Understanding Informed Consent - A Primer

When medical care or treatment is provided, medical practitioners are required in many situations to obtain a patient’s “informed consent.” But what does this term mean? What can happen if proper informed consent is not given?

A Definition

Although the specific definition of informed consent may vary from state to state, it basically means that a physician (or other medical provider) must tell a patient all of the potential benefits, risks, and alternatives involved in any surgical procedure, medical procedure, or other course of treatment, and must obtain the patient’s written consent to proceed. The concept is based on the principle that a physician has a duty to disclose information to the patient so he or she can make a reasonable decision regarding treatment.

The Role of the Physician

- Physicians themselves, rather than a representative, nurse, or other related health care professional, are the best choice to speak to the patient about informed consent. In discussing the matter with the patient, the physician should cover:
  - The patient’s diagnosis, if it is known.
  - The nature and purpose of the proposed treatment or procedure.
  - The benefits and the risks of that proposed treatment or procedure.
  - The alternatives to the proposed treatment or procedure.
  - Alternatives should be discussed regardless of their cost and regardless of whether they will likely be covered by the patient’s health insurance.
  - The risks and benefits of an alternative treatments or procedures.
  - The risks and benefits of not receiving or undergoing any treatment or procedure.

Note: A physician should also ensure that patients understand what they’re hearing. In fact, some hospitals now require physicians to participate in courses on communication skills.

- The patient, or the patient’s legally authorized representative consenting to the treatment on the patient’s behalf, must sign and date the informed consent documents.

- The patient or the patient’s legally authorized representative must be given a copy of the informed consent documents once they are signed and dated, and a copy should be placed in the patient’s file.

The Role of the Patient
Although a physician is required to inform a patient about benefits, risks, and alternative treatments, patients must also play a part in the informed consent process. Patients must listen to the physician and should ask questions of the physician if they do not understand, or if they would like more detailed information.

Example: You are a patient in a hospital being treated for a problem with your back. Your physician comes into your room and says, "John, you’ve got a herniated nucleus pulposus. Let’s do a discectomy and to do that we’ll start you off with some sodium thiopental, then hit you with a strong general anesthetic and wheel you into the OR. We’ll hope that while you’re under the knife you don’t have a myocardial infarction. Sound good?" You should look your physician in the eye and say, "I have no idea what you just said so I won’t say that plan sounds good. Explain it to me in detail and tell me exactly what all of those words mean."

**Situations in Which Informed Consent May Not Be Necessary**

- Situations Not Involving Medical Procedures or Treatment. Not all situations require that informed consent be given. For example, although listening to a heartbeat through a stethoscope may be considered a "treatment" or "procedure," to some people (especially those who are uncomfortable in physician’s offices), it’s rare that a physician and patient would have a lengthy discussion about the benefits and risks of listening to a heartbeat using that device.

In other situations, informed consent is an absolute necessity. For example, in any medical trials or experiments that receive federal funding, informed consent must be obtained from any human participant or subject. This requirement stems historically from the Nuremberg Trials that took place after World War II where the atrocities of Nazi medical experimentation on unwilling subjects came to light. Following the trials, the Nuremberg Code was drafted which emphasized the need for consent in any human medical experimentation.

- Emergency Situations: In emergency situations, there is not always time to obtain a patient's informed consent, nor is it always possible when the patient is unconscious or unable to communicate.

Example: The federal Food and Drug Administration allows for the use of experimental drugs or devices in emergency situations without informed consent if the community at large knows that the research into the drug or device is going on, a special committee keeps track of the results, and provisions are in place so that the experimental use can be stopped immediately if need be.

**Obtaining Consent from Incompetent Individuals and Minors**

When a competent adult seeks medical treatment, the process of obtaining informed consent may seem relatively easy. However, in situations where mentally disabled individuals or children need treatment, the ability to obtain informed consent becomes more difficult. In these situations, serious questions arise concerning who is able to give informed consent for those individuals.

- In most cases, a mentally disabled person has an appointed guardian authorized to make medical decisions, informed consent, for that individual. Medical providers need to make sure that when they obtain informed consent for incompetent individuals, they have obtained it from the correct person or persons.

- In most situations, parents can give informed consent for treatment for their minor children.

Note: Some states allow young adults under eighteen to play a more active role in their medical care and treatment, including the process of informed consent. Not every teenager is capable, however, of making informed consent decisions under these laws. Instead, most states focus on "mature minors" sufficiently ready to understand the nature and consequences of treatment. In those states, such young adults may be able to provide consent without consulting with their parents.

Example: Some states have passed specific laws that allow for minors to consent, without parental knowledge or approval, to health care treatments related to substance abuse, mental health, and sexual activity.
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