Informed Consent: Ethical and Legal Considerations for Advanced Practice Nurses

Linda Farmer, MSN, ACNP-BC, and Ann Lundy, RN, JD

ABSTRACT

The ethical principles of self-determination and autonomy govern the practice of informed consent. A patient's right to shared decision-making and assent prior to invasive procedures, therapeutic interventions, and research projects is protected by law. Foundational nursing roles of communication, education, and patient advocacy compel advance practice nurses to formulate methods that safeguard patients' rights. Legal implications of informed consent may vary, leaving nurse practitioners juxtaposed between judicial and ethical responsibilities. The goal of this study is to examine legal and ethical components of informed consent and to assist nurse practitioners in developing proactive practice strategies related to informed consent.

Keywords: autonomy, informed consent, self-determination, shared decision-making

The informed consent process is fundamental to proper care and treatment of patients. Nurse practitioners (NPs) face many challenges related to this function. The patient has a legal and ethical right to direct what happens to his or her body that can be effectively exercised only if the patient possesses enough information to make an informed choice. If adequate information is not provided, the legal consequences could potentially involve litigation, professional licensure actions, and negative accreditation implications for the provider and the entity wherein the treatment occurred.

Equally important are ethical considerations. NPs have an ethical responsibility to educate the patient through meaningful discussion in order for the patient to make rational, reasonable, and autonomous decisions regarding their care and treatment. The process of informed consent should involve an ongoing and dynamic exchange of information between the patient and his or her health care provider. Throughout the informed consent process, the NP can foster proactive care decisions by being a resource for information, facilitating meaningful discussion, and working to resolve situations where the patient refuses or withdraws informed consent.[1,2] The purpose of this study is to examine the legal and ethical components of informed consent and to assist the NP in developing proactive practice strategies related to this process.

ORIGIN AND ETHICAL ROOTS OF THE INFORMED CONSENT PROCESS

A patient's right to participate in health care decisions arises from the individual's moral right to choose one's own plan for life and action.[1,3] Far removed from today's litigious climate, the concept of informed consent may be traced as far back as Hippocrates, Plato, and Galen, and likely originally intended to protect the provider rather than the patient. In the Hippocratic Oath, physicians have historically sworn to "prescribe a regimen for the health of the sick" and "utterly reject harm and mischief," as well as other ethical charges that reflect the following assumptions: (1) that medical practitioners possess knowledge and skill that could be of potential benefit or harm to another; and (2) that the practitioner, as holder of that knowledge and skill, has the moral obligation to administer and

advocate on behalf of the less enlightened individual. The *Corpus Hippocraticum* actually expresses beneficence to patients by *withholding* information rather than providing treatment details.[4,5]

The perception of the patient's assumed vulnerability is deeply rooted in history. Archived medieval documentation from the 14th century BC exists in the form of *pro corpore mortuoto* (hold harmless document), indicating an early version of procedural informed consent was enacted as a means of protecting the physician from repercussion in the event of poor outcomes.[5] In the sixth century, the surgeons responsible for operating on the gravely ill Byzantine emperor Justin II feared they would face retribution for the Emperor's death and demanded that the Emperor physically hand them the scalpel before surgery as an act of implicit consent to operation.[4,5]

The 18th century saw the first documented example of informed consent litigation in the trial of *Slater v Baker and Stapleton*, 95 Eng. 860, 2 Wils. KB 359 (1767). In *Slater*, the patient claimed lack of informed consent after his physician refractured his healing leg as part of an experiment with external fixation methods. The physician carried out the procedure without prior discussion or the patient's approval. The court ruled in favor of the patient, reasoning that a radical experiment could itself be considered malpractice, at least in the absence of the patient's consent.[6]

The provocative line of reasoning in *Slater* stimulated more enlightenment on the topic during the Romantic period. In 1845, Edgar Allan Poe, illustrated patient consent in his novel, *The Facts of M. Valdemar's Case*. Terminally ill with tuberculosis, the character of M. Valdemar gives consent for the purpose of "yielding his person freely" to his physician's experiment in the hopes of "arresting death." The physician gave some form of explanation as to the nature of the experiment, and Valdemar was seemingly enthusiastic about participating.[5] This dynamic exchange of information shows a trend toward societal acceptance of patient participation and is a core concept in present-day elements of informed consent.

Early in the 20th century litigation ensued, ushering in the more contemporary and recognizable version of informed consent with respect to self-determination. In *Mohr v Williams*, 98 Minn 494 (Minn 1906), the patient alleged assault arising from an operation performed on the wrong side—the physician operated on the left ear instead of the right ear. The jury returned a verdict in favor of the patient, awarding her damages resulting from the injuries she sustained when the physician operated on her ear without her consent.

In *Schloendorff v Society of New York Hospital*, 201 NE 92 (NY 1914), the court also ruled in favor of the patient. In the *Schloendorff* case, the patient was admitted to the hospital and diagnosed with a fibroid tumor. The physician recommended surgery, but the patient adamantly declined. She did, however, consent to an examination under anesthesia. During the examination, the physician performed surgery to remove the tumor. The patient developed gangrene after the surgery, ultimately leading to the amputation of several fingers. The patient filed a lawsuit and the Court concluded that the operation to which plaintiff did not consent constituted medical battery.

Justice Benjamin Cordozo wrote in the Court's opinion:

> Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without the patient's consent commits an assault for which he is liable in damages.[5(p. 1408)]

Medical treatment is not the only area for which ethical solutions have evolved. At least 4 large, unethical research projects were exposed in the first half of the 20th century. The Willowbrook Study, the Jewish Chronic Disease Hospital study, the Tuskegee Syphilis Study, and the renowned Nazi medical experiments challenged the world research community and provided the impetus for widespread changes in biomedical research practices. After World War II, the Nuremburg Code was developed after revelations of inhumane and unethical treatment of research participants by Nazis. Numerous human rights and research principles were violated as subjects were exploited, sterilized, tortured, and exterminated in the name of medical and racial research.[7]

Many of the studies were poorly constructed, fraught with racial bias, and performed using