MEDICAL-LEGAL

Summary of Informed Consent and Refusal

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This is a brief summary of the salient points about informed consent and refusal. This is summarized from the American Medical Association website on Informed Consent and the American College of Obstetricians and Gynecologists Compendium of Selected Publications called Informed Refusal. The important points are summarized and discussed below.

Informed consent dates back to Old English Tort Law in the middle ages, in which the Tort of Battery was imposed for unpermitted touching of an individual.[1] Informed consent is relatively new in the United States, dating back only to the 1950s. Informed consent claims are usually based on negligence and center around whether sufficient information was given for the patient to make a decision regarding one's health care.[1] Informed consent is more than just getting a patient to sign a permit for a surgical procedure but a process of communication between physician and patient that results in a decision by a patient to undergo a procedure. Informed consent is comprised of many components discussed in this paper.[1, 2]

In the 1800s, it was not unusual for the physician to seek permission for an operation from his colleagues, the medical community, or the religious authorities, including the bishop of the church.[3] The patient often sought religious support for an operation.[3] "The patient . . . sought religious support and finally consented to the operation after six hours of labor."[3] Even during the author's residency training in the early 1980s, permit for sterilization on a woman had to be signed by her husband.

Informed consent claims are usually based on negligence and, thereby, are usually covered by liability insurance.[1] Battery claims occur when treatment occurs without permission. The distinction is important because battery claims may not be covered by liability insurance.[1] Informed consent is more than just getting a patient to sign a permit for a surgical procedure but a process of communication between a physician and his or her patient, resulting in the permission to perform a procedure or medical intervention.[1]

The informed consent and permission must be obtained by the physician or surgeon and not by his representative under ordinary circumstances.[1] A life-threatening emergency may dictate otherwise. The physician or surgeon must discuss a number of specific items enumerated below. The patient should have the opportunity to ask questions to the extent of understanding sufficiently to agree or disagree to have the procedure or intervention performed.[1] Obviously, this may be abbreviated when a life-threatening emergency is present, such as severe trauma and massive bleeding. The patient may not be conscious, and the next of kin may need to give permission. In some situations, there may be no one available to give permission at all and a life-threatening situation may exist requiring immediate treatment to try to save the patient's life. It is always better to stray to the side of giving life-saving, emergency treatment without consent than withholding treatment and risking the patient's life, while waiting on permission. The components of informed consent under normal circumstances are listed in Table 1 below, taken from the AMA website:[1]

Table 1: Components of Informed Consent[1]

- **The Patient's Diagnosis if Known**
- **Nature and Purpose of Proposed Treatment**
- **Risk and Benefits of Proposed Treatment**
- **Alternatives Regardless of Cost or Insurance Coverage**
- **Risks and Benefits of Alternative Treatments**
- **Risks and Benefits of No Treatment**

All components of informed consent must be discussed.[1] The patient's diagnosis must be conveyed to the patient if it is known. The nature and purpose of the proposed treatment or medical intervention must be discussed with the patient along with the risks and benefits of that treatment. Alternatives of treatment must also be discussed, regardless of cost or whether or not that treatment would be covered by health insurance. The risks and benefits of alternative treatments must be discussed as well. Finally, the risks and benefits of not receiving any treatment, whether recommended or alternative, must be discussed, with the patient's understanding to the best of their ability.[1]

The process of informed consent is a communication between physician and patient of which the most important component is "informed," which is necessary to make a decision regarding one's care. The communication must be documented thoroughly. The physician must have liability insurance to cover informed consent.[1] Medical records are the report card of medical care. If it is not documented in the patient's chart, it did not occur. Documentation must be thorough and timely and understood by the patient. Documentation protects the patient and is the evidence in court that the informed consent process took place.[1]

Informed consent is more than just exchanges of words and the written word. The spectrum of informed consent includes the eye contact, facial expressions, how a patient sits in the bed or chair, the facial expressions to the family and physician, the questions that they ask and their despair or enthusiasm. The patient must have the opportunity to ask questions. Answers must be given in a way in which the patient and family can understand. During residency training, an attending surgical oncologist at a quaternary referral center was trying to convey to the family the condition of their father, who had cancer. He told the family from rural Alabama that their father had a poorly differentiated, aggressive, metastatic malignancy. The family stared off in space because they had no idea what he meant. A senior surgery resident from a small town in Alabama stepped up and asked the attending if he could speak to the family. He turned to the family and said, "Your daddy has cancer, it's the eating kind and it's done commence to eat." They said, "Oh, OK, now we understand."

Informed Refusal is an even newer concept, stemming from informed consent in which, after a thorough understanding of the proposed treatment or medical intervention, the patient decides against treatment.[2] It is basically informed consent in which, after all the components have been achieved, the patient decides against any treatment. It includes the basic understanding of the facts and implications of not following recommended treatment.[2] These items must be adequately documented in the medical record. Courts have consistently upheld a patient's right to refuse treatment. After proposing what the physician feels is the best treatment for the patient, it is frustrating when the patient refuses care.

One of the most difficult challenges in informed consent is informed consent in another language.[4] Many of the above items are difficult to obtain even with a translator, which is essential to be present for the process. Informed consent is variable among cultures of the world. It is important that the translator not be related to or an acquaintance of the patient because of the potential for conflict of interest and not accurately translating the information.

In summary, informed consent is a process of communication, not a form to be filled out.

There are a number of components that must be discussed. From the process of informed consent comes the concept of informed refusal in which, after the patient is informed of all the components of informed consent, he or she decides against treatment, understanding the risks and benefits of no treatment.[2] When informed consent crosses language barriers, the problems are even greater.[4]

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