Healthcare

ALERTBULLETIN®

A Risk Management Update | 2021 Issue 3

Informed Consent and Refusal: A Guide to the Fundamentals

Informed consent (IC) is a two-way educational and communication process intended to prevent patients from being treated without their permission and understanding. By asking questions and obtaining information about proposed treatments or interventions – especially invasive procedures carrying some possibility of harm – patients become aware of potential benefits, risks and alternatives prior to authorizing care. The IC process is a legal and ethical obligation, serving to enhance decision-making and protect both parties.

The concept of informed consent was first articulated in 1914 by Justice Benjamin Cardozo, who stated that "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages."* This legal doctrine was bolstered by the federal Patient Self-Determination Act of 1990, which confirmed that all adult patients with decision-making capacity have the right to make an informed decision as to whether or not to proceed with a recommended procedure or treatment.

Physicians and other healthcare providers who treat a patient without his or her documented consent may be subject to litigation for battery, defined as unauthorized touching and intentional contact with another person's body, as well as exposure to medical malpractice claims alleging lack of informed consent.

Included in the doctrine of informed consent is the concept of *informed refusal*, which may arise when a patient declines a recommended treatment or procedure. If the refusal of treatment imperils the health of the patient, who then alleges that the decision was made without proper understanding of its foreseeable consequences, the situation may result in litigation. To avoid such lawsuits, healthcare providers should conduct documented informed refusal discussions with patients who reject their treatment recommendations. (See page 4.)

To help healthcare providers and organizations minimize potential conflict and liabilities associated with consent requirements, this *AlertBulletin*® addresses the informed consent and informed refusal process, which includes the provider-patient discussion, patient education, written or spoken confirmation of consent or refusal, and additional documentation. In addition, a sidebar on page 3 contains practical tips for obtaining IC in special circumstances, including emergency situations and the treatment of pediatric, adolescent or cognitively impaired patients.

Quick Links

- Informed Consent, from the American Medical Association.
- Informed Consent, from the National Telehealth Policy Resource Center.
- Informed Consent FAQs, from the Office for Human Research Protections, U.S. Department of Health & Human Services.
- "Informed Consent: More Than Getting a Signature." *Quick Safety*, February 2016, Issue 21. Published by the Joint Commission.
- "Making Informed Consent an Informed Choice: Training for Health Care Professionals," from the Agency for Healthcare Research and Quality.

* *Schoendorff v. Society of New York Hosp.*, 105 N.E. 92, 93 (N.Y. 1914).

Major Elements of an IC Discussion

State legislation generally establishes the framework to guide consent discussions between patients and their physicians or other healthcare providers. Some state laws address the general concept of informed consent, while others focus on certain conditions or procedures, such as the extensive Texas Medical Disclosure Panel, which specifies the medical and surgical risks that must be disclosed by state healthcare providers. Although laws and regulations vary, most states require that patients be given sufficient information on three major subjects:

1. **Nature of the proposed care**, including a description of the procedure or therapy, as well as the medical rationale, anticipated benefits and prognosis.
2. **Alternatives to the proposed treatment,** including an explanation of the risks and benefits associated with the alternatives, as well as reasons that the recommended care is preferable to other options, such as specialty referral or no treatment.
3. **Foreseeable risks,** including potential complications of the proposed treatment and probable consequences of refusing it. As with the discussion of alternative treatments, the list of risks need not be all-inclusive, but it should be reasonably thorough, reflecting the patient's overall health status and comorbidities.

In addition, if medical residents, interns, fellows or medical supply vendors will be present at and/or participating in a proposed surgery or procedure, their presence and roles should be disclosed to the patient, included in the IC discussion and documented in the patient healthcare information record.

Following the educational component of the consent discussion, patients should be asked whether they have any questions about the proposed treatment or any other information given to them. Both questions and answers should be noted in the patient healthcare information record.

Documentation Requirements

The IC process must be carefully documented. Many practitioners utilize a standard form, signed and dated by the patient, to memorialize the consent discussion. (A sample IC form is available on page 82 of "Risk Management Strategies for the Physician Office" from CNA Insurance.)

While a signed IC form – preferably supplemented by a progress note detailing the informed consent discussion – provides optimal legal defensibility in the event of a later claim, the consent process also may be conducted in spoken form. In such cases, it is sound practice for the provider to write a progress note about major steps in the process, including content of the IC discussion, questions asked and answers given, names of staff and/or family members present, educational materials provided, and whether the patient agreed to or declined the recommended treatment.

A Note About Delegation

The IC process is a non-delegable duty owed to the patient by the healthcare provider who will perform the proposed treatment or procedure. While nurses and other healthcare staff may witness a patient signature on a consent form, they are not permitted to conduct the consent discussion. IC rules vary regarding nurse practitioners, certified nurse midwives, certified registered nurse anesthetists and other non-physician providers. Refer to state statutes and regulations, as well as professional licensing board guidelines and ethical opinions, for specific guidance on the IC process in these cases.

IC Compliance Tips

The following strategies can help enhance the IC process and reduce associated liability exposure:

- **Draft a standard consent form** that addresses the three primary subjects mentioned at left, modifying it, as necessary, to reflect the complexity and degree of risk of the proposed procedure or treatment.
- **Consider translating standard consent forms** into commonly spoken foreign languages.
- **Tailor discussions and forms to the health literacy level of each patient,** avoiding abstruse medical terminology to the extent possible and defining any technical terms that must be used.
- **Have a staff member present** during the discussion to serve as witness.
- **Utilize brochures, visual aids, online resources and other educational tools** as needed to clarify and reinforce major messages, and document the use of these materials in a progress note.
- **If necessary, use a qualified interpreter,** noting the translator's name, address and telephone number in the patient healthcare information record. Relatives should not serve as interpreters unless the clinical situation is emergent and a qualified translator is unavailable. In that event, document the reason for utilizing a family member and the patient's consent to do so.
- **Ask patients to describe the proposed plan of treatment in their own words,** in order to confirm their understanding of the information.

Obtaining Informed Consent Under Special Circumstances

Under certain circumstances – such as when the patient is a minor, is cognitively impaired or is undergoing a life-threatening emergency – the process of obtaining informed consent (IC) becomes more complex. In such situations, risk management representatives and legal counsel should be consulted regarding relevant state statutes and regulations, and their input should be documented in the patient's healthcare information record, together with other relevant medical and treatment details.

Pediatric patients. Before rendering treatment to an unemancipated minor, providers must first obtain the IC of a parent or legal guardian. Adult siblings, grandparents and other adult caretakers are generally authorized to provide consent only if they have been granted legal guardianship by the court. If a parent or legal guardian cannot be contacted by telephone, determine the degree of urgency as indicated by presenting signs and symptoms, and then decide whether to proceed immediately or defer treatment until proper consent can be obtained. Document the factors taken into consideration in the patient healthcare information record.

Adolescents. Minors generally cannot consent to their own treatment unless they have been declared emancipated by the court or determined to be emancipated pursuant to state law, e.g., legally married, pregnant or seeking treatment for possible pregnancy, or a parent of a child. If an unemancipated adolescent presents for care and is unaccompanied by a parent or legal guardian, the following steps can help minimize potential liability exposure:

- **Make a reasonable effort to contact a parent or legal guardian.** Document all such attempts – whether made by telephone, text message, email or other means – in the patient healthcare information record.
- **If no parent or legal guardian can be contacted immediately, defer routine treatment** until a parent or guardian has been informed of the patient's situation and has properly authorized care.
- **If immediate intervention is warranted due to traumatic injury or other emergent conditions, provide necessary care to the patient** while continuing efforts to contact the parent or guardian. The patient healthcare information record should include the rationale for proceeding with emergency care, as well as ongoing efforts to obtain proper authorization.

Cognitively impaired patients. For patients to grant their informed consent to or refusal of treatment, they must have the capacity to comprehend the relevant issues. Therefore, if there is reason to doubt a patient's decision-making capability, it is the responsibility of the provider to assess his or her capacity in this area. Patients who can respond cogently to the following three requests are generally considered capable of giving consent to medical treatment:

- **Describe the reason for your visit/admission to the facility,** including major symptoms and concerns.
- **In your own words, repeat back what we have discussed** about your condition and treatment needs.
- **Tell me a little about yourself,** such as your age, birth date, address and name of an emergency contact person.

Emergency situations. States generally recognize special circumstances where delaying treatment to obtain IC may be detrimental, such as an emergency situation when the patient is unable to give consent and efforts to contact a family member or guardian have been unsuccessful. In addition, the IC process can be modified if, in the physician's judgment, full disclosure of risks would have a serious adverse effect on the patient or the therapeutic process, such as a depressed patient who potentially could become actively suicidal if given too much information during a mental health crisis.

Special cases such as these may present a high degree of both stress and risk for healthcare providers. For this reason, facilities and practices should hold regular training sessions about the IC process, with due attention paid to consent issues involving patients who are minors, are cognitively impaired and/or are experiencing a life-threatening emergency.

Informed Refusal Strategies

As noted earlier, every adult patient with decision-making capacity has the legal right to decline treatment recommendations. At the same time, the physician or other healthcare provider is responsible for clearly explaining the reasons for pursuing the recommended course of care, as well as the potential consequences of not doing so. Patients who experience serious injury after refusing care may later assert that their provider was negligent in failing to fully disclose the risks of forgoing treatment.

The following risk control measures, adapted to the unique needs and circumstances of individual practices or facilities, can help healthcare providers and organizations reduce liability exposure relating to patients' refusal of treatment:

- **Create a standard informed refusal form** that accompanies and documents the provider-patient discussion. (See sample language at right, which should be modified as necessary.)
- **Inform the patient that refusal of treatment may affect progression and treatment of other medical conditions,** and note this discussion in the patient healthcare information record.
- **Continue to examine and treat the patient for the duration of the provider-patient relationship,** periodically noting in the healthcare information record that the patient continues to decline the recommended treatment and is aware of continued risks associated with this refusal.

Informed consent is more than a form or formality: it is a cornerstone of the relationship between providers and patients. By implementing a sound informed consent and refusal process, healthcare providers and organizations help ensure that patients are consulted, their questions answered, and their rights and dignity respected, thus minimizing the possibility of subsequent complaints and litigation.

Sample Informed Refusal Language

1. I have been advised by my physician/healthcare provider, *(insert name)*, that the following procedure/treatment should be performed upon me: *(insert name of procedure/treatment)*.
2. My physician/provider has explained the following points to me in language that I understand:
   a. The **nature** of the recommended procedure/treatment.
   b. The **purpose of** and **need for** the recommended procedure/treatment.
   c. The **possible alternatives** to the recommended procedure/treatment, which I similarly refuse.
   d. The **probable consequences of not proceeding** with the recommended procedure/treatment and/or alternatives.
3. I have read the following educational materials provided to me: *(list materials, if applicable)*.
4. My reason for refusal is as follows: _____ .
5. I personally assume the risks and consequences of my refusal, and release myself, my heirs, executors, administrators or personal representatives, as well as the physicians/healthcare providers who have been consulted in my case and *(insert name of healthcare organization)*, its officers, agents and employees, from any and all liability for ill effects that may result from my refusal to consent to the performance of the proposed procedure(s)/treatment(s).
6. I acknowledge that I have read this document in its entirety and that I fully understand it: _____ .

Did someone forward this newsletter to you? If you would like to receive future issues of *AlertBulletin*® by email, please register for a complimentary subscription at go.cna.com/HCsubscribe.

For more information, please call us at 888-288-3534 or visit www.nso.com or www.hpso.com.