Informed Consent

Informed consent is more than simply getting a patient to sign a written consent form. It is a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention.

In the communications process, you, as the physician providing or performing the treatment and/or procedure (not a delegated representative), should disclose and discuss with your patient:

- The patient's diagnosis, if known;
- The nature and purpose of a proposed treatment or procedure;
- The risks and benefits of a proposed treatment or procedure;
- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);
- The risks and benefits of the alternative treatment or procedure; and
- The risks and benefits of not receiving or undergoing a treatment or procedure.

In turn, your patient should have an opportunity to ask questions to elicit a better understanding of the treatment or procedure, so that he or she can make an informed decision to proceed or to refuse a particular course of medical intervention.

This communications process, or a variation thereof, is both an ethical obligation and a legal requirement spelled out in statutes and case law in all 50 states. Patient autonomy is the overarching ethical consideration that forms the core of informed consent. The AMA’s Code of Medical Ethics states that physicians must provide relevant information to their patients. The full disclosure of relevant information to patients is intended to protect each patient’s right to self-determination, bodily integrity, and to protect his or her voluntariness in the healthcare decisionmaking process. See AMA Ethical Opinion 8.08. The Center for Medicare & Medicaid Services (CMS) codifies these ethical considerations. CMS imbues each patient with the right to participate in the development and implementation of his or her care plan. It is the physician’s responsibility to ensure that his or her patients can meaningfully exercise that right by sensitively and respectfully disclosing relevant medical information to each patient (or that patient’s representative) and allowing them to make his or her own determinations about treatment. The process of disclosing relevant medical information is an ethical duty that requires the physician to tailor disclosures to each individual patient.

(For more information about ethical obligations, see the AMA’s Code of Medical Ethics, contained in the AMA PolicyFinder. Providing the patient 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 in the tort of battery, under which liability is imposed for unpermitted touching. Though battery claims occasionally occur when treatment is provided without consent, most consent cases generally 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. That inquiry is colored by two objective considerations: (1) whether a reasonable patient would have considered the information sufficient to
make an informed decision and (2) whether the information provided would be sufficient to the reasonably prudent physician. Because informed consent claims, unlike battery claims, are based in negligence, they generally are covered by liability insurance.

To protect yourself in litigation, in addition to carrying adequate liability insurance, it is important that the communications process itself be documented. Good documentation can serve as evidence in a court of the law that the process indeed took place. A timely and thorough documentation in the patient's chart by the physician providing the treatment and/or performing the procedure can be a strong piece of evidence that the physician engaged the patient in an appropriate discussion. A well-designed, signed informed consent form may also be useful, but an overly broad or highly detailed form actually can work against you. 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. At the other extreme, listing all of the risks may not be wise either. A comprehensive listing will be difficult for the patient to understand and any omission from the list will likely be presumed undisclosed. If you are using a form that contains a list, consider, with your attorney, inserting language indicating that the list is not exclusive (such as "included, but not limited to") before the list begins.

Medicare participating physicians must particularly cognizant of CMS’s requirements for informed consent. Informed consent is a key component woven throughout CMS’s conditions of participation for hospitals treating Medicare beneficiaries. As noted above, CMS codified a patient’s right to make an informed decision by expressly stating that each patient has a right to participate in the development and implementation of his or her care plan. CMS dictates that this right includes the right to make informed decisions, which requires physicians to: inform patients of their health status, involve patients in care planning and treatment, and respect patient requests or refusals of treatment. The right to make informed decisions does not provide patients with the right to demand medically unnecessary or inappropriate care. As previously noted, and further expressed by CMS, properly documenting informed consent for each procedure and treatment is a necessary component of every physician’s daily practice.

Again, this is general knowledge you can use when you ask for further information and advice from qualified attorneys and/or other professional consultants. If you need a referral to a qualified attorney, please contact your state medical society.

AMA Publications

- The JAMA Network
- JAMA (The Journal of the American Medical Association)
- American Medical News
- JAMA Dermatology
- JAMA Facial Plastic Surgery
- JAMA Internal Medicine
- JAMA Neurology
- JAMA Ophthalmology
- JAMA Otolaryngology—Head & Neck Surgery
- JAMA Pediatrics
- JAMA Psychiatry
- JAMA Surgery
- Virtual Mentor - A Forum for Medical Ethics

Copyright 1995- American Medical Association All rights reserved.