

Ethics

Frequent questions on informed consent

The principles of informed consent are well known—patients have the right to make informed decisions about their care, including surgery. The primary purpose of informed consent is to ensure that the patient has the information necessary to make a decision before agreeing to any treatment.

The responsibility for informed consent is the physician's. Informed consent is a dialog between the patient and physician in which the patient learns and understands about the proposed treatment, including the risks, benefits, and alternatives. The patient also has an opportunity to ask questions and agree about what is to be done.

Though these principles may be understood, the details of informed consent raise a lot of questions. *OR Manager* asked David Balfour, an attorney with DiCaro, Coppo & Popcke, APLC, Carlsbad, California, a law firm that specializes in medical and health care law, to respond to frequently asked questions from readers.

Q How critical is the physician's signature on the consent form? We sign the surgery consents with a nurse witness and the patient. This is a convenience and customer service issue for the surgeons. The physician is required to document risks, benefits, and alternatives on the history and physical or dictated note. Do we need to change our process?

Balfour: While the physician's signature is not required on the informed consent form, requiring the physician's signature serves as an important double-check for the facility. The patient and a qualified, competent health care provider must personally interact for the requisite exchange of questions and answers. A physician is required to obtain consent from the patient for a surgical procedure after informing the patient about the procedure.

Informed consent is a process, not a signature on a form. The informed consent discussion cannot be delegated to the staff. Staff can assist in the process by providing educational materials such as pamphlets, brochures, videos, and online materials about the procedure generally (materials provided should be documented). But a physician must conduct the discussion with the patient about the expectations of risks, benefits, and alternatives for the procedure for that specific patient. Inappropriate assurances (or even guarantees) made by staff members may subject the doctor and facility to additional liability based on the inappropriate information given.

Informing the patient

Whatever format the informed consent form takes, it should not be

signed before the physician's discussion with the patient. A patient should be informed verbally, in nontechnical terms, about all of the following:

- a description of treatment procedures/products/devices/medications to be used
- a description of any attendant discomfort and risks to patient that can reasonably be expected from such treatment
- an explanation of any benefits to the patient that can reasonably be expected
- an explanation of any appropriate alternatives to procedures/products/devices/medications that might be advantageous to the patient, and their relative risks and benefits
- an offer to answer any inquiries concerning the treatment involved.

Documenting the consent

The physician should document the consent discussion in notes separate from the consent form. The more ironclad the documentation, the more likely the consent will be confirmed by anyone reviewing the case, including the patient's attorney should anything go wrong unexpectedly. In litigation, the adequacy of a written consent is a factual issue to be determined by a jury, and the mere existence of a signed written informed consent is not conclusive proof that informed consent was given.

Countless surveys and articles relating to medical malpractice actions have shown the majority of lawsuits arise due to poor communication between physicians and patients. The informed consent discussion is one of the most important conversations between doctor and patient and should not be minimized. In both the short and the long runs, improved patient-physician-facility communication minimizes the likelihood of medical errors and liability exposure. In the long run, the surgeons will thank you.

Q Do nurses witness the signature only or give their signature to verify patients' understanding? (Nurses never seem to get this right.)

Balfour: At a minimum, nurses or other care providers witnessing the signature should be confident the patient himself or herself is signing the consent, and the patient is competent to sign. The nurse should make sure the patient is not impaired by medications in agreeing to the procedure. Competency can also relate to age; for example, the nurse should ensure minor patients' consents are signed by the responsible parent(s) or guardian.

While the responsibility for informing the patient and obtaining consent rests with the physician, witnessing the patient's signature on the consent is the optimum time to ensure the patient has had all questions answered about the procedure. While the nurse may not be, the doctor is required to verify the patient's understanding and consent. (Sometimes doctors don't get this right.) The nurse asking, "Has the doctor answered all of your questions about the procedure?" is a good step. If not, the consent process is not complete, and the doctor should be sought out before the surgery to get the questions answered. Nurses should be careful, though, not to offer advice about the risk/benefit calculations; such calculations and advice should be left to the doctors.

The contemporaneous signature of a witness serves 2 purposes. First, it impresses upon the patient the importance of the document the patient is signing. Second, it documents a part of the informed consent process, namely the patient's agreement to undergo the procedure. The facility benefits from the

nurse assuring the patient's comprehension. The nurse is not required to verify the patient's comprehension of and consent to the procedure to protect his or her own liability, but the nurse's doing so helps to protect the facility from liability, both by assuring that the patient has consented and continuing good open communication with the patient.

Q Who can witness an informed consent (family member, surgical team member, housekeeper, etc)? This is a debate among physicians and nurses.

Balfour: Any adult may sign as a witness on the consent form. Given that consent forms are typically predrafted forms with handwritten entries describing the procedure and the name of the physician(s), the form will generally be interpreted in favor of the patient's interpretation and against the interpretation of the facility. For this reason, it is preferred that the witness to a consent be either a noninterested employee of the facility or a family member, friend, or escort of the patient.

Because informed consent is a process, the best person to witness the patient's signing of the informed consent form is the person who has witnessed the most of the informed consent process. If at all possible, it is helpful to have someone who has heard the physician discuss the risks, benefits, and alternatives with the patient.

'Reasonable patient' standard

In some states, the adequacy of the consent is determined using a "reasonable patient" standard. In those states, whether the consent is valid is determined by whether the patient was informed of all a reasonable patient would expect to be told, and in a way a reasonable patient could understand to assess the relative risks and benefits of undergoing the procedure. In these "reasonable patient" states, the physician must explain the procedure using nontechnical terms the patient can understand. In these states, having a family member or friend of the patient witness the consent can help to support the comprehensibility of the information given in the consent process. Inquiry should be made of the family member or friend to ensure all of their questions have been answered as well as those of the patient.

'Reasonable physician' standard

In other states, the standard for determining whether informed consent is appropriate is the "reasonable physician" standard, which looks at whether the physician gave all information a "reasonable physician" would have provided. In these states, it might be preferable to have a witness who is familiar with the process and who might note if all the parts of the procedure were covered in the informed consent discussion.

Failure to advise of risks

The failure to fully and adequately advise of the risks of a surgery to which the patient has consented is generally categorized as negligence. But performing a surgery that the patient has not consented to, or which is substantially different than what was consented to, is battery, an intentional tort. Intentional torts are, by their nature, uninsurable, so malpractice coverage will typically not cover the exposure created. Moreover, in states with malpractice litigation protection statutes, battery will destroy the protections of the statutes for the offending physician.

Without regard to the standard used in your state, prudent practice requires that the patient undergoing this procedure has been fully informed about the procedure and has freely made the choice to proceed, and the informed consent process was witnessed and documented.

Q Should we have separate surgical and anesthesia consent forms?

Balfour: Anesthesiologists should be having a conversation about the risks of anesthesia with the patient apart from the conversation of the risks and benefits from the surgical perspective. While the surgery consent should be obtained prior to the day of surgery, frequently the anesthesiologist's discussion with the patient takes place the same day as surgery. Anesthesia risks should be discussed generally in any discussion of the risks and benefits of surgeries involving anesthesia. Requiring the anesthesiologist to obtain informed consent for the anesthesia specifically is good practice because it helps to ensure that the process happens.

Q In our ambulatory surgery center (ASC), not all physicians have seen the patient in the office and had an informed consent discussion. This is especially true for GI endoscopy and pain management. The ASC staff must then present the informed consent form to the patient and get the signature. Rules do not allow the patient to be brought into the procedure room until the form is signed. So the physician must either come out to have the discussion with the patient, or the rules must be broken to allow the discussion to take place in the procedure room. Either way, this is not the best time to have an informed consent discussion. Do you have any suggestions?

Balfour: A consent obtained in the operating room could be later found invalid. It would at least face severe questioning on review. As with most contracts, the patient might be excused from having signed the form because of the pressure, known legally as duress, of the situation. The surgeon, the surgery team, and the facility could all be viewed as counting on the patient to undergo the procedure, and the patient could not want to "disappoint" them. The patient might fear, for example, that he or she would have to pay for the setup time for the surgeon and the facility if he or she were not to undergo the procedure. The patient's decision to consent to the procedure must be freely made without such pressures.

Consent should be obtained after the surgeon discusses the risks, benefits, and alternatives with the patient, and prior to the patient making the final decision to undergo the procedure. The earlier the consent discussion and the less the pressure during the consent discussion, the better. Given that most of the procedures performed in ASCs are elective, at least in their timing, the facility would be wise to require the informed consent discussion to take place before the patient arrives at the facility on the day of the surgery.

Surgery centers frequently have the referring physician's office complete a surgery scheduling sheet with patient demographics, type of procedure, equipment to be used, etc. This sheet could require physicians' offices to indicate whether the patient has given consent for the procedure, and the surgery center could require a copy of the signed consent to be forwarded to the surgery center before the surgery date.

If the same-day consent is all that is practicable, the surgeon must go out and have the informed consent discussion with the patient before the patient signs the consent. ❖

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