Just Sign Here: Managing Informed Consent

by Jill Callahan Dennis, JD, RHIA

There's more to ensuring the validity of a patient's consent than getting a signature. Is your organization making sure that patients are successfully informed about treatments and procedures? Here's what HIM professionals need to know about this communication process.

Getting a patient's consent-it's so routine, we may not even think about it. But is every patient's consent truly an informed one? If your organization is not taking steps to ensure that patients are giving informed consent, it may be at risk. Here's what you need to know about managing informed consent and some ways to minimize risk.

Sign Here, Please

In admitting and registration areas, in preoperative holding suites, in physician offices, or in special procedure areas, the process of obtaining patients' consent to various treatments and procedures takes place like clockwork.

The process seems simple enough. Staff members from many functional areas obtain patients' signatures on forms. They dutifully witness patient signatures and make sure a signed form is in place before the planned procedure goes forward. That form becomes part of the patient's health information as evidence that an informed consent has been obtained.

Many times, when we refer to obtaining "consent," we are really referring to getting a permit signed by a patient. But there's more to obtaining consent. Getting a consent is a communication process between the health professional and the patient. Unless that process successfully informs the patient about the anticipated treatment or procedure and meets certain requirements, the consent cannot be considered to be an informed one. And that can put the healthcare provider and organization at risk in a variety of ways.

What Are the Risks?

When patients believe they were not adequately informed about a surgical procedure-or, alternatively, that they were not informed at all about the procedure-they can pursue at least two legal options.

Typically, failure to obtain an "informed" consent is considered a type of negligence, and the patient would proceed with a medical malpractice claim against the provider. In this type of case, the patient alleges that the physician failed to provide sufficient information about the procedure and/or its risks or failed to adequately answer the patient's questions.

For a negligence/malpractice claim to succeed, the patient must show that the provider had a duty to adequately inform the patient, that the provider failed to do so, that this failure was the proximate cause of the patient's injury, and that the injury resulted in certain damages.

If, however, the provider failed to obtain any consent prior to the procedure, this would probably result in a claim of battery (which simply means that the provider has touched the patient in a harmful or offensive manner without the patient's consent). In a battery case, there is no need to prove that the provider had (or breached) a duty, or that the provider's actions resulted in damages to the patient.

Patients generally bring informed consent-related actions against their physicians, because the primary duty to obtain informed consent rests with the physician. However, healthcare organizations are often brought into these cases as well, with the patient alleging that the organization failed to have effective mechanisms to protect their patients (e.g., mechanisms to ensure that the patient's informed consent was obtained prior to surgery).

For those reasons, all healthcare organizations should check their processes for ensuring the presence of an informed consent prior to applicable procedures and strengthen those mechanisms where weaknesses are found.

Accreditation standards certainly speak to the need for informed consent. For example, the Joint Commission on Accreditation of Healthcare Organizations' standards manuals for hospitals, long-term care, home care, behavioral healthcare facilities, ambulatory care facilities, and healthcare networks all contain language addressing informed consent. See Standards for Informed Consent, for a summary of informed consent standards in the various standards manuals.

Evidence of informed consent in the patient's medical record is one of the items checked during the Joint Commission's open and closed medical record review. Failure to document the patient's informed consent can result in accreditation deficiencies. See Learn More Online, page 49, for a Web site reference to the Joint Commission's medical record review form.

Failures in the process of obtaining the patient's informed consent have also been a root cause of some sentinel events reported to the Joint Commission. In 1998, the Joint Commission reported that the failure to involve a patient (or family, when appropriate) in the process of identifying the correct surgical site, either during the informed consent process or when marking the intended surgical site, was believed to be one of the root causes of wrong-site surgeries (surgeries done on the wrong side of the patient or on the incorrect body part).1

Waivers and Privileges: Exceptions to the Requirement

There are some exceptions to the general requirement for informed consent. In an emergency, where a physician believes there is no time or chance to obtain an informed consent, he or she may do whatever is necessary to save the patient's life.

Alternatively, the patient may waive the requirement for informed consent. For example, if a patient tells a physician, "I really don't want to know the details; they just upset me. Do what you think is best," then the physician is not required to obtain an informed consent,
as long as the waiver is voluntary and the patient is aware that he or she has the right to
this information.

If a patient is incompetent to make decisions (physically, mentally, or legally), the physician is under no legal obligation to attempt to obtain an informed consent from the patient. However, the physician must obtain the informed consent from the patient's legal guardian or next of kin, whichever is applicable.

Generally, consent must be obtained from a parent or legal guardian prior to the treatment of a minor, unless an exception is provided in state law. Minors are generally considered to be "legally incompetent," but be aware that many state laws address a minor's capacity to consent. These laws may allow a minor to consent once the minor has married, given birth, sought treatment for certain conditions such as substance abuse, or become emancipated.

There are also circumstances in which a court order or a statute can override the requirement for an informed consent. For example, sometimes courts involved in criminal cases will order a specimen to be obtained, even though the patient/accused does not wish to provide it. If a court order or a law requires a procedure to be done, the physician is not required to obtain the patient's informed consent.

Finally, there is also a rather rare exception to the requirement in cases involving "therapeutic privilege." This refers to situations in which the disclosure of information may be harmful to the patient. However, courts view the use of therapeutic privilege with a good deal of skepticism, and this strategy should be used with caution (and careful documentation of the circumstances and other parties consulted).

Before relying on any of these exceptions, it is important to document the reasons that the patient's consent has not been obtained.

Are Your Patients Informed? Six Rules of Thumb

Generally, for a consent obtained by a healthcare provider to be valid, it must meet certain requirements. These requirements vary somewhat from state to state, but generally include the following key points:

1. **The informed consent should be obtained by the person who will perform the procedure.** In other words, the process of communicating the planned procedure/treatment and its risks, benefits, and alternatives should be handled by the person who will do or supervise the procedure. In the case of surgery, it would be the surgeon. Keep in mind that some states and case law permit the physical act of obtaining a signature on the consent form to be delegated to others, as long as the process of informing the patient has already taken place between the patient and physician

2. **The patient must be capable of giving an informed consent.** In other words, the patient must be legally and mentally capable of understanding what is being proposed and making a decision. If the patient has been judged legally incompetent, or because of emergency circumstances is unable to give an informed consent, the guardian or next of kin (designated by state law) acting on the patient's behalf must receive the information and sign the consent. An interesting aspect of this question is whether the otherwise competent patient can understand what's being said-either because of language barriers, hearing impairment, literacy problems, or other issues. Providers must take steps to ensure that patients understand the risks, benefits, and alternatives to the proposed procedure before they obtain the patient's signature. That may require translation services. In areas having large populations of non-English-speaking patients, it may be important to prepare patient educational materials and consent forms in the most common non-English languages. Access to persons competent to use sign language is also a common need

3. **The patient must be free from coercion or undue influence when giving consent.** The consent of a patient who agrees to a termination of pregnancy because her husband threatens her with divorce will likely not be considered valid. Although it is impossible for providers to know all the motives behind every patient's decision-making process, there should certainly be a process to evaluate the consent whenever the provider has reason to believe that coercion or undue influence may be present

4. **The consent should be granted for a specific procedure or treatment.** In other words, if the physician asks for permission to do "abdominal surgery," it would be difficult to argue that the patient is giving a truly informed consent. However, if the diagnosis is uncertain and exploratory surgery is required, the patient may indeed grant valid consent for the physician to do exploratory surgery and to proceed with more extensive surgery if, in the surgeon's opinion, it is warranted (e.g., where frozen section lab results indicate cancer). The key issue is whether the patient has been adequately informed of this possibility and agrees to proceed

5. **The patient must be sufficiently informed.** State laws provide some guidance on the standard to be used in judging questions as to whether the patient was given enough information. In some states, it is within the caregiver's discretion to decide whether enough information has been given. That is considered a "reasonable physician" standard. In other states, a "reasonable man" or "layperson" standard will be used. But generally, the standards require that the patient receive information about:

    - the **nature and purpose** of the proposed procedure
    - the **risks and benefits** of the proposed treatment
    - any **reasonable alternatives** to this procedure

- any **risks of refusing** the proposed procedure or treatment

6. **The patient is given the chance to ask questions and get answers.** This is a fairly common problem faced by healthcare facility staff trying to obtain the patient's signature on the consent form after the physician has already discussed the procedure with the patient. The patient may have been reluctant to pose certain questions to the physician, or may not have had time to think through all his or her questions, and staff are then left with a dilemma: does the fact that the patient still has questions mean that he or she has not been adequately informed? Policies should define how far staff should go, if at all, in answering questions, or whether they should immediately contact the physician so the patient may speak with him or her directly. Probably most facilities take an intermediate approach: if the question is not really related to the decision-making process, e.g., the patient merely wants to know about how long the procedure will last, staff may attempt to answer without questioning the validity of the consent. However, if in doubt, the physician should be involved. Otherwise, staff may find themselves involved in a post-procedure suit alleging a lack of informed consent

No Security Blanket: Is a Signed Consent Form Good Enough?

A written consent form does offer some evidence that the patient got certain information about the procedure before it was done. But in many cases, such a form does not offer the blanket protections that we assume it does.

For example, most consent forms are rather general and don't outline the actual conversation that took place between the patient and physician. So who is to say that the information given during the conversation was adequate? Patients can allege that they were confused, intimidated, not given time to ask questions, or not given information in an understandable way.

Procedure-specific consent forms can help somewhat, as they outline the actual expected risks, benefits, and alternatives to particular surgical procedures. But providing this information often results in a multi-page, complicated form written in college-level language. Using lay terminology is one way to avoid comprehension problems.

Many physicians and some surgical professional associations have begun to advocate the use of supplementary teaching tools to help patients understand the information given to them. For example, a surgeon may offer pamphlets on particular procedures and then sit down with a patient afterwards to answer questions. There are even multimedia computer-based teaching tools where patients' progress through the program is logged as evidence that they completed it (and associated post-tests) successfully. These don't, however, replace the need for a face-to-face communication between the patient and physician-but they can make that communication more successful.

Documentation of the informed consent discussion is also important for the physician to include in the patient's health information. Many courts find a contemporaneous progress note or history and physical (H&P) exam report that includes mention of the informed consent discussion to be much more convincing evidence that a conversation took place than the patient's signature on a standardized form.

The Role of the HIM Professional

The role of the healthcare organization with regard to informed consent is a limited one. The organization should simply have a system in place to verify that the physician has obtained an informed consent from the patient when one is required. The role of HIM professionals in this process is limited, as well, but it can be extremely important.

HIM professionals should not be involved in trying to answer patients' questions so that an informed consent can be obtained. We can, however, be of great assistance in analyzing physicians' success in complying with the requirements for informed consent. Many organizations include an analysis of informed consent-related documentation in their surgical case reviews or open and/or closed medical record reviews.

HIM professionals should also be aware that documentation of the informed consent process is an important factor in surveys by the Joint Commission. In fact, surveyors look specifically for evidence of informed consent as part of their open and closed medical record review. A copy of the survey tool for hospitals can be found on the Joint Commission Web site at www.jcaho.org.

HIM staff can analyze progress note and H&P documentation to determine whether the physician has documented his or her conversation with the patient to obtain consent. HIM staff can also review the signed consent forms for irregularities, such as a spouse's signature instead of the patient's when there is no evidence of incapacity on the part of the patient.

We also have a role to play in designing consent forms that contribute to the patient's understanding. For example, the use of lay language, whenever possible, can help patients better understand what they are signing. Including sufficient blank fill-in spaces for physicians to use in documenting the specific risks and benefits to the patient or assisting the medical staff in developing procedure-specific consent forms with this information pre-printed (with space available to document patient-specific issues) can be helpful in promoting patient understanding.

We can also help to ensure that consent forms address the particular needs of our patient population with respect to language barriers. Our patient demographics may indicate the need for consent form translations to the most commonly used non-English languages. If our medical staff often relies on translators for the informed consent discussion, we can assist in arranging for forms in the needed languages. We can also assist in providing confidentiality training to employees or contractors involved in verbal translations.

Informed consent is an important process, and weaknesses in that process can lead to patient harm and potential liability. Understanding the general requirements, any specific state requirements, and the degree to which an organization's documentation shows compliance with those requirements will enable HIM professionals to provide an important and valuable service to their organizations and its patients

Standards for Informed Consent

What do the Joint Commission standards say on informed consent? These resources offer guidelines for different settings:

- Comprehensive Accreditation Manual for Ambulatory Care 2000-2001-RI.1.2.2, TX.2.1, TX.5.2, TX.5.2.1
- Comprehensive Accreditation Manual for Behavioral Health Care 1999-2000-RI.1.2.2, RI.2.2, TX.3.2.1, TX.6.2
- Comprehensive Accreditation Manual for Health Care Networks 1998-2000-RI.1.3
- Comprehensive Accreditation Manual for Home Care 1999-2000-RI.1.1.1, IM.9.19
- Comprehensive Accreditation Manual for Hospitals: The Official Handbook-RI.1.2.1, TX.2.2, TX.5.2, TX.5.2.1, TX.5.2.2
- Comprehensive Accreditation Manual for Long-Term Care 2000-2001-RI.2.18, RI.2.21, RI.3, RI.3.1, PE.4.1.1, IM.7.2.10, TX.13.1

For detailed information, visit the Joint Commission Web site at www.jcaho.org and go to the "standards clarification" page.

Learn More Online

Visit these Web sites to learn more about informed consent:

www.informedconsent.org-An Illinois physician's Web page seeking to raise patients' awareness of their rights in consenting to medical procedures. Includes sample consent forms and ideas on legislation to improve the process for obtaining informed consent

http://cancertrials.nci.nih.gov/researchers/safeguards/consent/oprr.html-Informed consent materials for National Cancer Institute Clinical Trials. This site includes NCI recommendations, sample consent forms, and templates

www.informsoftware.com-This company is an example of software for physicians-in this case, plastic surgeons-to use in educating patients about procedures and obtaining informed consent

www.jcaho.org-Includes sample form used for open and closed medical record review by Joint Commission surveyors containing questions about documented evidence of informed consent

Note

1. "Lessons Learned: Wrong Site Surgery." *Joint Commission Sentinel Event Alert 6*, August 28, 1998.

References

Abdelhak, Mervat et al. *Health Information: Management of a Strategic Resource*. Philadelphia: W.B. Saunders Company, 1996, pp. 386-387.

American Society for Healthcare Risk Management. *Informed Consent Toolkit.* Chicago: ASHRM, 2000.

Joint Commission on Accreditation of Healthcare Organizations. *Comprehensive Accreditation Manual for Hospitals*, 2000. Oak Brook Terrace: Joint Commission, 1999

Jill Callahan Dennis *is a principal with HealthRisk Advantage in Parker, CO, a member of the Journal of AHIMA Editorial Advisory Board, and author of Privacy and Confidentiality of Health Information. She can be reached at jdennis@healthriskadvantage.com.*

Article citation:
Callahan Dennis, Jill. "Just Sign Here: Managing Informed Consent." *Journal of AHIMA* 71, no.10 (2000): 46-49.
