RISK MANGAGEMENT STRATEGIES FOR INFORMED CONSENT

Medical Protective

Clinical Risk Management Department

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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 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 preponderance 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 can (and should) ask questions and voice their concerns. This dialogue prevents misunderstandings about the plan of care and supports the patient's ability to provide knowledgeable consent.

The patient, once fully informed by the provider, is able to weigh various treatment options against his or her own cultural beliefs and values to make an informed decision.

OBJECTIVES

The objectives of this guideline are to:

- Describe the framework for providing informed consent;
- Discuss the process of providing informed consent;
- Identify essential elements of informed consent;
- Consider legal and professional aspects in providing informed consent; and
- Review health literacy considerations for informed consent documents and educational materials.

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

THE FRAMEWORK

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 the risks. However, as procedures become more complex and/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 or her specific condition or situation. Additionally, providers should always include documentation of the informed consent process in the patient record, 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 informed consent process by providing general educational information and reinforcing specific information that the healthcare provider has given 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.

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

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

The Essentials of Informed Consent

Basic informed consent elements include:

- Patient name;
- Procedure name (both in medical and layman's terms);
- Description of the procedure;

- Risks and benefits of the proposed treatment or procedure;
- Treatment and alternatives, including doing nothing;
- Patient signature memorializing understanding and providing consent; and
- 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 accept or reject the treatment or procedure.

Informed Refusal

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 or her refusal.

Similar to informed consent, informed refusal is a process and should be evidenced by either a document signed by the patient or documentation in the patient's health record.

Legal and Professional Considerations in Providing Informed Consent

States and their professional licensing boards may have statutes and regulations governing informed consent. Practitioners 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 Dental Association, etc. — also provide recommendations related to the informed consent process.

Health Literacy Considerations

Consideration of the issues on pages 6–7 as part of the informed consent process can improve patient understanding and compliance with care. Additionally, repeating and reinforcing the information provided to patients by providing a copy of the consent form and additional educational materials can improve a patient's retention and understanding.

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 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 right 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 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.[2]

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

- Centers for Disease Control and Prevention: Health Literacy, Get Training — http://www.cdc.gov/healthliteracy/gettraining.html
- Office of Disease Prevention and Health Promotion: Health Literacy Online — http://www.health.gov/healthliteracyonline/about.htm

[2] Temple University Health System, Fox Chase Cancer Center, Hablamos Juntos at the University of California San Francisco, Fresno Center for Medical & Education Research. (n.d.). A practical guide to informed consent. Retrieved from http://www.templehealth.org/ICTOOLKIT/html/ictoolkitpage1.html

- Temple University Health System: A Practical Guide to Informed Consent — http://www.templehealth.org/ICTOOLKIT/html/ictoolkitpage1.html
- The Medical Protective Company: Informed Refusal — http://www.medpro.com/ (username and password required)
- University of Maryland Center for Health Literacy: Health Literacy Resources for Health Practitioners — http://www.healthliteracy.umd.edu/resources/tools-for-healthcare-providers/