Informed Consent
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- It is more than simply getting a patient to sign a written consent form.

- It is a process of communication between the patient and physician that results in the patient’s authorization or agreement to undergo a specific medical intervention.
Physician’s responsibility

In the communications process, the physician providing or performing the treatment or procedure (not a delegated representative), should disclose and discuss with the patient pertinent risks.
CMS requirements for consent

- The responsible practitioner must provide information about treatment and alternatives sufficient to enable the patient to make intelligent choices from among the alternative courses of available treatment for their specific problem.

- Informed consent must be given despite a patient’s anxiety or indecisiveness.
CMS requirements for consent

- Requirements include: Name of patient, and when appropriate, the name of the patient’s legal guardian;
- Name of the hospital;
- An explanation of the nature and purpose of the proposed procedure(s); and
CMS requirements for consent

- Name of the practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon or practitioner.
CMS requirements for consent

“Significant surgical tasks” include:

- Opening and closing,
- Harvesting grafts,
- Dissecting tissue,
- Removing tissue,
- Implanting devices, and
- Altering tissues.
CMS requirements for consent

- Requirement’s further includes: disclosure of risks and consequences of the procedure and the risks and consequences if no treatment is rendered;
- Alternative procedures and treatments;
- Signature of patient or legal guardian;
- Date and time consent is obtained;
- Statement that procedure was explained to patient or legal guardian;
CMS requirements for consent

- Signature of professional person witnessing consent; and
- Name and signature of person who explained the procedure to the patient or legal guardian.
Patient’s role

- The patient should have an opportunity to ask questions to elicit a better understanding of the treatment or procedure, to make an informed decision to proceed or to refuse a particular course of medical intervention.
Ethical obligation

• Obtaining an informed consent is both an ethical obligation and a legal requirement spelled out in statutes and case law in all fifty states.

• Providing the patient with relevant information has long been a physician’s ethical obligation, but the legal concept of informed consent itself is recent.
The first case defining informed consent appeared in the late 1950’s.

Earlier consent cases were based on the tort of battery, under which liability is imposed for unpermitted touching.

Battery claims occasionally occur when treatment is provided without consent.
Legal concept

- Most consent cases center around whether the consent was “informed,” i.e., whether the patient was given sufficient information to make a decision regarding his or her body and health care.

- Thus, unlike claims of battery, informed consent claims are based on the theory of negligence which are generally covered under liability insurance.
Protection from litigation

- Document the communications process.
- Good documentation can serve as evidence in a court of law which would lend credence to how and when the process took place.
- A timely and thorough documentation in the patient’s chart by the physician providing the treatment or procedure can be a strong piece of evidence that the physician engaged the patient in an appropriate discussion.
Protection from litigation

- A well-designed, signed informed consent form may be useful.

- An overly broad or highly detailed form actually can work against the physician.
Protection from litigation

- Forms that serve mainly to satisfy all legal requirements (stating for example, that “all material risks have been explained to me”) may not preclude a patient from asserting that the actual disclosure did not include risks that the patient unfortunately discovered after treatment.
Protection from litigation

- However, listing all of the risks may be difficult for the patient to understand. Any omission from the list will likely be presumed undisclosed.
The patient’s right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice.

The patient should make his or her determination on treatment.

The physician’s obligation is to present medical facts accurately to the patient or to the individual responsible for the patient’s care and to make recommendations for management in accordance with good medical practice.

The physician has an ethical obligation to help the patient make choices with good medical practice.

Rational, informed patients should not be expected to act uniformly, even under similar circumstances, in agreeing to or refusing treatment.
References