PATIENT SAFETY & RISK SOLUTIONS

GUIDELINE

Risk Management Strategies for Informed Consent

MedPro Group

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INTRODUCTION

All too often, the concept of informed patient consent is mistakenly viewed as a rote process by which practitioners obtain patient signatures on template forms or make notes in patient health records. This oversimplification mischaracterizes the spirit of informed consent. Further, it fails to acknowledge the benefits available to practitioners and their patients when true informed consent is obtained.

This guideline provides a short overview of the principles underlying the concept of informed consent, followed by a series of practical practice pointers regarding informed consent issues.

BACKGROUND

The history of American jurisprudence is replete with cases that address a citizen's right to make decisions about his or her healthcare. The majority of these rulings supports the premise that competent adults can determine the course of their own care.

This freedom is so inviolable that many such rulings also protect a patient's right to refuse care, even when refusal may cause injury or death. Informed consent is a key component to protecting this fundamental right.

Today, most Americans know that they have the right to fully participate in their healthcare decisions.[1] When interacting with healthcare practitioners, patients should ask questions and voice their concerns. This dialogue prevents misunderstandings about treatment recommendations and supports patients' ability to provide knowledgeable consent.

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Patients, once fully informed by providers, are able to weigh various treatment options against their own cultural beliefs and values to make informed decisions.

OBJECTIVES

The objectives of this guideline are to:

- Describe the framework for providing informed consent, including the scope, process, and essential information
- Discuss risk management considerations for informed consent in special populations

[1] Some exceptions may apply related to emergencies, safety of self and others, mental health issues, etc.

- Review the ways in which new healthcare technologies, such as telemedicine and robotic surgery, affect the informed consent process
- Discuss the process of informed refusal and important documentation considerations
- Review legal and professional aspects in providing informed consent
- Suggest health literacy recommendations for informed consent documents and educational materials

THE FRAMEWORK FOR INFORMED CONSENT

The Scope of Informed Consent

The thoroughness and complexity of the informed consent process will depend on the type of procedure or treatment involved. Minor procedures — such as the removal of a minor skin lesion or the filling of caries — may require only a simple discussion of risks. However, as procedures become more complex or have a greater degree of risk, the consent process should be more comprehensive.

Healthcare providers should individually tailor the consent process to each patient and his/her specific condition or situation. Patients should have ample time to ask questions, voice concerns, and clarify information. Additionally, providers should always document the informed consent process in patient health records, regardless of the complexity of the procedure.

The Process of Informed Consent

The informed consent process is a nondelegable duty that the healthcare provider must perform through discussions with the patient. Staff members may also participate in the

Surgery and Anesthesia

Healthcare organizations providing surgical treatments should carefully consider whether to have separate informed consent processes for surgery and anesthesia. The American Society of Anesthesiologists recommends that healthcare institutions consider the varying viewpoints on separate consent processes and determine which method will best meet the needs of their patient populations.[1]

The American Association of Nurse Anesthetists recommends separate surgical and anesthesia consent processes and notes that "Combining the informed consent for anesthesia with the procedural or surgical consent deemphasizes anesthesia's role and may increase exposure to lawsuits. The anesthesia professional is most qualified to discuss with the patient the risks and benefits for each type of anesthesia/pain management modality, perioperative management of preexisting comorbid conditions, and patient preferences."[2]

informed consent process by providing general educational information and reinforcing specific information that the healthcare provider has given to the patient.

A common misperception among providers is that a signed consent form demonstrates consent. It does not. By itself, a consent form may not verify that true consent was obtained. Rather, it merely documents one phase of the informed consent process. For the patient to be truly "informed," he or she must understand the information that the healthcare provider has disclosed.

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When determining how to effectively support patient comprehension, practitioners should consider:

- The patient's current understanding of his/her condition and the proposed treatment plan
- The patient's overall capacity to understand
- Cultural considerations that might affect the patient's decision-making
- Any language barriers that could impede the consent process

The Essentials of Informed Consent

Although the information provided during informed consent should be tailored to each individual patient and his/her clinical condition, some basic elements include:

- The patient's name
- The name of the hospital or healthcare practice
- The treatment/procedure name (both in medical and layman's terms)
- A description of the procedure
- The names of all practitioners performing the treatment/procedure and the significant tasks of each
- A statement that the procedure was explained to the patient (or patient's guardian)
- The name and signature of the person who explained the procedure to the patient or guardian
- The risks and benefits of the proposed treatment/procedure

- Alternatives to the proposed treatment/procedure, including doing nothing
- The patient's signature memorializing understanding and providing consent
- The date and time consent is obtained
- A witness signature

When determining which treatment or procedural risks should be disclosed to the patient, the healthcare provider should evaluate which risks are important or would affect the patient's decision to accept or reject the treatment/procedure.

INFORMED CONSENT IN SPECIAL POPULATIONS

The right to refuse or consent to healthcare treatment generally applies to competent adults. However, healthcare organizations also should be cognizant of special populations that might require a different approach to informed consent, such as minors and people who have cognitive impairments or limitations.

Informed Consent in Minor Patients

In the United States, consent for treatment of minors in nonemergency situations is addressed in state laws. As noted in guidance from UpToDate, "The circumstances in which adolescents may consent for their own care and in which confidentiality is protected vary from state to state depending upon the adolescent's status as a minor or adult, the service involved, and the provider's level of concern regarding harm to the patient or others."[3]

State laws generally include definitions of "mature or emancipated" minors, and they might have provisions allowing minors to consent for treatment of sexually transmitted diseases, sexual assault, pregnancy, and substance abuse. Healthcare providers, particularly those who treat adolescents, should know their state laws and develop office policies regarding treatment of unaccompanied minors.

Risk Resource

The Guttmacher Institute provides a state-by-state overview of minors' consent law in the United States, including consent for medical services related to contraception, sexually transmitted infections, prenatal care, abortion, and more.

Office policies also should take into account situations in which minors may present to the office for clinical care or treatment without their parents or guardians present. For example, the patient might arrive alone or be brought in by a grandparent or sibling. Each organization's policies should include specific guidance for managing such scenarios.

For example:

- Determine if and under what circumstances minors will be seen without a parent or guardian present.
- Explain your policies related to informed consent in minors and treatment of unaccompanied minors in your organization's welcome brochure or informational packet.
- Determine the types of procedures/treatments that will be made available to unaccompanied minors.
- Communicate in advance the limitations of services and care provided to unaccompanied minors.
- Require parents/guardians to provide a phone number where you can readily reach them in the event that questions arise about minors' care.

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- Specify that additional treatment (beyond what office policy allows for unaccompanied minors) will require specific consent discussions.
- Have parents/guardians sign a consent form in advance permitting general treatment of unaccompanied minors.
- Document all care provided in accordance with the organization's informed consent policies.

Consent policies for minor patients also should include guidance related to assurance of parental/custodial rights for informed consent or refusal, particularly in cases of divorce, separation, protection from abuse orders, etc. For example, for minors whose parents are divorced or separated, "reasonable steps should be taken to determine which parent(s) has the legal authority to consent to treatment, to what extent each parent must be involved in the decision-making process, and who may access information regarding the minor."[4]

Healthcare organizations and providers should consult their legal counsel to help review and provide guidance on consent policies for minors and to address questions that arise related to the care and treatment of minor patients.

Informed Consent in Cognitively Impaired Patients

In addition to considerations related to informed consent in minors, healthcare organizations should have policies and guidance about informed consent for individuals who have cognitive impairments or other disabilities that affect their decision-making capacity (e.g., patients who have Alzheimer's disease, dementia, certain mental illnesses, or developmental disabilities).

Key considerations include using best practices and standards for (a) identifying patients who may lack capacity, (b) evaluating capacity, (c) determining competence, and (d) using appropriate alternative consent procedures.[5]

The Vanderbilt Kennedy Center offers a Health Care for Adults With Intellectual and Developmental Disabilities Toolkit for primary care providers that includes detailed information about determining capacity, obtaining and documenting consent, and identifying a surrogate decision-maker.

INFORMED CONSENT AND TECHNOLOGY

Technology in healthcare is advancing at a rapid pace and becoming more integrated into the delivery of patient care and services. As new therapies and applications — such as telemedicine and robotic surgery — grow in popularity and use, healthcare organizations must consider how technologies' unique risks affect the informed consent process. Examples of such risks include technological glitches and failures (including transmission errors), technology-related privacy and security concerns, lack of hands-on patient evaluation and access, and issues related to provider training and experience.

Using Technology to Improve Informed Consent

Although technology can create new risks that need to be disclosed as part of the informed consent process, it also can present opportunities to improve consent discussions with patients. A 2016 study showed that the use of multimedia (e.g., videos, animations, and graphics) as part of patient education enhanced the consent process, helped patients remember more information, and narrowed the gap in the amount of information assimilated by patients with different levels of education.[6]

In terms of telemedicine, some states have implemented informed consent laws that pertain specifically to this technology. However, these laws vary among states, so providers should be aware of the laws in the states in which they practice. For example, some states may require written informed consent for telemedicine services, while others permit verbal consent.

Even in the absence of state guidance, healthcare providers using various technologies should carefully consider their informed consent processes. Whether developing a separate informed consent process or modifying an existing process to cover telemedicine, robotic surgery, or other technologies, healthcare providers may want to include (in addition to all standard and state-required informed consent information):

- The names of all involved healthcare providers and their credentials and locations, as well as any other staff that may help facilitate the treatment
- A description of the treatment/procedure that will be performed and the technology that will be used
- Alternative options for treatment and care, including traditional methods if applicable
- Any risks specifically related to the electronic nature of the care delivery (e.g., technology disruptions, failures, or limitations)
- Specific security and privacy measures that have been implemented, as well as any increased privacy risks relative to the technology
- A plan for ongoing care, including details about who is responsible for various aspects of the patient's care
- A plan for alternative care in the case of an emergency or technological malfunction

Further, all providers involved in the patient's care should have a clear understanding of the informed consent process, and — as with traditional informed consent — the process should be documented in the patient's health record.

INFORMED REFUSAL

As part of patients' rights to make informed decisions about their care and treatment, they also have the right to refuse care, even if the consequences are dire. The basis of informed refusal is identical to informed consent. This process ensures that the patient who is refusing the practitioner's recommended treatment or procedure is informed about the potential risks and complications that may occur as a result of his/her refusal.

> "When a patient refuses treatment or wants to abandon a treatment plan, the provider should carefully document the decision in the patient's health record."

Patients also have the right to change their minds and withdraw consent for treatment they have previously authorized, even when the treatment has already been started. When a patient refuses treatment or wants to abandon a treatment plan, the provider should

carefully document the decision in the patient's health record. Documentation should include the following considerations:

- Was the patient given adequate information about the diagnosis and treatment options that meet the current standard of care?
- Were the risks and benefits of treatment options discussed with the patient?
- Did the provider and patient discuss and agree upon their mutual expectations for a satisfactory outcome?
- Was the patient encouraged to ask questions and voice his/her concerns? Were these questions and concerns addressed to the patient's satisfaction?
- Did the provider ask for the patient's reason for the decision? Knowledge of the patient's reason for refusal might help the provider propose an alternative treatment that the patient will accept.
- Did the provider document his/her explanation of the risks associated with refusal of treatment? If the provider opts to use an informed refusal form, the patient should be given a copy of the signed document, and the original should be retained in the patient's health record. The form should include:
    - The diagnosis.
    - Treatment options and the risks and benefits associated with each.
    - Acknowledgment that the patient refused or terminated treatment.
    - Specific risks that might occur if the patient doesn't receive care, and acceptance of the risk on the part of the patient. Risks might include:
        - ✓ Fewer treatment options as the condition deteriorates.
        - ✓ Less opportunity for the healthcare provider to affect a successful outcome.
        - ✓ The increased possibility of complications.
        - ✓ Remaining treatment options that are more expensive than the treatment that was initially recommended.
    - The patient's signature (if he/he agrees to sign).

Although it is not always necessary for the patient to sign an informed refusal statement, the request forces the patient to acknowledge the seriousness of the untreated condition. Many patients sign; some refuse. In the event of refusal, the provider should document that the patient was asked to sign the statement and would not do so.

Some providers like to have a witness present when a patient refuses needed care. When an employee has been asked to witness the informed refusal process, he/she should sign the statement and date the signature — whether the patient agrees to sign or not.

LEGAL AND PROFESSIONAL CONSIDERATIONS IN PROVIDING INFORMED CONSENT

States and their professional licensing boards may have statutes and regulations governing informed consent. Healthcare organizations and providers need to ensure that their informed consent processes and forms incorporate these requirements because they define the standard of care specific to that state or profession.

Further, although some states and professional licensing boards may not address informed consent, national professional associations — such as the American Medical Association, the American Osteopathic Association, the American College of Surgeons, the American Society of Anesthesiologists, the American Association of Nurse Anesthetists, and the American Dental Association, etc. — also provide recommendations related to the informed consent process. Healthcare providers should check with their professional associations for specific guidance and best practices.

HEALTH LITERACY CONSIDERATIONS

Health information and services often are unfamiliar, complicated, and technical, even for people who have higher levels of education. Taking steps to ensure that patients understand information is a critical component of the informed consent process. Strategies that support patient comprehension include the following:

- Involve patients' families and significant others in the patients' care (with permission).
- Use lay language and explain medical terms when communicating with patients verbally. Explain to patients why the information is important.
- Don't overload patients with information. Focus on the most critical points and the necessary actions that patients should take.
- Present information in a simple, organized way; discuss the most important information first.
- Ensure that patient education materials are written in plain language. Healthcare practices that are conscientious about developing or using easy-to-read materials may increase the likelihood that patients will understand and use the information correctly.

> "Taking steps to ensure that patients understand information is a critical component of the informed consent process."

- Carefully consider whether patients' cultural beliefs, values, or practices might influence the consent process.
- Provide comprehensive language access services and assistive technologies to meet the needs of diverse patient communities. (**Note:** Healthcare practices that receive federal financial assistance and/or funding are generally responsible for providing auxiliary aids or other service accommodations at no cost to the patient.)

Patient Education Materials

Patient education is an essential part of the informed consent process, and healthcare providers should carefully consider written materials used to supplement verbal information.

The following guidance on content, text, fonts, and layout can help organizations and providers develop or select materials that enhance patient knowledge and understanding, which in turn may improve adherence to treatment and follow-up care. Additionally, providing patients with a copy of the consent form can reinforce key information and support information retention.

Content

- Limit content to what patients really need to know. Put the most important information first, and avoid information overload.
- Present information in a logical order, group related information together, and use descriptive headings and subheadings to help patients navigate the content.
- Use short paragraphs and focus on one topic per paragraph.
- Use words that are well known to individuals without medical training. For example, use "high blood pressure" instead of "hypertension," or use "tooth decay" instead of "caries."
- Use examples and visual aids (e.g., illustrations or tables) to make complex material easier to understand.
- Ensure that content is appropriate for the age and culture of the target audience.

Text

- Write at or below a sixth-grade level. Several readability formulas (e.g., Fry, SMOG, and Flesch-Kincaid) can help determine how difficult a piece of writing is to read.
- Use one- or two-syllable words when possible. For example, use "blood clot" instead of "embolism."

- Eliminate jargon and technical terms.
- Use the same term consistently to identify a specific thought or object.
- Favor active voice over passive voice. For example, use "report new or worsening symptoms to your doctor" instead of "new or worsening symptoms should be reported to your doctor."
- Avoid wordy phrases. For example, use "because" instead of "due to the fact that."

Fonts

- Use a large font (minimum 12 point) in a familiar typeface (e.g., Arial, Times New Roman, or Tahoma).
- Although you may want to differentiate font style for headings and body text, avoid using multiple font styles on a page or throughout a document.
- Ensure consistency in appearance throughout printed and online materials (e.g., consistent font sizes, colors, spacing, etc.)
- Use uppercase and lowercase text. All uppercase text is more difficult to read.

Layout

- Use white space effectively, and consider opening up line spacing or space between paragraphs to lighten the page.
- Use left justification instead of full justification.
- Use headings and subheadings to separate blocks of text.
- Use bulleted lists to focus on specific material, highlight information in a visually clear way, or clarify the chronological order of steps in a process.
- Keep the design of any graphics or illustrations as simple as possible.

EVALUATING THE EFFECTIVENESS OF THE INFORMED CONSENT PROCESS

Several methods have been developed to help evaluate the effectiveness of communication with patients. Two best practice examples of these methods are the "teach-back" or "show-me" methods. These techniques involve asking patients to explain in their own words or demonstrate the information that has been shared with them.

The teach-back and show-me techniques are designed to replace the common practice of simply asking a patient, "Do you understand what I have told you?" Experience

shows that patients often answer "yes" to such questions, even if they don't understand.[7]

Healthcare providers should document in patient health records their use of the teach-back and show-me techniques as part of patient education to support the informed consent process.

Risk Resource

For more information, resources, and tools on using the teach-back technique, see the Agency for Healthcare Research and Quality's *Guide to Improving Patient Safety in Primary Care Settings by Engaging Patients and Families*.

CONCLUSION

The informed consent process creates many challenges for practitioners as they seek to ensure that patients understand the information they receive and are able to make informed decisions about their healthcare.

Understanding the scope of informed consent, defining the consent process, and incorporating health literacy considerations and evaluation tools can help healthcare providers increase the likelihood that patients will be able to understand the information they receive. This understanding supports patient compliance and may reduce the risk of claims and suits related to allegations of "lack of informed consent."

RESOURCES

- A Practical Guide to Informed Consent (Temple University Health System)
- AMA Code of Medical Ethics, Chapter 2: Opinions on Consent, Communication & Decision Making (American Medical Association)
- An Overview of Minors' Consent Law (Guttmacher Institute)
- Clear Communication (National Institutes of Health, U.S. Department of Health and Human Services)
- Consent in Adolescent Health Care (UpToDate)
- Culture, Language and Health Literacy (Health Resources and Services Administration, U.S. Department of Health and Human Services)
- Health Literacy (Centers for Disease Control and Prevention)
- Health Literacy Online (Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services)
- Health Literacy Resources for Healthcare Professionals (University of Maryland, School of Public Health, Horowitz Center for Health Literacy)

- Informed Consent for Anesthesia Care (American Association of Nurse Anesthetists)
- Informed Consent: More Than Getting A Signature (The Joint Commission)
- The Legal Authority of Mature Minors to Consent to General Medical Treatment (*Pediatrics*, Volume 131, Issue 4)
- Making Informed Consent an Informed Choice: Training Modules for Health Care Leaders and Professionals (Agency for Healthcare Research and Quality)
- Minor's Rights Versus Parental Rights: Review of Legal Issues in Adolescent Health Care (Medscape)
- Toolkit for Making Written Material Clear and Effective (Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services)

ENDNOTES

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