COMMENTARY

The Legal, Ethical and Therapeutic Advantages of Informed Consent

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This article summarizes the process of informed consent from its legal, ethical and therapeutic vantage points. Helping the patient understand procedures provides legal protection to the technologist, fulfills ethical duties and helps the patient by making the process of patient care therapeutic.

Key Words: informed consent; ethics; law; patient communication

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Information is power (*1*). Patients need information in order to make informed decisions about therapeutic and treatment options. The most accepted way of providing information to a patient is through the informed consent process. The patient is provided with the information needed to agree to have a procedure done. In some cases, very little information is needed. This is called simple consent.

In nuclear medicine, simple consent from the patient is always required to perform procedures. The patient must agree, sometimes simply by rolling up a shirt sleeve or climbing onto a table.

In some cases, written informed consent is required. Although consent must not be in writing to be valid, it is difficult to prove the existence of a verbal contract. For any procedure in which the risks outweigh those encountered in everyday living, or in any research setting, informed consent must be secured. In nuclear medicine according to Mundy (*2*), any experimental procedures, treatment with ^{131}I [and other radionuclide therapy procedures] cardiac stress testing, and the use of certain drugs for intervention require informed consent.

It is reasonable to view consent as a continuum of duties from simple consent to written informed consent. In simple consent, a professional simply asks for permission to perform a procedure and explains the procedure as needed. For written informed consent, the patient must be educated at length about risks, benefits and treatment alternatives.

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A health care professional should recognize three basic advantages to securing consent: legal, ethical and therapeutic (*3*). This article will review these three advantages as a guide to the technologist.

LEGAL ADVANTAGES

Obtaining consent from patients can provide legal protection in criminal or malpractice cases (*4*). The common law origin of informed consent and malpractice can be traced to a 1767 judgment in England. In this case, the court found that a surgeon used a new instrument without the patient's consent (*5*).

Simple consent has long been recognized as necessary for procedures. The case of *O'Brien v. Cunard Steam Ship Co.* (1891) found that a ship passenger's action of joining a line to have an injection constituted implied consent (*6*). Since the passenger joined the line voluntarily, could see the act being performed and was free to withdraw at any time, consent was given voluntarily.

The U.S. case law basis of informed consent is found in the 1914 decision handed down in the Schloendorff case. Justice Cardozo stated, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and the surgeon who performs an operation without his patient's consent commits an assault for which he is liable for charges (*7*)."

The doctrinal basis for informed consent can be traced to the 1957 case *Salgo v. Leland Stanford Junior University Board of Trustees* (*8*). In that case, the following was stated:

> A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment.

The central issues of informed consent come from the 1972 case *Canterbury v. Spence* (*9*). The patient must be given information that indicates the risk, benefits and alternatives to suggested treatments. Also, the outcomes which could result if a recommended treatment is not chosen by the patient must be provided.

A recent case affirmed that the process of informed consent is to be seen as information sharing, with the patient making the decision and the health care professional seen as a fiduciary to the patient. A fiduciary is one who handles the affairs of another in contrast to a traditional arms-length business relationship. This implies an element of trust, and if that trust is violated the professional is liable.

In *Arato v. Avedon*, the California Supreme Court affirmed an appeals court decision that physicians were liable to disclose statistics concerning life expectancy to patients to allow the patient to take timely action to plan for death (*10*). Without such information, the physician rather than the patient is making the treatment decision and, as Annas notes, "this is precisely what the doctrine of informed consent is designed to prevent (*1*)."

The Patient Self-Determination Act (PSDA) of 1990, which took effect in December 1991, mandates that health care institutions receiving Medicare and Medicaid funding provide written information about patients' rights to participate in medical decision making and the formulation of advance directives (*11*). Each state was required to:

> . . .develop a written description of the law of the State (whether statutory or as recognized by the courts of the State) concerning advance directives that would be distributed by providers or organizations under the requirements of [the Act] (*12*).

It should be recognized that simply signing a document does not mean that consent has been secured (*13*). For a health care professional to enjoy as much legal protection as possible, there should be a personal reassurance that the patient understands as much about the procedure as is needed to agree to have it.

ETHICAL ADVANTAGES

Ethical obligations present a higher calling than the law. Nuclear medicine technologists are expected, as are other professionals, "to maintain the highest ethical standards (*14*)." Consent is not simply a form, it is a means of assuring that ethical practice is being followed. Consent extends ethically from the concepts of autonomy and fidelity. Autonomy recognizes that the patient is always the primary decision maker in health care. These decisions are based upon truthful information (fidelity) provided by health care practitioners.

Health care providers have been criticized for failing to secure informed consent, especially in research settings (*15*). In some cases, patients are assuming that they are participating in studies designed to improve their own health, but are in fact undergoing research procedures that are designed to secure additional information, not improve the current patient's health. Faden states:

> Based on our studies, the committee concluded that many subjects agree to participate in research largely because of their trust in their doctors or in the hospitals where they are being treated. They do not understand some of the important differences between research and standard medical care, and thus may assume that anything done to them in the context of research is done for their potential benefit (*16*).

Also, if consent is not given willingly, then fraud or deception has occurred. The Nuclear Medicine Technology Code of Ethics clearly speaks against the use of fraud or deception (Principle 6).

Skotnik (*17*) provides an interesting viewpoint of a technologist's, nurse's or any other allied health professional's duty, in the consent process, as a patient advocate to report the failure to obtain informed consent to an appropriate authority within the treating facility. This is a logical outgrowth of Principle 1 of the Nuclear Medicine Technology Code of Ethics establishing the patient's rights (autonomy) and the role of the technologist as a patient advocate.

THERAPEUTIC ADVANTAGES

Informed consent has been called a "fallacy of law" since it is impossible for a patient to understand the risks and benefits of a procedure from the standpoint of an expert such as a physician or a nuclear medicine technologist. However, it is an extremely advantageous process, from a therapeutic or communication standpoint, since it helps the patient understand why a procedure is necessary. Understanding will increase patient compliance, and some studies have indicated that increased understanding helps in the healing process (*18,19*). This aspect of consent logically overlaps with consent as an ethical duty.

Who is responsible for securing informed consent? In most states, this duty is legally assigned to the physician (*20*). In many cases, however, professionals such as nuclear medicine technologists or nurses are responsible for ensuring patient consent. From a number of standpoints, this certainly makes sense. Physicians are often very busy and do not interact with the patient in the same manner as other health professionals, lacking the time needed for effective interaction (*21,22*). As Obergfell (*23*) has noted:

> Patients may feel more comfortable with the technologist than with the physician and therefore may express concerns about the course of treatment which had previously been left unsaid. Also, the technologist or therapist is the person who will perform or actively participate in the procedure or treatment and therefore will be better able to answer the patient's questions.

Nuclear medicine technologists often take courses during their education that help them to communicate effectively with the patient (*24*). Since they are performing the procedures, and have expert knowledge in radiation exposure, it makes sense that they should be able to secure simple consent or make sure that written consent has been secured. In cases where it is obvious that the patient does not have sufficient information to make an informed decision about a procedure

(whether they are willing to undergo the procedure or not), the technologist should attempt to provide that information. If the technologist is unable to do so, she should find someone who can.

Epstein (*25*) has described this as a dyadic relationship in which both the provider of a service and the recipient (the patient) come to clearer understandings of the limitations of the service or procedure. By explaining the procedure, the technologist will perform self-education as well as educate the patient. Education is an obligation of the nuclear medicine technologist (*14,26*).

For example, nuclear medicine technologists can help educate the patient and secure consent if they explain the procedure to patients before they inject a radiopharmaceutical. Oftentimes, the referring physician has given the patient very little information about the procedure. If the procedure is explained at the outset, it will be easier to secure compliance when the scan is performed, and the patient is actually under the camera.

One trap to avoid, in communicating with patients to secure informed consent, is that of beneficence (*27,28*). Beneficence is the basis of all ethical action in the health professions—a "doing good."

There is a tension between the principles of autonomy and beneficence. Health care professionals have a view of a good outcome based on their own experiences and biases. These are not necessarily the same as the patient's view. In fact, it is the patient's right to make both good and bad decisions. To properly communicate with the patient, the information provided must be without bias. There is sometimes a felt need on the part of the technologist to use phrases like "this exam won't give you radiation like x-ray." This is ethically untenable as well as a block to the communication process. Technically, the statement is true but it tends to make the patient think that there is no radiation involved or that there is no possible harm, unlike a radiographic examination.

CONCLUSION

Previously, patients did pretty much what their physicians told them to do. This is changing, and the importance of securing informed consent has increased in a litigious and consumer-oriented health care market. Technologists need to understand that making sure that the patient has given proper consent has a number of advantages: possible legal protection; an adherence to their code of ethics and a therapeutic component that helps the patient.

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