Reducing Risk

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Informed Consent

Introduction

Informed consent is an important communication process between a physician and patient that helps to create trust and foster joint decision making. The informed consent process can support and enhance the physician-patient relationship. Properly done and documented, the informed consent process also may better align the patient's and physician's expectations of the treatment outcomes, increase patient confidence, and help to prevent a malpractice claim.

Medical ethics and legal mandates require that a physician must obtain a patient's informed consent before treating or operating on the patient. The purpose of this requirement is to protect the patient's right to self-determination in medical treatment matters.

Informed consent is not merely a signature on a consent form. The physician must personally advise the patient, in a manner the patient understands, of all material medical information and risks of treatment. Providing this information enables the patient to make an intelligent and informed decision about whether to undergo a proposed treatment or procedure.

Failure to provide patients with sufficient information for informed consent places a physician at risk for a legal claim for injury from a complication or unanticipated outcome of the procedure—even if it was not the result of negligence.

The Physician's Duty

A physician has a non-delegable duty to obtain the patient's informed consent before he or she may treat or operate on a patient. The physician must communicate—in a manner understandable to the patient—the treatment options and their benefits and risks.

A doctor has a duty to communicate to the patient the treatment alternatives that he or she recommends, as well as all medically reasonable alternatives, including non-treatment, which the doctor does not recommend. The physician also must discuss the probable benefits, risks, and outcomes of each alternative. A physician may not impose his or her treatment preferences on a patient, or disregard a patient's expressed choice.

An informed consent requires that the patient be informed of material medical information and the risks of the proposed treatment. Material medical information is that which a "reasonably prudent patient" in the patient's situation, as known or that should be known by the physician—taking into account factors such as the patient's age, sex, occupation, diagnosis, and medical history—would be likely to attach significance to in making a treatment choice.

The patient does not have to be told of every conceivable risk. Material risks include any risk where the possible harm is great, even if the probability of occurrence is small. Material risks also include those risks where the potential harm is minimal but the possibility of occurrence is high.

In the situation where the proposed procedure or treatment is purely elective, such as cosmetic surgery, the prudent physician will provide a more exhaustive disclosure concerning the risks and other significant relevant information such as possible unpleasant side effects, what to expect during the recovery period, and associated lifestyle changes.

Information Essential for an Informed Consent

Taking into account what the physician knows or should know is the patient's need for information, the information generally required to be discussed with a patient in order to obtain an informed consent includes:

- A description of the patient's condition, including diagnosis or suspected diagnosis

- The nature and purpose of the proposed treatment or procedure and the anticipated benefits
- The material risks, complications, or side effects of the proposed treatment or surgery, including death or serious injury, if applicable
- Medically reasonable available options or alternatives, including non-treatment, and the probable benefits and risks of each alternative
- The material risks of not having the proposed treatment or procedure

Use non-technical language to communicate the above essential information to your patients. Involve the patient's family members to the extent possible. Encourage questions. It is also recommended that you ask the patient confirmatory questions or to restate in his or her words the information that you provided in order to assess their understanding and to identify any areas requiring clarification or more information. Never guarantee a result or tell a patient that a proposed procedure is routine or simple.

Exceptions

Exceptions to the obligation to obtain an informed consent include the following:

- Emergency—the patient presents with a life-threatening injury or illness requiring immediate attention and is unable to communicate and there is no time to obtain consent from another appropriate person. Only care that is medically necessary to remedy the emergency situation is permitted.
- Waiver by Patient—the patient may expressly waive the right to be informed of the risks and alternatives to treatment. A patient's waiver of informed consent is treatment-specific; informed consent must be obtained for other proposed treatments or procedures.
- Therapeutic Privilege—disclosure of all known risks of treatment believed to cause the patient the risk of significant harm (typically psychological). The patient should be evaluated by a provider not otherwise involved in his/her care before invoking this exception. Permission from the patient to discuss the information with his or her family should be sought.

The facts surrounding the application of any of these exceptions must be carefully evaluated and documented by the physician in the patient's medical record.

Legal and Mental Capacity to Consent

Informed consent is based upon the premise that a patient has the legal right to make his or her own decisions on medical treatment. The law presumes that an adult is competent to make a treatment choice, i.e., has the mental capacity to consent to or refuse treatment. However, minors generally do not have the legal right to consent. An adult may in some circumstances also lack the mental capability to consent. In such instances the law provides:

Minors

A. A minor under the age of 18 generally may not give consent.
B. Exceptions:
    1. Emancipated or married minors may consent.
    2. A minor who is pregnant may consent to treatment related to the pregnancy.
    3. A minor who is a parent may consent to treatment for his or her child.
    4. Minors may consent to treatment for drug or alcohol use/dependency, sexual assault, and venereal disease.

Adults

A. Unless otherwise determined, an adult individual is deemed competent to consent.
    1. Circumstances such as being under the influence of alcohol or drugs, medications, etc. may constitute grounds to determine that a patient is temporarily incompetent to consent.
    2. An individual with a condition that may eventually render him or her incompetent to consent, such as dementia, may still be competent to consent at a given point in time. Evaluation of the patient's ability to understand, ask questions, etc. is required.
B. A legal guardian or court-appointed representative may consent to treatment for an incompetent adult.

Documentation of Informed Consent

The informed consent process must be fully documented in the patient's medical record. Record the date(s) and time(s) and pertinent content of your informed consent discussions with the patient. Also document any other activities that were part of the process to inform the patient, such as providing the patient with informational pamphlets or audio-visual materials. Your documentation must be detailed enough to reflect that the patient was provided with the information required to give an informed consent, demonstrated understanding of the information, and gave or refused consent to treatment.

Use of a "boiler plate" consent form routinely used by physicians and healthcare facilities does not relieve a physician of the obligation to discuss the material risks, benefits, and alternatives with the patient. The patient's signature on a "boiler plate" consent form stating that the patient is giving informed consent, unaccompanied by supporting documentation of the consent process, may not protect a provider against a claim alleging failure to obtain a proper informed consent.

Any consent form that you use should be written in lay language at a fifth grade reading level, and medical terms used in it should be explained. The form must be dated, timed, and signed by the physician and the patient or the patient's authorized representative. Any adult member of your office staff may witness the patient's signature on the consent form.

If you use a procedure-specific consent form to assist you with informing your patients, file the original signed and dated form in the patient's medical record. Give the patient a copy to have for review and discussion at home with family members. Note in the patient's record that the patient was given a copy of the signed form.

If an interpreter was used for the informed consent discussion(s), document in the patient's medical record the interpreted language, the name and relationship, if any, of the interpreter, and the date and time of the discussions. Also keep a copy of any translated documents that were used in the process.

Documentation of Informed Refusal

In the same way that there must be documentation of informed consent, there must be documentation of a patient's informed refusal of care or treatment. A signed, preprinted refusal form is only written documentation that the patient refused care or treatment, not that the refusal was made with knowledge of the potential consequences of refusing care.

Carefully document in the patient's medical record the information about the proposed treatment or procedure that was communicated to the patient for an informed consent, including the material risks of not having the proposed treatment or procedure, and that the patient expressed his/her understanding of the probable consequences of refusal.

Your office practices manual should contain policies and procedures explaining the informed consent and informed refusal processes utilized in your office.

The Nurse or Allied Healthcare Professional's Role

A nurse, dental or medical assistant, or other allied healthcare professional may witness the informed consent process between a patient and physician, and may witness the patient's signature on a consent form. They may not be delegated the responsibility of obtaining an informed consent on behalf of a physician.

However, in much the same way that the physician must discuss with the patient medical information concerning the treatment or procedure, a nurse also has an independent duty to inform the patient of nursing care and services rendered.

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