PEACE OF MIND

EXPERTISE

CHOICE

THE MEDPRO GROUP DIFFERENCE

GUIDELINE

Risk Management Strategies For Informed Consent

MedPro Group
a Berkshire Hathaway company

medpro.com

PATIENT SAFETY & RISK SOLUTIONS

Contents

Introduction

The concept of informed patient consent is too often 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/her healthcare. Most of these rulings support the premise that competent adults can determine the course of their own care. This freedom is so absolute that many such rulings also protect a patient's right to refuse care, even when the 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.[*] When interacting with practitioners, patients should ask questions and voice concerns. This dialogue prevents misunderstandings about treatment recommendations and supports patients' ability to provide knowledgeable consent. Once practitioners provide patients with ample and appropriate information about tests and treatments, patients can weight these options in relation to personal 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

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

- Review legal and professional aspects in providing informed consent
- Discuss risk management considerations for informed consent in special populations
- Review the ways in which some healthcare technologies affect the informed consent process
- Describe other important considerations related to informed consent, including separate consent processes, technology, and patient comprehension
- Discuss the process of informed refusal and important documentation considerations

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 tailor the consent process to each patient and his/her specific condition or situation.”

Healthcare providers should tailor the consent process to each patient and his/her specific condition or situation. When determining which treatment or procedural risks should be disclosed to the patient, the healthcare provider should evaluate which risks:

- Are common and significant
- The patient might consider important
- Might affect the patient’s decision to accept or reject the treatment/procedure

Regardless of the complexity of the procedure and the scope of the informed consent process, providers should always document consent discussions and any related forms in patient health records.

The Process of Informed Consent

The informed consent process is a nondelegable duty that the healthcare provider who is performing the treatment/procedure must perform through discussions with the patient. Staff members may also participate in the informed consent process by providing general educational information and reinforcing specific information that the treating healthcare provider has communicated to the patient.

“The informed consent process is a nondelegable duty that the healthcare provider who is performing the treatment/procedure must perform through discussions with the patient.”

A common misperception among providers is that a signed consent form demonstrates consent. It does not. By itself, a consent form does not verify that true consent was obtained; it merely documents one phase of the informed consent process. For the patient to be truly “informed,” he/she must understand the information that the healthcare provider has disclosed. Thus, as part of the consent process, the provider should consider:

- The patient’s current knowledge and understanding of his/her condition and the proposed treatment plan
- The patient’s overall capacity to understand
- Cultural factors, personal values and beliefs, and other considerations that might affect the patient’s decision-making
- Any language or communication barriers that could impede the consent process

Additionally, patients should have ample time during appointments to ask questions, voice concerns, and clarify information with the treating provider.

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

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 state requirements because they define the standard of care specific to that state or profession.

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. — provide recommendations related to the informed consent process. Healthcare providers should check with their professional associations for specific guidance and best practices.

Informed Consent in Special Populations

The right to refuse or consent to healthcare treatment generally applies to competent adults. However, healthcare providers 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."[1]

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 align their policies accordingly.

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 might present to the office for clinical care or treatment without their parents or guardians present. For example, the patient might arrive alone or with a grandparent or sibling. Each organization's policies should include specific guidance for managing these types of scenarios. For example:

- Determine if and under what circumstances minors will be seen without a parent or guardian present.
- Explain your policies for informed consent 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 that office staff can call to quickly reach them in the event that questions arise about minors' care.
- 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, and protection from abuse orders.

Consent policies for minor patients . . . should include guidance related to assurance of parental/custodial rights for informed consent or refusal, particularly in cases of divorce, separation, and protection from abuse orders."

For example, in relation to 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."[2]

Organizational leaders 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

Healthcare organizations also should have policies and guidance about informed consent for patients who have cognitive impairments or other disabilities that affect their decision-making capacity (e.g., patients who have dementia, certain mental illnesses, or developmental disabilities).

Key considerations include using best practices and standards for:

- Identifying patients who may lack capacity
- Evaluating capacity
- Determining competence
- Using appropriate alternative consent procedures[3]

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

Other Informed Consent Considerations

Separate Consent Processes

In some situations, providers might find that combining elements of the informed consent process can save time and reduce paperwork. Yet, despite efficiency, this might not always represent the best approach.

One common example of this strategy involves combining consent discussions and forms 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.[4]

Risk Tip

Some states mandate a separate informed consent process and documents for anesthesia administration. Healthcare organizations and providers should make sure their informed consent protocols comply with state laws.

The American Association of Nurse Anesthetists (AANA) 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."[5]

A journal article from the Anesthesia Patient Safety Foundation (APSF) concurs with AANA's position, noting that including the consent for anesthesia as part of the surgical consent:

> is problematic as the consent document may be completed in the surgeon's office before the patient has an opportunity to talk with an anesthesiologist or nurse anesthetist . . . Informed consent for anesthesia should be provided by those who are competent to do so. This important task pertains to a unique scope of practice and should not be delegated to those lacking this specialized knowledge and training.[6]

The article also notes that separating surgical consent from anesthesia consent helps facilitate appropriate documentation for the increasing number of patients who require anesthesia for nonsurgical procedures.

Other situations in which it is prudent for providers to engage in separate consent (or refusal) processes include the following:

- When a patient is going to be photographed or videotaped as part of a procedure or surgery
- When a patient is going to receive blood or blood products in any situation other than a life-threatening emergency
- When technicians or health professionals are going to observe a patient during a procedure or surgery for educational or technical support (e.g., a representative from a surgical device vendor or equipment manufacturer)

In these types of situations, separate consent processes can facilitate patient understanding of what will happen during the treatment/procedure, help highlight important risks, and prevent misunderstandings that might arise from consolidating information.

Technology

In today's healthcare landscape, technology is a routine part of patient care and services, and it continues to advance at a rapid pace. As these methods and applications — such as telehealth, robotic surgery, and artificial intelligence — evolve and become more commonplace, healthcare organizations and providers must consider how technology's 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
- Reliability of algorithms used for diagnosis and clinical decision support
- Lack of hands-on patient evaluation and access
- Unrealistic patient expectations
- 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 recent 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.[7]

In terms of telehealth, 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 telehealth 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 certain technologies, practitioners should consider including (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 members that might help facilitate the treatment
- A description of the treatment/procedure that the healthcare providers will perform and the technology they will use
- Information about the healthcare providers' experience using the technology
- 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 privacy and security 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.

Patient Comprehension

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-understand materials may increase the likelihood that patients will understand and use the information correctly.
- Allow time for questions at the end of each patient encounter and restate information as needed.

Learn More About Plain Language

Plain language allows readers to find what they need, understand what they find, and use what they find to meet their needs. In the context of health information, plain language materials can help patients make informed decisions about their care. For more information, go to plainlanguage.gov.

- Carefully consider whether cultural factors, personal values or beliefs, or other considerations might influence the patient's decision-making.
- Provide comprehensive language access services and assistive technologies to meet the needs of diverse patient communities.[†]

As noted earlier, healthcare providers should evaluate patient comprehension and the effectiveness of consent discussions. Two approaches that can assist providers with evaluation

[†] 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. For more information, see MedPro's *Risk Q&A: Interpreters and Auxiliary Aids*.

are the teach-back and 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 patients closed-ended questions that elicit a "yes" or "no" response.[8] Experience shows that patients might provide an answer to closed-ended questions even if they don't understand them.

Risk Resource

For more information about 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*.

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.

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.

> "[The informed refusal 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."

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, consider the following:

- 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 explain the risks associated with refusing treatment? Risks might include:
    - Fewer treatment options as the condition deteriorates.
    - Lower probability of a successful or optimal outcome.
    - Higher probability of complications.
    - Remaining treatment options that are more expensive than the treatment that was initially recommended.
- 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.

If the patient has received adequate information and education, but still refuses treatment, the provider should carefully document the decision in the patient's health record. Documentation should include the patient's diagnosis, recommended treatment options and their benefits and risks, the outcomes that might occur if the condition isn't treated, and all patient education efforts.

If the provider opts to use an informed refusal form, he/she should give the patient a copy of the signed document and retain the original form in the patient's health record. The form should include:

- The diagnosis.
- Treatment options and the treatment plan the patient elected (if any), as well as 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.
- The patient's signature (if he/she 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 will sign the form, but 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 — regardless of whether the patient agrees to sign.

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.

Careful planning and development of consent protocols that take into account the scope of informed consent, the consent process, essential elements of consent, legal and professional standards, and other special considerations can help practitioners provide patients with appropriate information to facilitate the shared decision-making process and potentially mitigate risks related to allegations of inadequate informed consent.

Resources

MedPro's *Risk Resources: Informed Consent* publication offers a range of curated resources that provide additional information about informed consent protocols, strategies, and standards. *Risk Resources: Health Literacy and Cultural Competence* offers information about improving communication and supporting patient comprehension.

Endnotes

[1] Olson, K. A., & Middleman, A. B. (2019, December). Consent in adolescent health care. UpToDate. Retrieved from www.uptodate.com/contents/consent-in-adolescent-health-care

[2] McNary, A. (2014). Consent to treatment of minors. *Innovations in Clinical Neuroscience, 11*(3-4), 43–45. Retrieved from www.ncbi.nlm.nih.gov/pmc/articles/PMC4008301/

[3] Fields, L. M., & Calvert, J. D. (2015). Informed consent procedures with cognitively impaired patients: A review of ethics and best practices. *Psychiatry and Clinical Neurosciences, 69,* 462–471.

[4] Souter, M. J. (2016, May). Frequently asked questions for informed consent on procedures (Version 1.5). American Society of Anesthesiologists, Committee on Ethics.

[5] American Association of Nurse Anesthetists. (2016). Informed consent for anesthesia care: Policy and practice considerations. Retrieved from www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/informed-consent-for-anesthesia-care.pdf

[6] O'Leary, C. E., & McGraw, R. S. (2008). Informed consent requires active communication. *APSF Newsletter, 23*(1), 4-5. Retrieved from www.apsf.org/article/informed-consent-requires-active-communication/

[7] Michalski, A., Stopa, M., & Miśkowiak, B. (2016). Use of multimedia technology in the doctor-patient relationship for obtaining patient informed consent. *Medical Science Monitor: International Medical Journal of Experimental and Clinical Research, 22,* 3994–3999. Retrieved from www.ncbi.nlm.nih.gov/pmc/articles/PMC5085339/

[8] Temple University Health System, Fox Chase Cancer Center, Hablamos Juntos at the University of California San Francisco, Fresno Center for Medical & Education Research. (2009). *A practical guide to informed consent*. Retrieved from www.rwjf.org/en/library/research/2009/04/a-practical-guide-to-informed-consent.html

medpro.com

PATIENT SAFETY & RISK SOLUTIONS

MedPro Group

a Berkshire Hathaway company