Informed Consent

Essential Legal and Ethical Principles for Nurses

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ABSTRACT

Before surgery, the informed consent process is the practical application of shared decision making between a surgeon and a patient. However, nurses, as enlightened patient advocates, also have an entrusted interest in fully understanding the legal and ethical considerations of the informed consent process. Some of the ethical principles impacting informed consent are existing cornerstones of professional nursing practice. Nevertheless, surgeons bear the ultimate responsibility for the informed consent process before surgery. The ideal completion of the informed consent process may be achieved if surgeons and knowledgeable nurses collaborate for the patient's good.

Shared decision making is at the foundation of a mutually respectful relationship between a health care provider and a patient. Before surgery, the informed consent process serves as the practical application of mutual participation and respect for the patient's autonomy.[1] In addition, the patient's legal right to participate in decisions about his/her medical care is supported by oversight regulations such as the Patient Rights Condition of Participation.[2] The underlying principles of the informed consent process, autonomy, and disclosure may come naturally to many nurses and physicians. Nevertheless, the actual practical application of these principles and implementation of the informed consent requirements are troubled with difficulties and obstacles.[3]

Rationale for Nurses' Engagement in Informed Consent

Ultimately, physicians are responsible for informing patients of the (*a*) risks, (*b*) benefits, and (*c*) alternatives of a proposed treatment or surgery. Therefore, the informed consent process is the (*a*) legal, (*b*) ethical, and (*c*) moral responsibility of the physician.[4] Nevertheless, as enlightened patient advocates, hospital nurses also have an entrusted interest in fully understanding the legal guidelines and

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ethical considerations of the informed consent process. With this understanding, educated nurses possess a unique opportunity to facilitate patient autonomy, especially in the presence of special circumstances, such as (*a*) patients who refuse surgery, (*b*) patients with limited mental capacity, and (*c*) patients with surrogate decision makers.[5] Therefore, the topic of informed consent, especially when the process involves health care surrogates, is worthy of study for nurses.

Review of Literature

History

Historically, the requirement that physicians involve patients in decisions has evolved from simple consent to informed consent.[5] Although the evidence of this evolution has been presented in legal cases, the basis for the shift from simple to informed consent is actually based on longstanding ethical, not legal, principles. The historical requirement that a patient agrees to be treated, simple consent, was based on the prevailing ethical obligation for physicians to act with beneficence toward their patients. The current requirement that a patient is informed of the (*a*) risks, (*b*) benefits, and (*c*) alternatives to the proposed treatment is based on the increasingly valued principle of patient autonomy.[6] The paternalistic relationship between surgeons and patients has been ethically and legally replaced by the evolved concept of informed consent.[5] Full disclosure of information and true informed consent are actually relatively new concepts for physicians. Only in recent years have physicians widely adopted the ethical principle of autonomy as a basis for patient-physician discussion.[3]

Although nurses have never been assigned direct legal responsible for disclosing the information necessary to enable a patient to evaluate a proposed invasive procedure, they have been historically challenged with facilitating the documentation of the process.[2] An evolving comprehensive understanding of the informed consent process may empower these nurses to advocate for patients and surrogates by distinguishing between a signature on an informed consent form and the important ethical element of informed consent.[5]

Principles of Informed Consent

SCOPE

To meet the accepted definition of informed consent, the patient needs to willingly accept medical intervention after adequate disclosure of (*a*) the nature of the intervention, (*b*) its risks and benefits, and (*c*) its alternatives with their risks and benefits.[1] In addition, the informed consent process represents an opportunity to move beyond physician disclosure of information to shared medical decision making between the patient and the physician. In shared medical decision making, the physician conveys the required information and the patient shares with the physician all relevant personal information that might influence the decision to consent.[6] The content of the information disclosed during the informed consent process is impacted by whether the procedure is emergent or elective and the patient's ability to comprehend complicated facts.[1]

DELIVERY METHODS

The method of providing for informed consent for surgery may vary among different surgeons and even among different patients of the same surgeon.[7] Traditionally, the process includes an oral discussion between the surgeon and the patient, followed by the patient signing a document affirming his/her consent. The use of oral communication and written documents remains common. Videos and computer software are also used to disclose important information needed to obtain a valid informed consent. Any delivery method may be used as long as it necessitates providing patients with the (*a*) indications, (*b*) risks, (*c*) benefits, and (*d*) alternatives about a planned surgery.[7]

ETHICAL CONSIDERATIONS

The ethical significance of informed consent is based on the opportunity that the process presents for the patient to exert autonomy. For moral philosophers, the principle of autonomy represents the moral right to choose and follow one's own plan for life and action.[1] Informed consent represents a challenging dilemma for surgeons.[6] To establish effective informed consent, surgeons must balance their obligation to protect the patient's health through beneficence and their obligation to respect the patient's autonomy. The ethical principle of self-determination is a subset of autonomy commonly associated with informed consent. Through self-determination, a decision to consent to surgery would originate freely from an autonomous patient, who understands the facts and can engage in practical reasoning to make that decision.[6]

Additional ethical tension may arise between respect for patient autonomy and the practice of paternalism in health care. When surgeons or nurses practice paternalism during the informed consent process, they override or ignore patient preferences in an attempt to benefit or enhance the patient's welfare. Ethically, paternalism represents the health care provider's belief that beneficence is more important than autonomy.[1] One manifestation of paternalism may be underestimating the extent of a surgeon's influence over the patient's independent decision. Although the surgeon's recommendations have a proper role in the informed consent process, surgeons and nurses may alter the patient's objective frame of reference by excessively emphasizing either the benefits or risks of a surgery. Health care providers may also exhibit paternalism by exaggerating the gravity of a patient's situation or substituting descriptive terms for quantitative terms during the informed consent process.[5]

Essential Concepts for Nurses

NURSE'S ROLE IN INFORMED CONSENT

Nurses may strive to ensure patient autonomy and rights through appropriate participation in the informed consent process. Nevertheless, compliance with legal and regulatory requirements as well as ethical and patient family concerns can make the concept of informed consent baffling and challenging. Furthermore, confusion exists concerning the important distinction between a signature on the surgical consent/authorization form and the patient's informed consent. The misconception that informed consent is the same as a signature on a consent form can be problematic for nurses who are frequently charged with facilitating the legal documentation form.[5] As patient advocates and direct care providers, nurses have a unique opportunity to meaningfully advocate for mutual decision making, a process that promotes (*a*) patient autonomy, (*b*) comprehension, and (*c*) self-determination.[6] Empowered by a comprehensive understanding of the informed consent process, nurses can serve in that advocacy role without running the risk of practicing outside their professional scope by assuming the responsibly for ''consenting'' the patient.

PATIENT EDUCATION

Consent forms are potential meaningful education tools that nurses may use as springboards into important discussions about what to expect before and after surgery.[8] Health care professionals may, within the scope of the informed consent process, move beyond simply informing a patient of risks to actually educating a patient. Approaching the informed consent process for surgery using an educational model may result in liability reduction by serving to develop an alliance between the patient and the surgeon.[8] Using this educational approach, the informed consent form evolves from a waiver of liability to an educational tool. In the end, the consent form, frequently completed by nurses, is essentially evidence that the appropriate discussion between the surgeon and patient occurred; it is not a substitute for that important discussion and patient education.[8]

PATIENT COMPREHENSION

Comprehension of the information provided is a precondition for obtaining a valid informed consent.[3] Ideally, a patient would demonstrate full comprehension, but the practical application of that ideal can be problematic in implementation. Even highly intelligent patients have difficulty in fully comprehending complicated information and potential hazardous outcomes.[3] Important factors such as (*a*) the disease itself, (*b*) anxiety, (*c*) pain, and (*d*) various therapeutic interventions can hinder a patient's ability to participate in shared decision making. To maximize comprehension, information should be carefully provided in a manner that increases patient understanding of what is being explained.[3]

In the context of elective surgery, the surgeon is responsible for ensuring patient comprehension to the extent possible. Nurses could contribute toward maximizing comprehension by using a repeat-back process on comprehension after informed consent discussions.[9] Nurses may be more familiar with and skilled in the repeat-back method, which could be used by asking patients to recount what they had learned in the informed consent discussion. The repeat-back methodology has been shown to have an effect on patient comprehension of information disclosed during informed consent for surgery.[9]

EFFECT ON PATIENT ANXIETY

Surgeons may occasionally circumvent satisfactory consent negotiations because they do not want to alarm the patient or increase the patient's anxiety. Therefore, in an attempt to avoid undesirable patient anxiety, a surgeon may fail to completely disclose adequate information needed for shared decision making.[1] A surgeon may be concerned that providing comprehensive information about all of the risks of a planned surgery may have an adverse effect on patient anxiety.[7] In addition, patients overcome by anxiety have limited ability to comprehend information provided.[1]

The nurse-to-patient relationship facilitates nurses' ability to identify and address patient anxiety that may both impact comprehension and be influenced by disclosure of information during informed consent. The format in which the informed consent is provided (oral, written, or video) has no significant effect on patient anxiety.[7] Therefore, nurses could skillfully recommend a preferred format identified through a patients' individual learning methods assessment.

DISTINCTION BETWEEN FORM AND PROCESS

The informed consent form may be regarded by some hospitals or surgeons as offering legal protection. This perception can overshadow the ethical goal of providing for patient autonomy. Actually, the signing of the form itself may be more of a formality than the actual conclusion of a mutual decision-making process.[1] The distinction between the form and the process can be best conceptualized if surgeons and nurses recognize that informed consent is a continuing process, not a static event. Therefore, it is not simply the patient's signature on a form. The form is legal documentation but does not equate to the ethical obligation of respect for patients' rights.[5] Frequently, patients make decisions about elective surgery well before viewing the form but after consulting with (*a*) family, (*b*) friends, and (*c*) their health care providers. Therefore, the attention given to the consent form signing may be misdirected.[10]

Surrogate Decision Making

DECISIONAL CAPACITY

For informed consent to be valid, the patient must have capacity to process information received and communicate a meaningful response. This determination of capacity

is different from determination of competence, which is a legal matter.[4] Decisional capacity or incapacity is a clinical situation and must be established as part of the informed consent process. For patients who lack decisional capacity, such as the unconscious or extremely disoriented and delusional, a surrogate decision maker assumes authority to provide informed consent for treatment.[1]

SURROGATES AND PROXIES

State statutes frequently provide guidance for hospital policies and procedures delineating who can provide informed consent for treatment for a patient when the patient lacks capacity. For example, according to the Florida Health Care Advance Directive Statute, a health care surrogate is an adult expressly designated by a patient to make health care decisions on behalf of the patient in the event the patient's incapacity.[11] The statute also provides guidance on documentation of the selection of a health care surrogate. The designation of a health care surrogate does not expire and remains in effect until revoked by the patient. In addition, state statutes such as the Florida Health Care Surrogate Act may provide guidance on the extent of authority entrusted to surrogates. The surrogate has the legal authority to make all health care decisions for the patient during the patient's incapacity.[12] The surrogate has the responsibility to provide informed consent, which he/she believes the patient would have made under the circumstances.

In the event a patient lacks capacity but has not designated a health care surrogate, the Florida Advance Directives Statute provides for the designation of a proxy to make health care decisions for that patient.[11] The statute provides a list of individuals, in order of priority, who are to be designated to provide informed consent on the patient's behalf. If no individual at the top of the list, such as a judicially appointed guardian or patient's spouse, is reasonably (*a*) available, (*b*) willing, or (*c*) competent to act, then the designation goes to a subsequent individual on the list, such as an adult child or parent of the patient. Like the health care surrogate, the proxy has the responsibility to provide informed consent based on the decision the proxy reasonably believes the patient would have made under the circumstances.[11]

Both proxies and predetermined health care surrogates have an obligation to exercise substituted judgment.[1] Therefore, when the incapacitated patient's preferences are known, for example, expressed by the patient before incapacity, the surrogate must use that knowledge in making medical decisions. This principle of substituted judgment is applicable whether the patient expressed those preferences in writing or verbally.[1]

Refusal of Consent

A competent patient's right to refuse a recommended treatment is an important principle in the informed consent process. Respect for patient autonomy and self-determination requires that decisions to consent to or refuse treatment originate freely from the patient as an autonomous agent.[6] Not only must consent be freely given, but it may also be freely withdrawn at any time. With some exceptions, even patients with mental illness are usually considered competent to refuse treatment at any point in the informed consent process.[4] The granting of autonomy to refuse consent to a recommended treatment requires health care providers to accept the free choice of each person even if that choice seems inappropriate, foolish, or hazardous.[3]

Refusal of surgical intervention is possible after an appropriate informed consent discussion.[5] It does not mean the surgeon did not provide adequate information during the process. The patient may find alternatives to surgery equally attractive to having an operation. In addition, refusal to consent is not itself evidence of the patient's incapacity to make health care decisions.[5]

Discussion, Conclusions, and Implications

Discussion

The practice of informed consent is multifaceted and presents complex legal and ethical challenges. The informed consent process has even been accused of being (*a*) culturally biased, (*b*) legalistic, (*c*) ritualistic, and (*d*) unevenly enforced.[10] Surgeons and nurses facilitating the informed consent process could benefit from remembering that the seemingly complex process is simply the practical application of respect for persons. Without a clear understanding of the underlying concepts and legal requirements that guide the process, informed consent may fall short of its aspirational goals.[10]

The right to consent is considered a basic patient right that guarantees that patients or surrogates have rights to make informed decisions regarding medical care. Ultimately, surgeons bear the burden of providing the key information that a patient needs to exercise that right and make an informed decision for elective surgery. Nevertheless, nurses can be integral to the process while still practicing within their defined scope of practice. State Nurse Practice Acts define the scope of nursing practice. For example, the Florida Nurse Practice Act validates that the practice of professional nursing includes the performance of those acts requiring substantial specialized knowledge and judgment based upon applied principles of psychological and social sciences.[13] Planning, intervention, and evaluation of care as well as health teaching and counseling of the ill while contributing toward the informed consent process are well within this legal scope of practice. For example, nurses may serve to (*a*) ensure patient comprehension, (*b*) facilitate documentation of consent, (*c*) address patient anxiety, and (*d*) identify the appropriate surrogate decision maker when needed. Hospitals, as employers of nurses, also have an interest in ensuring that the informed consent process is completed in accordance with law and regulation. Hospitals may rely on nurses to facilitate compliance with Joint Commission standards that

require that patients participate fully in decisions about their care, treatment, and services.

Conclusions

When nurses and surgeons collaborate to properly execute an informed consent, patient autonomy can be achieved. Through professional education, nurses may be empowered to effectively participate in the process if they obtain an understanding of the ethical considerations and the legal and practical implications in favor of collaborative informed consent.

For surgeons, the informed consent process might be considered a waiver of liability or a preoperative release. Alternatively, nurses may be more inclined to recognize the informed consent process as an important exchange of information upon which a patient or surrogate can make imperative choices reflecting their autonomous health care decisions.[8] With a broadened knowledge base on the realities and requirements of the informed consent process, nurses and surgeons may each contribute within their legal scope of practice to reduce risk of litigation by fully meeting the legal obligations imposed by informed consent statutes.

Ideally, nurses, as patient advocates, would understand the ethical principles of (*a*) autonomy, (*b*) beneficence, and (*c*) paternalism as they relate to informed consent. An understanding of these principles would help nurses to identify potential ethical dilemmas and recognize tools for their resolution.[3] Specifically, a comprehensive understanding of autonomy would assist a nurse in recognizing potential outside control or pressure interfering with a patient's freedom to make a decision. Furthermore, familiarity with the concept of beneficence could empower a nurse participating in the informed consent process to rise above the role of a technical consultant to meet their moral obligation to help a patient in an active way.[3] Finally, exposure to the potential pitfalls of paternalism would be beneficial to a nurse's contribution to the informed consent process. For example, a nurse could recognize when a surgeon was practicing physician paternalism and assuming that his/her medical judgment alone should determine the course of care.[1] Contemporary medical ethics rejects paternalism in the informed consent process, and educated nurses could take action to promote patient autonomy in self-determination.

Implications

Some surgeons erroneously conceptualize informed consent as a formal legal document that serves as a waiver of legal liability when executed by the patient. Paradoxically, this focus on consent as a legal preoperative release can increase liability as it detracts from the actual exchange of information upon which a patient can make a choice about proposed surgery.[8] The implication is that, when appropriate, knowledgeable nurses can collaborate with surgeons in the informed consent process, distinguishing between the consent form (often completed by nurses) and the legal obligation to disclose relevant information to the patient (the responsibility of the surgeon).

The implication for enlightened nurses would be evident when the nurse facilitates the documentation of consent process. Simple consent would involve 1 question: ''Did the patient agree to the surgery?''[5] On the basis of an understanding of the evolution of the current concept of informed consent, the nurse would more likely now ask, ''Did the physician provide the patient with an adequate amount of information for the patient to consent?''[5]

As patient advocates and essential members of the health care team for surgical patients, enlightened nurses can contribute meaningfully to the informed consent process. In addition, nurses can augment the process to elevate it from simple consent or empty documentation to an avenue for meaningful shared decision making.

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