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The What, Why, Who, When and How of Informed Consent and Informed Refusal

Informed consent is an interactive process between a patient and the physician, not a form or a one-time conversation. The same holds true for informed refusal, which is the process of communication when a patient refuses medications, treatment, diagnostic tests or procedures, or interventions such as surgery. This advisory will review the what, why, who, when and how of informed consent and informed refusal, as well as best practices for documentation and risk management to emphasize the importance of engaging patients with their treatment while reducing potential liability.

What Is Informed Consent?

Informed consent is a ***process*** of communication between a physician and a patient. Although laws differ from jurisdiction to jurisdiction, the basic requirements for a valid consent process are essentially the same. That means a discussion of:

- The clinical indications for the treatment, such as medication or a diagnostic or surgical procedure
- A description of the treatment or procedure
- Intended benefits and probable risks for the specific recommended treatment or procedure and the alternatives, including the risks and benefits of the alternatives, which may include doing nothing.

Why Obtain Informed Consent?

Physicians have both a legal and an ethical obligation to ensure that patients are informed about their healthcare so they can participate in decision-making related to their care. Obtaining a patient's informed consent to treatment is guided by professional codes of ethics, statutes, regulations and case law.

Despite this, failure to obtain informed consent is **among the most common allegations in medical malpractice claims** against healthcare providers.[1] Failure to obtain informed consent occurs when a physician does not provide adequate information for the patient to make an informed decision about treatment. When making a claim of failure to obtain an informed consent, the patient must show that if adequate information had been provided, (s)he would have made a different decision. Signing an informed consent form is validation that the process has occurred and that an agreement has been reached.

A battery occurs when a patient is treated or touched without prior consent. In claims for battery, the treatment need not have been negligent or have caused an untoward result. Nonetheless, often the plaintiff will assert a claim of negligence along with a claim of failure to obtain informed consent or battery. The only negligence that needs to be shown is that the physician failed to obtain the consent of the patient.

Who Can Be Asked for Informed Consent or Informed Refusal?

Assessing a patient's medical decision-making capacity is generally part of every medical encounter. Often, it is very clear that a patient can make rational decisions and there is no reason to believe otherwise. Still, there are times when a patient may not be capable of making decisions, require a surrogate decision-maker or is deemed incompetent.

Should a surrogate be involved with decision-making, ensure that they have the legal authority to make healthcare decisions by asking for a copy of the court documents or evidence of a durable power of attorney for healthcare decisions, and retain the document in the medical record. Each state has differing requirements for appointment of a substitute decision-maker. As such, healthcare providers should refer to specific state laws and regulations regarding surrogate decision-making.

State laws also vary regarding decision-making for minors, such as whether both parents are required to agree on the decision versus allowing one parent to make the decision for treatment and medications for the minor. For divorced parents, ask for a copy of the custody agreement or divorce decree as part of your initial intake to learn whether one parent or both parents have decision-making authority.

Some states allow minors to make their own medical decisions related to specific medical conditions, such as treatment for sexually transmitted disease, pregnancy, substance abuse and/or mental health treatment. The age to consent varies by state. When a mature minor does not have a legal right to make decisions under state law, it is important for the physician to involve both the parent/legal guardian and the minor in the decision-making process, including discussion about the risks/benefits and alternatives of the proposed treatment. Involving the minor patient in the treatment decision process is critical to forming an alliance with the patient and allows them to express their wishes despite their legal inability to give consent.

When Do I Need to Obtain Informed Consent?

Informed consent should be viewed as an ongoing process and should be obtained by the physician prior to initiating treatment. Case law has established that informed consent is a non-delegable responsibility.

When prescribing/recommending medications that are FDA-approved but have black box warnings – or that are considered off-label – be sure to specifically discuss these warnings and associated risks and benefits with the patient. Furthermore, after prescribing medications with a black box warning, the physician should document at each office visit that the patient is aware of the warnings associated with the use of the medication when reviewing the presence or absence of any side effects from any medications.

For healthcare providers who participate in clinical trials, a specific consent document is important for each individual study. The informed consent process should be continued throughout the duration of a clinical trial. As with any treatment or procedure, the clinicians involved in the trial should explain the details of the study before the participant becomes involved. The informed consent document should contain details explaining the study, including purpose, duration, required procedures (if any) and the provider to contact if there are any questions/concerns. Further, risks and potential benefits of the experimental treatment should be explained both verbally and within the informed consent document.

How Do I Obtain Informed Consent?

A valid consent process must be put in terms that the patient or parent/guardian/surrogate decision-maker can understand, which means using simple, plain language (such as "do not use" rather than "abstain"). Use lay terms instead of medical jargon, avoid acronyms, such as "NPO", or abbreviations, such as "N/V" for nausea and vomiting.

A valid consent process is one in which the patient or parent/guardian/surrogate decision-maker can ask questions and receive responsive, understandable answers. One way of assuring that the individual understands the treatment and/or use of medication is the "teach-back" method. Teach back confirms the patient's understanding of treatment and medication instructions by asking them to repeat the information or instructions using their own words. Keep in mind that the purpose of asking a patient to tell you about the medication regimen is not a test of the patient's knowledge but rather a test of how well you explained the instructions in a manner the patient understands.

Use a qualified medical interpreter for any patient who is deaf or hard of hearing or has limited English proficiency (LEP). Providers should not use office staff that can speak the language of the patient without ensuring the staff member is a qualified interpreter. This requirement pertains to Section 1557 of the Affordable Care Act (ACA) which states that any healthcare provider or health insurance company receiving federal assistance must provide LEP patients with a qualified interpreter. The use of friends and family to translate for patients is strongly discouraged. Friends and family members may not be impartial, may not know medical terminology, may not use the patient's own words and may not be comfortable asking sensitive or potentially embarrassing questions (consider a teenager asking her grandfather about his substance abuse history). Inappropriate/inaccurate translation increases the risk for medication errors, avoidable readmissions and other adverse events. Failure to provide interpretation services can make patients feel their needs have been ignored and is associated with medical malpractice allegations, including inadequate explanation of diagnosis, inadequate explanation of treatment and inadequate or negligent informed consent.

What Is Informed Refusal?

A patient who has the capacity to make decisions (or his/her designee) has the right to refuse treatment. As with informed consent, the physician has the duty to explain, in lay terms and in the language the patient/designee can understand, the information needed for the patient to make a truly informed decision about refusing treatment or medication. A provider cannot force or coerce a patient to undergo treatment against his or her will.

As with informed consent, the **process** of communication regarding informed refusal includes education on the recommended treatment, high risk medication or other interventions. It requires candid discussion of the recommended care and treatment, the reasons for the proposed treatment or medication, the potential consequences of refusal (including significant risks beyond "your condition may worsen"), but more specifically, risks related to progression of the disorder (such as worsening pain, undiagnosed cancer, or death).

Why Obtain Informed Refusal?

Informed refusal cases arise from situations where patients or their families claim that the patient was not made aware of the risks associated with refusing the proposed treatment or medication. Even if it seems that the risks of refusal are blatantly evident, the physician needs to review the consequences of the patient's refusal.

When Should Informed Refusal Be Obtained?

Patients who have the capacity to make decisions have the right to refuse care even if the consequences might be irreversible. Patients also have the right to change their minds and withdraw consent for treatment they have previously authorized, even when the treatment has been started.

If a patient does not adhere to the treatment plan or medication regimen, there needs to be discussion on why the patient is noncompliant. If the patient understands the treatment plan (for example, not eating salty foods with cardiac disease), the physician should discuss the risks of not following the prescribed diet and reiterate why the recommendations are made. The healthcare provider should consider obtaining informed refusal related to noncompliance with the treatment plan, medication regimen or recommended procedure.

Forcible Administration of Medication

A refusal may not be accepted if in an emergency or if the unavoidable and forcible administration of a medication is required due to the patient being a threat to themselves or others. Once the emergency passes, consent must be obtained from the patient for future administration of medications/treatment. In psychiatric inpatient settings, even an involuntarily committed patient generally has a right to refuse recommended medications. Depending on the state, however, a court order may be required to administer medications/treatment without a patient's consent. As each state has specific laws and regulations, it is important to check with your state regarding this issue.

Minors and Informed Refusal

In a minority of states, a "mature minor" doctrine allows minors who demonstrate a required level of maturity the right to consent for, and potentially refuse, treatment.[2] While many states recognize the doctrine to varying degrees and in different settings, only a handful of the states have allowed an adolescent to refuse life-saving treatment, such as blood transfusions or chemotherapy.[3]

Check with your hospital risk manager or legal counsel if a minor refuses blood transfusions. In most situations, when blood is emergently needed to save a minor's life, hospitals likely will provide the blood and document it in the patient's medical record. After the emergency ends or in non-emergent or chronic condition situations, hospitals generally seek a court order to provide blood products. The court will typically hold a hearing, allowing the hospital and the parent and/or minor to explain their positions. The judge decides the course of treatment, documented via a court order, which should be entered into the patient's medical record.[4]

How Do I Obtain Informed Refusal?

The same techniques and tools used for informed consent need to be used for informed refusal. However, informed refusal requires asking the patient **WHY** they are refusing the care, treatment or medication. Is it because they cannot afford the medications? Are there transportation challenges to get to appointments? Could it be a high deductible for diagnostic testing? If you know the reason(s) behind the refusal, you may be able to help the patient or refer them to resources available for support. You may also, with patient consent, include family members in the discussion, as both a patient education and a risk management technique to help understanding.

Teach back is a good tool to clearly hear from the patient what they understood from the conversation: "I understand that you are refusing the treatment – I want to be sure you are aware of the consequences with not having the testing, medication, etc. – please tell me what you understand from our conversation and about your decision to refuse."

An informed refusal and the recommendations should be revisited, if possible, at subsequent office or treatment visits. Always respect the patient's right to refuse care and treatment.

Asking the patient to sign a specific informed refusal form is advised. If the patient refuses tosign a form, the discussion, the potential risks of noncompliance, the patient's reasons for refusal and any follow-up should be documented in the medical record.

What Are Best Practices for Documentation?

Documenting the informed consent or the informed refusal process should be done in a manner that reflects the education process undertaken with the patient, and not done in a conclusory way. The documentation needs to be in the medical record and should reflect the discussion, plan, patient understanding by teach back and any educational materials provided to the patient. If a form is used, ensure that each and all areas are filled out completely, leaving no blanks; that it is dated and signed by the patient/surrogate decision-maker and the provider; give the patient a copy of the signed form and retain the original in the patient's health record.

Conclusion

The informed consent process is crucial in the practice of medicine to not only demonstrate concern for your patients but also to protect you from liability if a claim for intentional or negligent informed consent or battery is brought against you. This process should not be taken lightly and is an important step in the overall treatment of the patient. Should you have questions or concerns, contact your risk management professional or legal professional.

Resources

American Medical Association, Informed Consent, Code of Medical Ethics Opinion 2.1.1 https://www.ama-assn.org/delivering-care/ethics/informed-consent

Department of Health and Human Services, Office of Human Research Protections, Informed Consent FAQs. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html

Department of Health and Human Services, Civil Rights, Section 1557 of the Patient Protection and Affordable Care Act. https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html

The Joint Commission Quick Safety Issue 21: Informed Consent: More than getting a signature, February 2016. https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/quick-safety--issue-21-informed--consent-more-than-getting-a-signature/#:~:text=%20Quick%20Safety%20Issue%2021%3A%20Informed%20consent%3A%20More,Provide%20a%20formal%20training%20program%20to...%20More%20

Rozovsky, Fay. Consent to Treatment: A Practical Guide 5th ed. Edition. Wolters Kluwer Law & Business; 5th ed. Edition, 2014.

End Notes

[1] Power Rogers Trial Lawyers. 5 of the Most Common Claims for Medical Malpractice. https://www.powerrogers.com/news/2019/july/5-of-the-most-common-claims-for-medical-malpract/#:~:text=Common%20allegations%20made%20by%20injured%20patients%20include%20negligence,errors%2C%20C-section%20errors%20and%20birth%20injuries%2C%20and%20more. (last accessed September 24,2020)

[2] Coleman D.L., & Rosoff P.M. (2013) The legal authority of mature minors to consent to general medical treatment. Pediatrics 131(4), 786-793. doi:10.1542/peds.2012-2470

[3] Ibid.

[4] Winiarsky, Denise, Klatt, Emily, and Kazerounia, Amir. Risks and Legal Issues in Caring for Minor Jehovah's Witnesses Patients. American Society of Healthcare Risk Management Forum, March 29, 2018. https://forum.ashrm.org/2018/03/29/risks-and-legal-issues-in-caring-for-minor-jehovahs-witness-patients/ (last accessed 9/25/2020)

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