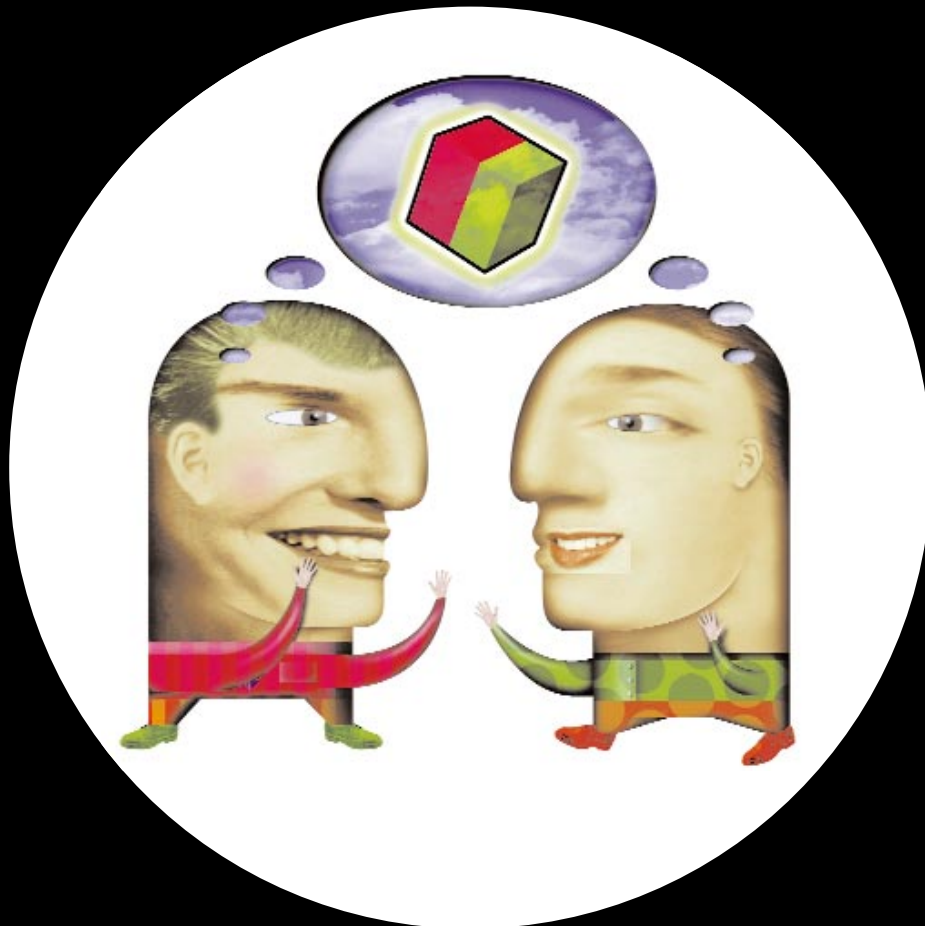


YES *isn't always* YES

Informed consent means more than just getting patients to agree to a procedure. Protect yourself by knowing what's required and when.



By Julie Silver, MD

On December 14, 1999, singer-actress Julie Andrews sued two of her former physicians, Drs. Scott Kessler and Jeffrey Libin, alleging that they had not informed her of the “irreversible loss of vocal quality” when they removed benign throat nodules. Andrews alleges not that she did not give consent for the procedure, but rather that her consent was not informed.

This brings up an important question: What do doctors need to know about having a patient consent to treatment in order to avoid litigation? Pose this question to Susan Donnelly, a partner in the Boston-based law firm of Murphy and Riley, P.C., who specializes in representing physicians in medical malpractice cases, and she’ll say that “physicians need to focus on the requirement of informed consent.” In fact, according to Donnelly, “Patients do not usually claim lack of consent [in litigation]. The claim is lack of informed consent.”

What is informed consent?

The law recognizes that a patient has the right to refuse medical invasion of his or her body—regardless of the consequences. This is termed “inviolability of the person.” This right is preserved in the body of law that addresses informed consent.

This means that physicians are no longer able to steer patients in the direction that they think is best without a comprehensive explanation of the risks and benefits of the proposed treatment and a discussion of all reasonable treatment options. This latter requirement is often the sticking point in litigation.

Under the law, patients can rightly contend that even if their doctors gave them a thorough explanation of the treatment or procedure that was rendered, if they were not told of all other reasonable treatment options and the presumed consequences of no treatment, their consent was not informed.

The dilemma physicians often face is trying to deter-

mine in a variety of different circumstances (for example, emergencies, urgent care, patients who are anxious or even have altered consciousness) what constitutes a reasonable explanation of possible treatment options.

Attorney Donnelly gives the example of a case she recently won where she defended an orthopedic surgeon who had treated a woman in her 40’s for a Colles’ fracture. The patient was treated with a closed reduction and casting. Unfortunately, when the fracture healed, she had radial shortening with a claimed loss of range of motion in the forearm.

The patient sued the doctor and claimed that she was never told of other treatment options including both internal and external fixation procedures. The patient’s attorney had the burden of proving three things: (1) that other options did exist, (2) that those options would have left the patient without any radial

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shortening or loss of range of motion, and (3) that had the patient been apprised of the other options, she would have selected an alternative to a closed reduction and casting. Donnelly successfully defended the physician by claiming that at the time of presentation, there really was only one treatment option because a good reduction had been obtained. Donnelly explained to the jury that there were far too many risks associated with both internal and external fixation procedures to consider them first-line treatment options for a Colles' fracture in which a good reduction is obtained. The plaintiff's attorney failed to meet the burden of proving all three requirements.

For the treating physician, the outcome in this lawsuit was positive. But, how could the litigation have been avoided altogether? After all, litigation is expensive, time consuming, and disheartening. In this case, the treating physician would have been prudent to have had a thoroughly documented discussion with the patient about alternative treatment options and the inherent risks associated with them. All that would have been needed was a simple statement on the consent form or documented in the medical chart such as "Discussed internal and external fixation with patient—advised patient that the most reasonable treatment at this time would be closed reduction and casting—she agreed."

In the case described above, simple documentation of that discussion would have likely provided sufficient evidence that the patient gave informed consent and the likelihood of litigation would have been minimized. It is important to note that even when a physician strongly believes that a particular treatment option is preferable, he or she is still bound by the obligation of informed



Susan Donnelly, a partner in the Boston law firm of Murphy and Riley, P.C., points out that documenting informed consent will not protect physicians from malpractice claims but it will make the defense of these physicians much easier. Dr.

consent to discuss all reasonable treatment options.

Barriers to informed consent?

Ted Lennard, a clinical assistant professor of physical medicine and rehabilitation at the University of Arkansas for Medical Sciences and editor of the medical textbook *Pain Procedures*, states that one of the main barriers to physicians obtaining informed consent is that it is "time consuming." Lennard explains, "We [physicians] tend not to give the patient adequate information or time to make an informed decision."

Lennard, a practicing physiatrist who specializes in musculoskeletal procedures that are generally done on an optional basis in order to improve pain and quality of life, says that in his practice it is imperative that he engage in "a complete discussion about realistic outcomes" with patients who are considering procedures to improve pain. To do this he utilizes a variety of techniques including written materials explaining the proposed procedure, videotapes, and discussions with skilled staff members. However, Lennard is quick to note that

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he is “actively involved” in the consent process.

Another potential barrier is that patients often hear what they want to hear rather than what the physician actually tells them. This has been borne out in multiple studies in different areas. One documented area of medicine where the process of informed consent is clouded by patients hearing what they want to hear is in clinical research trials.

Dr. Greg Koski, an associate professor of anesthesia at Harvard Medical School and the director of human research affairs at Partners Healthcare System, says this is not uncommon in Phase 1 cancer trials. According to Koski, these trials are “solely designed for the purposes of determining the safety and dose limiting toxicity [of a drug].” These trials are “not intended to provide clinical benefit.”

Yet studies have shown, and Koski concurs, that many enrollees in these studies consent to participate because they believe that they will receive clinical benefit—regardless of what they were told during the consent process.

However, Koski concedes that the consent process, while never perfect, may be flawed in clinical research trials when investigators receive financial incentives for each participant recruited or when investigators are simply overly zealous because they truly believe that the study will ultimately lead to safer and more effective therapies. Koski reminds investigators that, “The goals of research are secondary. The most important goal is to protect the interests of the research subject.”

When do doctors need to get informed consent?

Physicians already burdened by managed-care time constraints and an inordinate amount of paperwork should not burden themselves further by unneces-



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sarily obtaining consent for everything they do. However, some simple guidelines for when to obtain informed consent are useful.

Informed consent is appropriate to obtain when a procedure or surgical intervention is proposed. Informed consent also is important to obtain when medications or therapies are prescribed with known potentially serious side effects.

Keep in mind that informed consent is particularly important to obtain if more than one treatment option exists.

Attorney Donnelly gives the example of a blood draw or a flu shot and says, “Things like blood draws and flu shots clearly require consent, but the patient is alert and by having the procedure is giving consent.” Donnelly makes the point, “There are no options for a flu shot—you can take it or leave it.”

However, what about other office procedures? The gold standard test is if there is more than one treatment option, informed consent is necessary. Consider the common problem of treating warts. There are several different

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treatment options, most of which are considered safe and generally effective.

For practical purposes, physicians should be encouraged to discuss various options with their patients and let their patients ultimately decide which option they want to pursue. From a legal perspective, informed consent is necessary because multiple treatment options exist. However, this will never become a medical/legal issue unless the patient suffers an injury from the treatment—regardless of whether informed consent was obtained.

Donnelly states, “Usually the injury has to be a significant and permanent complication in order to be actionable.”

Likewise, there are situations when injury can occur and litigation may ensue when there was clearly only one reasonable treatment option. Attorney Donnelly gives the example of a patient who has a peripheral intravenous line placed for a serious medical condition. Suppose the intravenous line infiltrated and resulted in a significant injury to the patient? The issue of informed consent would not generally be a problem, because as Donnelly asserts “there really weren’t alternatives.” Moreover, Donnelly asks the rhetorical question that would be asked during any judicial proceedings, “Would a reasonable patient refuse this IV if they knew the risks?” Donnelly answers, “No reasonable patient would refuse.”

Donnelly is quick to point out, however, that although a patient who claimed lack of informed consent would not likely get very far in the legal system, this doesn’t preclude the patient from filing a claim based on other issues such as medical negligence.

Obtaining informed consent

The process of obtaining informed consent can be time consuming in-

deed, especially for physicians caught in a time crunch such as in the emergency room or in a busy office practice. In order to streamline this process there are several options.

Dr. Lennard suggests using videotapes for major procedures and delegating “portions of the process” to a trained staff member. Dr. Koski suggests that both the discussion and any written consent forms avoid all medical terminology. He advises physicians to keep the discussions focused and basic, because “too much detail can be confusing.” This helps both streamline the process and insures the patient is informed.

Both Koski and Lennard agree that the physician who is ultimately responsible for the procedure or treatment needs to be involved in the consent process. This means that while some parts of the process may be delegated or audio and written materials may be used, it is still critical for the attending physician to be certain that the patient understands both the treatment being offered and any available options.

What documentation is necessary?

The process of documenting recommendations and the actual treatment of patients has become a necessary part of protecting oneself from future legal entanglements. As with many legal claims, those made against physicians regarding lack of informed consent often occur months to years after the consent process occurred.

It is unlikely that a busy physician will accurately recall a consent process that took place in the distant past, so documentation of this process is vital in order to refute any claims that involve lack of informed consent.

Attorney Donnelly points out that documenting informed consent will not protect physicians from malpractice claims

but it will make the defense of these physicians much easier. In fact, most attorneys won’t even waste their time with a disgruntled patient who claims lack of informed consent if the chart documentation clearly indicates otherwise.

Once again, excessive documentation can hinder a busy physician and in order to streamline this process Donnelly suggests tailoring your documentation to the specific patient and situation. Although in many instances physicians can use standard consent forms, Donnelly strongly advises that the physician either write on these forms or in the medical record some indication that a discussion took place and what was discussed. Donnelly notes that the preference is to tailor the consent process to each individual patient and that the best way to prove that this was done is to make notes in the medical record or on the consent form itself. Donnelly recommends, “Put something to show that the discussion was unique [to the patient].”

In order to save time and make sure that both the consent discussion and subsequent documentation is done properly, Donnelly suggests developing a routine, much the same as a physician develops a standard order for dictating a physical exam. This routine simply insures that the requirements of informed consent have been met (informing the patient of all reasonable treatment options, explaining the risks and benefits of the proposed treatment and tailoring the discussion to the patient).

What informed consent doesn’t cover

The lack of informed consent is only one of many reasons why patients sue their physicians. Any time an individual sustains a serious injury as a result of medical intervention, physicians may be

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at risk. Claims resulting from a lack of informed consent only arise when a physician does not disclose a risk that subsequently becomes an injury. In other words, the doctrine of informed consent assumes that treatment is rendered appropriately and that a known and accepted risk occurred in the absence of negligence. Consequently, properly obtaining informed consent will not protect physicians against claims of medical negligence.

In order to protect oneself against claims of medical negligence, it is important to understand that the law recognizes as inherent in the doctor-patient relationship an understanding that the physician must possess and exercise a similar degree of knowledge and skill as the average physician in the same specialty. Any breach of this standard may be actionable as a medical negligence malpractice claim.

In short, physicians must be able to demonstrate that they have had adequate training to perform the treatment in question. This includes new procedures that a physician may not have been trained in during the medical school, residency, or fellowship training. Therefore, keeping careful records of continuing medical education coursework and any additional seminars or other training is important.

Attorney Donnelly also says that typically physicians are shown to be negligent by having medical experts, who are usually doctors in the same specialty, testify against them. Successful claims are often won in court because these experts convince judges or juries that the physician in question did not meet the standards of care of the average physician in the specialty.

In general, these experts are required to examine the facts of the case, which frequently are obtained exclusively from

the medical record. Once again, Donnelly stresses the importance of documentation, not in protecting physicians against claims of medical negligence, but rather in defending them against these claims.

Avoiding lack of consent claims

Most physicians know that studies on malpractice claims often have more to do with the patient's perception of quality of care rather than the care that was actually delivered. What this means is that competent physicians are at risk to be sued more often than their equally competent colleagues (and perhaps more often than their less competent peers) if they lack the ability to connect with patients on a personal level.

Patients want to know that the person in charge of their medical treatment actually cares about them. Simply stated, doctors who do not leave patients with the feeling that they care about them are at greater risk for malpractice claims, regardless of the merit of these claims.

Although patients' interpretations of the quality of their care may in part be related to how much time their doctors spend with them, length of time is only one variable. Other factors that influence patients' perceptions of their relationships with their physicians include:

- **During the visit was the doctor focused and attentive or distracted?**
- **Did the doctor remember the patient's name, diagnosis, previous discussions with the patient and perhaps some personal information about the patient? For example, is the patient working or too ill to work, does the patient have family members who want to be involved in the care and is this appropriate?**
- **Did the physician appear humble and**

respect the imbalance of power in the doctor-patient relationship?

- **Did the doctor sit down and appear relaxed and thorough regardless of the length of the visit?**

All of these factors play a role in how patients perceive their relationships with their physicians. Of course, it goes without saying that competence in one's chosen area of medicine is also extremely critical and will affect patients' perceptions as well.

Clearly, the best way to avoid medical malpractice claims that involve a lack of informed consent is to have a thorough discussion with the patient about the risks and benefits of the proposed treatment and what other reasonable treatment options are available. It is important also to include a discussion on what is likely to occur if no treatment is undertaken.

However, even under the best of circumstances, doctors are keenly aware of the litigious society that we live in, and inevitably there will be patients who suffer unwanted consequences of medical treatment despite state-of-the-art medical care. Some of these patients will pursue litigation. The best way to defend oneself against claims of lack of informed consent is to document clearly that a thorough discussion took place which included the risks and benefits of the treatment rendered and confirmation that all other acceptable treatment options were explained to the patient and dismissed by the patient. ■

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