Informed Consent

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Where there is a bad outcome in claims, we frequently find the consent process, or at least, documentation of that process, was lacking. Plaintiffs' attorneys are eager to assert the old adage that, "if it's not documented, it wasn't done." While that is not necessarily true, it is certainly more difficult to prove that it *was* done if it wasn't documented.

Lack of informed consent can be a sole basis for a negligence claim or can be asserted as an additional claim in connection with other alleged acts of negligence. In the event of such a claim, thorough documentation of the informed consent discussion may prove to be the defining factor of a successful defense.

While informed consent is rarely the central issue in a lawsuit, it is almost always included as an allegation. In claims we have reviewed in which consent was an issue, it was related to the failure to review specific risks, benefits, and alternatives associated with a proposed procedure, as well as to ensure the patient had an opportunity to have his or her questions answered. It's well-settled that physicians have a legal and ethical obligation to provide patients with enough information with which they can make an informed election about the course of their medical treatment. What frequently gets overlooked in the informed consent process is that this discussion is an additional opportunity to establish or solidify rapport with patients, because it involves them in their medical care and helps to set realistic expectations regarding the proposed treatment plan or procedure. Many physicians seem to view informed consent as merely a necessary formality, a time to obtain the patient's signature on a form in order to allow a specific procedure to be performed or treatment or medication to be administered. In actuality, it is often the most important discussion a physician will have with the patient. It lets the patient know that

complications can and do occur.

Generally, it is the duty of the physician who performs the medical test or procedure in question to disclose pertinent information to the patient and ensure that valid consent is obtained. The physician may also be assisted by other healthcare professionals in providing patient education information or obtaining a signature on the consent form, but the individual who renders the care bears the ultimate responsibility for obtaining informed consent.

To be valid, the process must include adequate opportunity for the patient to have direct and meaningful dialogue with the physician and to be afforded the opportunity to ask and have questions answered to his or her satisfaction. The discussion should consist of language appropriate to the patient's level of understanding (i.e. in lay terms) rather than using complex medical terminology. It should be accomplished in an atmosphere that allows the patient to make thoughtful, well-considered decisions regarding his or her healthcare, which means the process should not take place after certain medications have been administered or in a rushed fashion just prior to a procedure. It is also important to remember that false reassurances intended to calm anxious patients may create unrealistic expectations.

The American Medical Association's (AMA) Ethical opinion E-8.08[1] sets forth the obligation of a physician to give a patient adequate information so that he/she may effectively exercise a right of self-decision. A patient may bring a lawsuit against a healthcare provider based solely on the allegation that he/she did not give consent to be touched. This type of claim is called a "battery." Examples would be the extension of surgery beyond what was authorized or operating on a part of the body other than that which was consented to by the patient. A second, and much more common, legal claim is that consent was not given based upon proper and adequate information. This is a "lack of informed consent" claim. Informed consent allegations are usually found as part of a typical medical malpractice action and arise from all types of medical situations in virtually every area of specialization. Thus, from a risk management perspective, the informed consent process plays a vital role in minimizing exposure to medical negligence lawsuits.

Informed consent may be either "express" or "implied." Express consent is given in writing or verbally and, generally speaking, is required for surgery, anesthesia, invasive treatments, and those situations specifically defined by statute as requiring consent (for example, HIV testing). Consent not given by a patient in writing or verbally, but understood from the circumstances surrounding the procedure or treatment at issue, is known as implied consent. Implied consent normally is given in routine office practice. Implied consent may be inferred when a patient seeks treatment or shows a willingness to go through with a particular course of treatment. For example, if a patient, without speaking, rolls up his or her sleeve and holds out an arm in response to a request to take a blood pressure reading, that conduct indicates implied consent to the process.

Consent is also implied in emergency medical situations. Typically, the patient must have a life- or health-threatening medical condition, and it must be severe enough that any

delay in treatment would have a serious negative impact on the health and well-being of the patient. Also, the patient must be so incapacitated that he or she cannot be expected to make an informed choice regarding treatment. Under these circumstances, a physician is justified in undertaking medical treatment without consent. However, if there is a spouse (unless legally separated), parent, adult child, adult sibling, or grandparent available, it is advisable that consent be obtained from that person.

A competent adult or parent may consent to treatment. If the patient does not possess the mental capacity to understand the nature and consequences of authorizing treatment, someone who holds a durable healthcare power of attorney may consent. In the absence of such individual, the next course would be to turn to a surrogate decision maker – spouse (unless legally separated), adult child, parent, adult sibling, or grandparent.

Generally, a physician is required to disclose information that the average patient would need to know in order to be an informed participant in the decision. This "reasonable patient standard" is applicable in a majority of states, including Tennessee, Arkansas, Kentucky, Alabama, Mississippi, Georgia, North Carolina, and Oklahoma. Virginia's standard for informed consent, however, is a "reasonable *physician* standard".[2] Regardless of which standard applies, a physician need not disclose all of the risks or complications that may occur, but he/she should discuss those risks most commonly associated with the procedure or treatment and which have a reasonable chance of occurring, as well as those risks which have a small chance of occurring but have grave consequences.

A thorough consent process optimizes patient care and rapport and helps to minimize medical malpractice exposure, which is a win-win situation for all involved. Engage in a full and clear discussion with patients about the nature of their medical condition, the recommended treatment plan, and the risks, benefits, and alternatives. Doing so not only discharges your legal and ethical obligation to provide patients with sufficient information with which to make an educated election about the course of their medical care but may also help create realistic expectations on the patient's part as to the outcome of treatment. Be careful not to educate above a patient's comprehension level.

Risk Management Tip: Be sure the details of all discussions with patients are documented in your office record rather than relying on hospital consent forms that are not procedure-specific and may not capture all details of the conversation.

In the next issue, we will discuss best practices with documentation of the consent process.

[1] Ethical opinion E-8.08

[2] This reasonable physician standard requires disclosure of the information that a typical physician would give about the treatment, procedure, or surgery.

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change over time.