Informed Consent: Substance and Signature

Robert Morton, CPHRM, CPPS, Assistant Vice President, Department of Patient Safety and Risk Management

For decades, consent documents have helped protect physicians against the claims of dissatisfied patients. Times have changed, however, and modern medicine requires a more complex and complete acknowledgment of both the patient's and the physician's rights and responsibilities to each other.

True informed consent is a process of managing a patient's expectations; it is not just a signature on a document. Achieving an accurate diagnosis requires the patient to provide accurate information to the physician. The physician must then provide sufficient information to the patient so that he or she can make a reasonable and informed decision regarding a comprehensive plan for medical or surgical treatment. This physician responsibility cannot be delegated.

A successful exchange of information between the doctor and the patient accomplishes two things. First, when the physician explains diagnoses, treatment alternatives, expected outcomes, and potential risks to the patient, it demonstrates that the physician recognizes the patient's rights and will remain responsive to them. Second, it shifts the decision-making responsibility from the physician alone to a mutual responsibility of both physician and patient. At its best, informed consent should protect and inform the patient and the doctor.

Litigation often results from a discrepancy between the patient's expectations and the outcome of treatment. Informed consent cannot eliminate malpractice claims, but an established rapport between the patient and the physician based on robust exchanges of information can prevent patient disappointment from ripening into a claim.

Physician-Patient Dialogue

Avoid medical jargon when discussing diagnoses, treatment plans, risks, and expected outcomes with the patient. Define and explain medical words and concepts using simple pictures and analogies. If there are alternative treatment options, discuss them in detail. Also, outline the recovery process and the expected short- and long-term effects on the patient.

Identify any uncertainty and risk involved with a specific treatment plan, including the probability factors, if possible. Discuss reasonable assumptions the patient may

make about the treatment plan. Whenever possible, supply reading materials and the consent document for the patient to take home and discuss with his or her family.

Encourage questions. Questions provide a better understanding of the patient's comprehension of the information and facilitate the dialogue between the patient and the physician. If time permits, consider scheduling a second visit with the patient to review the consent form, clarify expectations, and ensure patient comprehension of the proposed treatment—especially with elective procedures.

Documentation

Documentation is another key component of the informed consent process that cannot be entirely delegated to a nurse or another member of the healthcare team. If the doctor-patient discussion proceeds successfully and the patient requests treatment, the doctor is required in some jurisdictions to write a note in the patient's record. Additionally, the consent document must include the patient's name, doctor's name, diagnosis, proposed treatment plan, alternatives, potential risks, complications, and benefits.

To some extent, physicians who use an informed consent document can protect themselves further by including a statement to the effect that the form only covers information that applies generally and that the physician has personally discussed specific factors with the patient. The consent document must be signed and dated by the patient (or the patient's legal guardian or representative). Many consent forms also require a physician signature.

Consent forms should include statements to be signed by the patient and the physician. The patient attests that he or she understands the information in the treatment agreement. The physician attests that he or she has answered all questions fully and believes that the patient/legal representative fully understands the information. These statements help defend against any claim that the patient did not understand the information.

Some states have specific requirements for informed consent forms, procedure-specific disclosures, and legal standards for disclosure of risks. For example, Texas maintains lists of procedures and attendant risks and hazards through the Texas Medical Disclosure Panel. Check your state for requirements.

Informed Consent in Special Situations

The informed consent process for same-day surgery patients may occur in the physician's office before scheduling the procedure. That will allow the patient time to think about the information, ask questions, and make an informed decision.

Hospitalized patients must be informed as far in advance of the procedure as practicable. If time permits in an emergency in which the patient is unable to provide consent, the physician must contact a legally authorized representative to obtain an informed consent. If the nature of the emergency does not permit time to contact a legally authorized representative, consent is implied. Consent may be waived under emergent conditions that threaten life, limb, eyes, and the central nervous system. If the patient is incompetent or otherwise cannot consent, the physician is legally bound to obtain informed consent from the incompetent patient's authorized representative, except in an emergency. This type of consent should be thoroughly documented in the medical record.

Additional Tips and Suggestions

- Develop and use procedure-specific forms that the patient can sign when the informed consent discussion takes place.
- Obtaining consent from the patient after a sedative or sleep-inducing medication is administered is not recommended. However, when a change in the patient's condition requires a change in treatment, secure the patient's consent. Thoroughly document in the medical record the facts and conditions surrounding the need for the revised consent.
- Additions or corrections to the consent form must be dated, timed, and signed by both parties.
- Any member of the healthcare team may sign as a witness to the patient's signature, although this serves only to verify that it was the patient who signed the form. The witness does not obtain consent or verify the patient's competency to give consent.
- A patient's questions or obvious lack of understanding about the procedure should be referred to the attending physician as soon as possible.
- Translate consent forms to the most common non-English languages that you encounter in your practice, and verify that the form is translated correctly.

Patient Safety Measures

Every physician should develop his or her own style and system for the informed consent process, making it easier to avoid omissions and—more importantly—ensuring consistency of application.

Do not speed through the process. Give the patient and the family time to absorb and comprehend the information. Preprinted materials are extremely helpful for patient understanding and will serve as a trigger for other questions.

Assess the patient's level of understanding just before documenting the process. One way of doing this is to ask the patient to repeat back to you his or her understanding of the information you have communicated. This will increase the likelihood that you will be able to manage the patient's expectations effectively.

If you and your patient have completed the informed consent process and your patient declines your recommendations, see our article on "Informed Refusal" for further guidance. You can also contact the Department of Patient Safety and Risk Management for assistance. Contact us at patientsafety@thedoctors.com or (800) 421-2368.