Informed Consent: Addressing What Patients Need to Know

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The allegation of lack of informed consent is common in medical liability claims. Typical to these types of claims is a dispute over who said what and whether a particular side effect was discussed. International experts published a study in PLOS Medicine1, an open access journal for research on world health, which found that physicians in Australia routinely underestimate small risks that vex patients.

The research analyzed 481 medical liability claims in an effort to understand disputes in the process of obtaining informed consent. The authors found that almost half were disagreements over whether a particular side effect should have been discussed. The vast majorities of these cases were surgical procedures and revolved around five adverse outcomes: the resultant need for further surgery, poor cosmetic results, impaired vision or hearing, pain, and infertility or sexual dysfunction.

The authors suggest that surgeons are often unsure what risks should be discussed prior to a procedure or treatment. Even though the research focused on Australian physicians, there are important points that apply to how we practice medicine here, what we need to know about informed consent and how to perform it properly.

In addition, the research found that doctors reported the most common cause for not going over a particular risk was the perception that the risks were too rare or that a specific risk was covered under the discussion of a more general risk. Approximately 90 percent of the disputes were around who said what and when, otherwise known as “he said, she said” disagreements.
“Documentation of the details of consent discussions in the lead-up to surgical procedures is particularly important, as the vast majority of informed consent disputes involve complications following operations,” stated the article. “Our findings suggest that doctors may underestimate the premium patients place on understanding the risks of them in advance of treatment...Improved understanding of these situations helps to spotlight gaps between what patients want to hear and what doctors perceive patients want (or should want) to hear. It may also be useful information for doctors eager to avoid medico-legal disputes.”

Informed Consent Guidelines Informed consent is a process; the informed consent document (or the term “surgical permit” in some instances) refers to the signed written document that affirms and memorializes the informed consent process. Informed consent should be given on the basis that a patient has a clear appreciation and understanding of the facts, implications, and future consequences of an action. In order to give informed consent, the individual concerned must have adequate reasoning faculties and be in possession of all relevant facts at the time consent is given. Competency can also be alleged to be impaired if significant medications were given prior to the consent.

Proper Use of Informed Consent The informed consent process is important prior to any procedure or long-term medication that carries significant risks and benefits. The informed consent document needs to be completed for specific procedures in many institutions prior to performing a procedure. Many states have very specific consent statutes with specific requirements. The MagMutual Patient Safety Institute has compiled state-specific informed consent articles, so please refer to the article outlining your state's statute and requirements. In general, however, we recommend that the informed consent process is completed before the following:

- All surgical procedures usually requiring general or regional anesthesia
- Any other procedure usually requiring general or regional anesthesia
- Cerebral and coronary angiography
- Endoscopy/flex sigmoidoscopy
- All sterilization procedures
- Amniocentesis
- Diagnostic procedures involving the injection of IV contract material
- Any procedure where the usual risk is substantially increased because of some aspect of the patient's medical condition
- All plastic surgery procedures
- All surgical procedures upon the eye
- Needle biopsy of internal organs
- Allergy treatments (initial treatment)
- Treadmill tests
- Vaginal birth after C-section
- Long-term steroid therapy
- Long-term anticoagulation

While assistants and delegates can assist in providing educational materials and responding to questions, the essential step of assessing the six elements of informed consent (see infobox below) should be completed by the person performing the procedure. This essential step should not be delegated. What should you disclose to the patient? Again, your state's law may have very specific requirements so please be sure to familiarize yourself with the legal requirements in your state. Certainly any common side effects should be mentioned. A substantial risk is one that a physician knows or that a reasonably careful physician should know would be important to the patient to understand in deciding whether to agree to a particular course of treatment. One question you might ask is “what would a reasonable person want to know prior to agreeing to this procedure?” In general, we recommend the following:

- Discuss the clinical issues, illness, injury or condition and the nature of the clinical decision.
- Discuss the nature of the treatment you suggest.
- Discuss the alternative, including doing nothing.
- Discuss the substantial risks, if any, involved in undergoing the treatment and the substantial risks, if any, of
alternative treatments, and the risks of not proceeding.

• After discussing, assess the patient’s understanding.
• Explore the patient’s preferences.

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