

Informed Consent

Informed consent is a process of communication between a patient and a health care provider that results in the patient's agreement to undergo a procedure or treatment. It is both a legal and ethical obligation. The provider educates the patient about the benefits, risks, and alternatives of the intervention. Informed consent is required for invasive procedures, procedures requiring sedatives or anesthesia, non-surgical procedures that carry risk (e.g., blood transfusion), and procedures involving radiation. Nurses are key participants in the informed consent process in both educating the patient and verifying understanding.

Background

- The concept of *informed consent* in healthcare usually calls to mind the written contractual acknowledgment *form* signed by a patient or legal representative in advance of a procedure.
- Legal restrictions on who can obtain informed consent varies by state, making it vital for nurses to be aware of the policy where they practice.
- Informed consent is also a *process*, extending beyond the paperwork, in which nurses must fully understand their legal, moral, and ethical roles.

Terminology

- *Informed decision-making*: Can only be completed by a patient with the mental capabilities to understand the decision to accept or reject the medical treatment being offered.
- *Decisional capacity*: A patient who is unconscious, disoriented, or delusional may have a surrogate decision-maker assume authority for providing informed consent on their behalf.
- *Healthcare surrogate*: A person designated by the patient to make healthcare decisions should the patient become incapacitated.
- *Substituted judgment*: If a patient cannot make decisions on their own, statutes in many states allow for the assignment of a proxy to make decisions, who must consider any and all known wishes of the patient.

Ethical and Moral Considerations

- **Autonomy**: the moral right of the patient to make their own decisions
 - Nurses and physicians can support patient autonomy by using neutral language and not emphasizing benefits over risks.
 - The trusted roles of physicians and nurses make it imperative that they exercise discretion and fairly represent balanced information to patients, particularly during the consent process.
- **Self-determination**: the ethical principle which supports providing patients with the facts necessary to make a rational decision on their behalf.

Patient Education

- Several factors related to the nature of the illness, the severity of symptoms, and the treatments required can interfere with a patient's capacity to fully understand and voluntarily agree to medical procedures. These factors include pain, fatigue, cognitive impairment, and psychological factors such as anxiety, shock, and denial.

- Nurses should closely monitor the patient's mental status to determine if they have the capacity to make informed decisions. If there is doubt, involving a healthcare provider with expertise in assessing decision-making capacity (e.g., neurologist, psychiatrist) may be necessary.
- Nurses should assess patients' knowledge of their condition and provide education when needed. Nurses spend more time educating patients than most other healthcare disciplines. Nurses fill trusted roles as patient caregiver, advocate, educator, and steward.
- During bedside care, nurses may be asked by both the patient and family to answer questions related to upcoming procedures, tests, and surgeries.

Informed Consent

- At its core, informed consent requires patients to be aware of the risks, benefits, and alternatives of the proposed surgery, intervention, or treatment and be given an opportunity to ask questions.
- The process of informed consent is complex, may require the participation of multiple parties, and usually begins well in advance of the point of obtaining a signature on a form.
- The signed and witnessed informed consent form is the legal obligation of the physician or advanced practice provider performing the procedure in question.
- Nurses are usually charged with verifying the informed consent paperwork has been obtained just prior to surgery or procedures.
- Consent should *never* be considered a waiver of liability.
- Patients have the right to know who is performing their procedure, as well as how many times the person has successfully completed this procedure.
- If the nurse believes the patient has not been fully informed or has less than a full understanding of the proposed treatment, the nurse must act as a patient advocate to ensure that the patient receives the necessary information.
- In emergencies where the patient is unable to give consent and immediate treatment is necessary, healthcare providers may proceed without consent under the doctrine of implied consent, provided that there is a reasonable expectation that the patient would have consented if able to do so.

Refusal of consent

- It is within the rights of the autonomous patient to refuse a recommended treatment.
- A competent patient may verbally *withdraw* consent at any time, and refuse to continue a treatment pathway, even in the presence of a signed consent form.

References:

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