



INFORMED CONSENT: GENERAL RISK MANAGEMENT STRATEGIES

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Introduction

Informed consent is an essential part of patient-centric care. Patients have the right to make decisions about their own body; and informed consent is the process by which patients are given the information necessary to make an informed choice about their health care.

From a risk management perspective, there are two important elements in the informed consent process: (1) communication between the physician and the patient, with the physician giving the patient appropriate information so that the patient understands the options for care and can make an informed decision regarding treatment; and (2) appropriate documentation. Informed consent is not just obtaining a signature on a form.

This article focuses on treatment that requires a patient's express written consent. It describes legal and regulatory requirements regarding informed consent, and also provides practical risk management tips for obtaining informed consent. This is a general discussion about basic informed consent matters. Information about other specific topics, such as obtaining informed consent for minors or incapacitated adults, may be discussed in future postings on the Fund's LinkedIn site, as described at the end of this article.

Please note that as used in this article, "treatment" includes tests, surgeries, procedures, and other care.

Wisconsin Law Regarding Informed Consent

Wisconsin physicians have a statutory obligation to obtain a patient's informed consent. The informed consent law, which was revised in 2013 (Wis. Stats. §448.30), has several key elements:

- It sets forth a "reasonable physician" standard for what information should be provided to the patient, which requires disclosure only of information that a reasonable physician in the same or similar medical specialty would know and disclose under the circumstances.
- §448.30 says that the patient only needs to be informed about "reasonable" alternate medical modes of treatment, not about "all" viable alternate modes of treatment.
- The statute does not require disclosure of information about modes of treatment for any condition that is not included in the physician's diagnosis at the time that the patient is informed.
- It also does not require disclosure of:
 - Detailed technical information that a patient would probably not understand.
 - Extremely remote possibilities that might falsely or detrimentally alarm the patient.
 - Risks that are apparent or known to the patient.
 - Information in emergencies where failure to provide treatment would be more harmful to the patient than treatment.
 - Information in cases where the patient is incapable of consenting.

The statute was changed in response to the Wisconsin Supreme Court's 2012 decision in *Jandre v. Wisconsin Injured Patients and Families Compensation Fund*, 340 Wis.2d 31 (WI Supreme Ct., 2012). In *Jandre*, the emergency room physician considered stroke in her differential diagnosis, but ultimately ruled out stroke after performing various tests and diagnosed Bell's palsy. The court used a "reasonable patient" standard and held that the physician was required to disclose information that would enable a reasonable person to make an intelligent decision with respect to choices involving diagnosis, not just treatment. The court therefore ruled that the physician should have told the patient that she could have a carotid ultrasound to test for stroke, even though the physician had already diagnosed Bell's palsy. It said that the physician should disclose information about tests and treatments for conditions that were consistent with the patient's symptoms, even if the physician had ruled out those conditions. The 2013 revised statute relieved physicians of the burdensome duty that they would have had under *Jandre*.

Other Regulatory Requirements Regarding Informed Consent

In addition to Wisconsin State law, providers should be aware of other regulations regarding informed consent. For example, the Joint Commission (previously the Joint Commission on Accreditation of Healthcare Organizations) has accreditation standards for healthcare facilities involving informed consent. One such standard provides that hospitals must establish policies that describe which procedures, treatment, care, or services require informed consent.

In addition, CMS (Centers for Medicare & Medicaid Services) has Conditions of Participation and Interpretive Guidelines for healthcare entities regarding informed consent. The CMS requirements deal with: hospital policies that should be in place for informed consent; what should be discussed during the informed consent process; and what should be contained in the informed consent form. For example, CMS says that the hospital's policy should describe who may obtain consent; when a patient's representative may provide consent; and circumstances when no consent is required, such as emergencies. CMS also states that a properly executed informed consent form should be specific to the patient and should contain at a minimum:

- The name of the specific procedure or type of treatment for which consent is being given.
- The name of the responsible practitioner who will perform the procedure or administer the treatment.
- A statement that the procedure or treatment, including anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal representative.
- The signature of the patient or patient's legal representative.
- The date and time that the form is signed by the patient or patient's legal representative.

Risk Management Tips Regarding Informed Consent

The purpose of informed consent is to give the patient an understanding of what is involved in the proposed treatment, so that the patient can make an informed decision about their health care. This requires physician-patient communication and discussion, not simply obtaining a signature on a form. Keeping the purpose of informed consent in mind, we now address some common questions, and discuss risk management practices that providers could use.

1. What type of procedures require written informed consent?

Healthcare facilities typically develop their own list of surgeries, procedures, or other treatment situations where informed consent is needed. In general, though, the type of treatments that require informed consent may include:

- Surgical procedures.
- Invasive procedures, including invasive diagnostic tests such as lumbar puncture (spinal tap).
- Non-invasive procedures that could present significant risk to the patient, such as cardiac stress tests.
- Radiation or chemotherapy.

2. Who should obtain informed consent?

In general, the physician who is administering the treatment should obtain informed consent. The Wisconsin statute states that a physician who treats a patient shall inform the patient about reasonable alternate medical modes of treatment and about the benefits and risks of those treatments. The American Medical Association has said that the physician, not a delegated representative, should discuss informed consent with the patient. And even if a hospital has developed a form that is used as part of the process, informed consent requires dialogue between the physician and the patient, not discussion with a different type of provider such as a nurse.

3. What should be included in the discussion about informed consent?

In order for the patient to be an informed participant in the healthcare decision making process, a discussion about consent should generally include the following items:

- Nature and purpose of the proposed treatment.
- Relevant risks and benefits of the proposed treatment, customized for the patient, including likelihood of achieving the care plan's or patient's goals.
 - Wisconsin's "reasonable physician" standard only requires disclosure of information that a reasonable physician in the same specialty would disclose under the same circumstances.
 - In Wisconsin, a physician is not required to disclose extremely remote possibilities that might falsely or detrimentally alarm the patient.
- Reasonable alternatives to the proposed treatment, regardless of the cost or whether covered by insurance, and risks and benefits associated with those alternatives.
- Risks and benefits of not having treatment.
- Opportunity for the patient to ask questions and have them answered in a way that is understandable to the patient.
- Assessment of the patient's understanding.
- Patient's agreement to treatment.

In explaining these elements, physicians should keep in mind that many patients have limited "health literacy", and that their comprehension may also be clouded by anxiety about their condition and the proposed treatment. However, physicians can take steps like the following to improve the process of informed consent:

- Minimize use of medical jargon and medical terms.
- Use clear, simple, everyday language where possible.
- Use decision aids such as diagrams, 3-D models, audiovisual aids, and interactive media.
- Provide a qualified medical interpreter if needed because of language barriers.
- Encourage the patient to ask questions.
- Use the "teach back" method, asking the patient to describe in their own words the proposed treatment and potential risks, to assess the patient's comprehension.

4. What should be included in the informed consent form signed by the patient?

The informed consent form that is signed by the patient serves to acknowledge the patient's conversation with the physician. Basic or standard templates need to be individualized for the specific patient. In general, the informed consent form should include the following:

- The name and nature of the treatment, including the side of the body or digit if appropriate.
- The specific risks associated with the treatment. Consider saying that the risks "include" x, y, and z, or that "common" complications are x, y, and z, to prevent a plaintiff from saying that if a risk was not listed it was not discussed.
- A boilerplate statement saying that the treatment was explained, that the patient had the opportunity to ask questions about complications and alternatives, that the patient has read and understood the form, and that the patient consents to the treatment.
- The signature of the patient or patient's representative, and the date and time that consent was obtained.
- The name and signature of the physician who obtained consent.
- The form should use simple language and avoid medical jargon wherever possible.

5. What should be included in the physician's note in the medical record?

It is prudent risk management for the physician to make a note in the chart documenting the informed consent discussion, in addition to obtaining a form signed by the patient. Writing such a note reinforces that informed consent is a communication process, minimizes the possibility that the physician will simply rely on a signature on a form, and could be helpful if the patient brings a claim down the road.

The physician's note could be fairly simple, however, particularly if the informed consent form signed by the patient is made part of the record. As a risk management matter, the physician's note should mention:

- The specific risks that were discussed, either by referring to the informed consent form or by listing them, possibly saying that the risks "included" x, y, and z, to prevent a plaintiff from saying that if a risk was not listed it was not disclosed.
- That the patient said that they understood the risks, or demonstrated an appreciation of the risks.
- That the patient agreed to the treatment.
- The note should also mention any individuals besides the patient who were present, such as family members or a guardian.

6. What risk management measures should a hospital or other facility implement regarding informed consent?

Hospitals and other facilities could utilize risk management measures such as the following to address informed consent:

- Have a written policy that describes: what treatment and procedures require informed consent; substituted consent, if the patient is unable or incompetent to consent; interventions for patients with limited health literacy, English proficiency, or visual or hearing impairments; and the documentation and verification process.
- Check the hospital's policy for compliance with Joint Commission, CMS, and other applicable guidelines or requirements.
- Simplify the content, language, and length of informed consent documents and patient educational material.
- Educate providers that informed consent is a process of effective communication between the provider and the patient, not just a signature on a form.

Conclusion

Informed consent is a process. The best risk management tools for obtaining informed consent and avoiding potential liability are clear effective communication and appropriate documentation.

Disclaimer: This article should not be considered to be legal advice or a statement about the applicable standard of care. It simply provides risk management guidance regarding informed consent.

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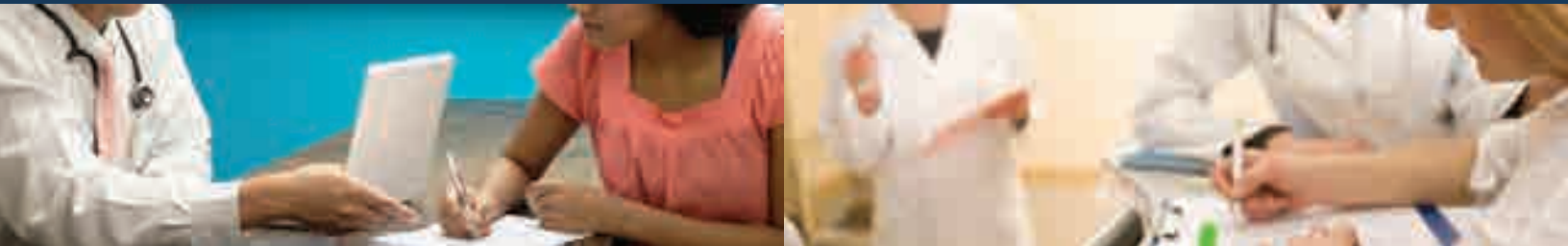
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