

Informed Consent - Principles and Practice

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The concept of informed consent stems from the fundamental ethical principle of the right of self determination. This principle recognizes that patients are autonomous, independent agents with the right to make decisions regarding their well-being without coercion from others. Anesthesiologists must obtain informed consent for anesthesia care. This article will review elements of the informed consent process (Table 1).

Table 1. Elements of Informed Consent Process

Competency and capacity

Discussion with patient

Disclosure of information

Treatments and alternatives

Material risks (common and rare serious risks)

Autonomous authorization

Documentation

Competence and Capacity

The term “competence” refers to a patient’s legal authority to make decisions. Adult patients, generally considered patients who are 18 or older, are presumed legally competent to make health care decisions unless otherwise determined by a Court.

Consent to treat a minor must be given by a parent or legal guardian unless State law

recognizes certain conditions which may qualify as an exception to the general requirement for parental or guardian consent. Minor patients who themselves are parents may be legally authorized to consent to their own health care. A minor who is pregnant and consenting for prenatal care, is married, is otherwise emancipated, or is in the active military may be authorized to consent for health care depending on State law.

“Capacity” refers to a determination made by medical professionals that a patient has the ability to make a specific decision at a specific time. To have capacity, patients must have the ability to understand and reason about their medical conditions, and to appreciate the indications, risks, benefits, and alternatives to proposed treatments. If a patient lacks capacity, consent must be obtained from an authorized decision maker unless an emergency or other exception applies.

These concepts are clarified by the following example: A healthy adult patient who presents for a laparoscopic cholecystectomy is competent and has capacity to consent for the surgical procedure. Five days later, the same patient is readmitted in septic shock from a bowel perforation, is intubated and sedated in the emergency room, and requires an emergency laparotomy. The patient will now not have capacity to consent for the second surgery, requiring the consent discussion to occur between the surgeon and the patient’s authorized decision maker.

Disclosure of information

Obtaining informed consent is an ethical obligation of the practice of medicine and a legal requirement per statute and case law in all 50 States.¹ It requires thoughtful dialogue between physician and patient wherein “sufficient information” is imparted so that a

patient can make an educated decision with respect to the medical treatment proffered. There must be an opportunity for the patient's questions to be honestly addressed. What constitutes "sufficient information"? Twenty-five states and the District of Columbia use the "reasonable person" standard² (i.e., what a reasonable patient would consider pertinent in making an informed decision"), and 23 states use the "professional practice" (i.e., what another physician in the community would disclose under similar circumstances). The laws in the remaining 2 states are vague.³

Specifically, the informed consent discussion should focus on the indications for the proposed treatment, a description of the procedure in terms a layperson can understand, and an explanation of available alternatives. A frank disclosure of material risks of the recommended and alternative treatments is important. Material risks are those that a reasonable person would want to be made aware of before deciding to undergo or reject the recommended therapy. Material risks include those which occur frequently, but have little long term consequence, as well as those that are rare but may result in serious, long term morbidity or mortality. A recent informal survey of anesthesiologists at both private and academic institutions across the country was undertaken to determine commonly disclosed risks of general (Table 2) and regional anesthesia (Table 3). In addition to discussion of risks, benefits, and alternatives, some states require disclosure of the identity of all persons reasonably anticipated to be involved in the patient's anesthetic care.

Table 2. Commonly Disclosed Risks of General Anesthesia

Frequently occurring, minimal impact	Infrequently occurring, severe
<ul style="list-style-type: none">▪ Possible oral or dental damage▪ Sore throat▪ Hoarseness▪ Postoperative nausea/vomiting▪ Drowsiness▪ Urinary retention	<ul style="list-style-type: none">▪ Awareness▪ Postoperative visual loss▪ Aspiration of gastric contents▪ Postobstructive pulmonary edema▪ Organ failure▪ Malignant hyperthermia▪ Drug reactions▪ Failure to recover▪ Coma/death

Table 3. Common Disclosed Risks of Regional Anesthesia

Frequently occurring, minimal impact	Infrequently occurring, severe
<ul style="list-style-type: none">▪ Prolonged numbness▪ Spinal headache▪ Backache▪ Failure of technique	<ul style="list-style-type: none">▪ Bleeding▪ Infection▪ Nerve damage/paralysis▪ Persistent weakness, numbness▪ Seizures▪ Coma/death

Autonomous authorization

Upon completion of a dialogue where indications for the therapy, disclosure of material risks, benefits and alternatives have been considered, and the patient's questions have

been answered, he or she will be positioned to make an informed decision regarding the proposed care. The patient's authorization to proceed with an intended course of treatment is an expression of his/her right of self-determination and is the basis for informed consent.

Documentation

The informed consent process must be documented in the medical record. There are several different methods for documentation, including a handwritten note, a separate preprinted anesthesia consent form (required by some states and liability insurers), an anesthesia section on the preprinted surgical consent form, or new interactive computer programs.

Proponents of the handwritten note believe it is the most accurate way to document the specific discussion held with that particular patient.. The advantage of the preprinted anesthesia consent form is that common risks of all techniques can be clearly detailed in an efficient documentation process, patient specific risks can be added in long hand, and the patient and a witness can sign the form.⁴ Use of the preprinted surgical consent form does not eliminate the need for an anesthesia informed consent discussion by the anesthesiologist. An interactive computer program may provide the best evidence that a meaningful exchange of information has taken place between the patient and physician.

What are the current requirements for informed consent?

Health care organizations must meet the Centers for Medicare & Medicaid Services (CMS) Conditions of Participation (CoP) to participate in the Medicare and Medicaid

programs. In April, 2007, CMS announced revisions to its Hospital Interpretive Guidelines for informed decision-making and informed consent. In the Patients' Rights CoP, (42 CFR §482.13(b)(2)), the interpretive guidelines state: ***“Hospitals must utilize an informed consent process that assures patients or their representatives are given the information and disclosures needed to make an informed decision about whether to consent to a procedure, intervention or type of care that requires consent.”*** The Surgical Services CoP, (42 CFR 482.51 (b)(2)), further clarifies the scope of information to be provided: ***“Typically, this information would include potential short and longer term risks and benefits to the patient of the proposed intervention, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner’s professional judgment. Informed consent must be obtained, and the informed consent form must be placed in the patient’s medical record, prior to surgery, except in the case of emergency surgery.”***

References:

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