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Revisiting Informed Consent Issues

How to ensure that informed consent has been achieved

The concept of informed consent has been around for centuries. In New Jersey, the duty to provide a patient with the information necessary for the patient to make an informed decision regarding proposed medical treatment lies with the doctor or other practitioner providing the treatment. But in the context of a malpractice lawsuit, one misstep in the informed consent process between a doctor and a patient can mean a mountain of legal trouble for a doctor.

In short, informed consent requires that, except in emergency situations, the risks, benefits and alternatives to a particular medical treatment be explained to a patient before that patient decides whether to undergo such treatment. This duty emanates from New Jersey case law and the New Jersey Patient Bill of Rights. The latter gives every person admitted to a licensed hospital the right “[t]o receive from the doctor information necessary to give informed consent prior to the start of any procedure or treatment and which...shall include at a

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minimum, the specific procedure or treatment, the medically significant risks involved, and the possible duration of incapacitation, if any, as well as an explanation of the significance of the patient’s informed consent.” N.J.S.A. 26:2H-12.8(d). Similarly, New Jersey’s Hospital Licensing Standards give patients the right: “[t]o give informed, written consent prior to the start of specified nonemergency procedures or treatments only after a physician has explained — in terms that the patient understands — specific details about the recommended procedure or treatment, the risks involved, the possible duration of incapacitation, and any reasonable medical alternatives for care and treatment.” N.J.A.C. 8:43G-4.1(a)(7). Thus, hospitals and physicians must work together to ensure that an informed consent process is established and followed.

Typically, informed consent is accomplished through a detailed conversation between a doctor and a patient that is subsequently documented in a form signed by both parties. While the written form may serve to verify and summarize the doctor-patient conversation, the form does not replace the conversation. In New Jersey, for informed consent to be valid, it must meet the “prudent patient” standard which emphasizes the importance of a patient’s right to self-determination in medical decision-making. *Largey v. Rothman, M.D.*, 110 N.J. 204, 214 (1986). The prudent patient standard requires that the doctor’s explanation be given in terminology understandable to

the patient and comprehensive and clear as judged by what a reasonable person in the patient’s position would need to know to make an informed decision. *Id.* While every possible foreseeable risk or complication need not be explained, the patient must be informed of: inherent and potential risks of the proposed treatment; the nature of the treatment; possible duration of incapacitation, if any; feasible alternatives to the proposed treatment; and the likely consequences if treatment is not undertaken. *Id.*

One case illustrating the importance of providing information on alternative treatments involved an elderly woman who was admitted to the hospital with a broken hip. Her doctor determined that the patient’s bones were too brittle and that surgery to repair her hip was too risky. The doctor elected for the patient to receive bed rest. However, the patient was never presented with the option of choosing surgery instead of bed rest. *Matthies v. Mastro Monaco*, 160 N.J. 26, 34 (1999). The Court held that the doctrine of informed consent applies even when the course of treatment is noninvasive — such as bed rest, and allowed the informed consent action against the doctor to proceed to trial. *Id.* at 40-41.

To prove a case of lack of informed consent in New Jersey, the plaintiff must show that: (1) the doctor failed to give the patient all of the information that a reasonable person in the patient’s position would expect a doctor to disclose so that the patient might make an informed decision about the course of treatment; (2) the undisclosed risk (of

the treatment or nontreatment) occurred; (3) a reasonable person under the circumstances of this case would not have consented to the treatment or operation had he/she been so informed; and (4) the course of treatment or operation (or failure to treat or operate) was a proximate cause in producing the patient's injuries. *Howard v. University of Medicine and Dentistry of New Jersey*, 172 N.J. 537, 549 (2002), citing *Teilhafer v. Greene*, 320 N.J. Super. 453, 465 (App. Div. 1999).

Comprehension, Competency & Voluntariness

In addition to the prudent patient standard established by case law, a doctor must ensure that three elements are present before a patient's informed consent is valid. The patient must 1) comprehend the information given, 2) be mentally competent to give consent, and 3) give consent voluntarily. If any element is missing, the consent may be invalid.

To ensure that the patient comprehends her own medical condition and the doctor's explanation, the doctor should speak in terms the patient can understand and avoid any unnecessary or highly technical medical terms. One useful technique is for the doctor to ask the patient to repeat the information back to the doctor. This technique will help reveal misunderstandings and minimize confusion. The patient should also have an opportunity to ask questions and get answers about the proposed treatment. If a language or other communication barrier exists between the doctor and patient, the doctor must take reasonable steps to remove the barrier. For example, if the patient is deaf or doesn't speak English, an interpreter should assist in the informed consent process. It is also advisable to have a third party, such as a nurse, present as a witness.

Second, the patient must be mentally competent to give informed consent. Mentally incompetent patients, such as senile or comatose patients, generally cannot provide informed consent to medical treatment. When a patient's competency is at issue, the patient's next-of-kin or legal guardian should be contacted to act on behalf of the patient. Similarly, with some limited excep-

tions, minors are generally not permitted to provide informed consent on their own behalf. Rather, a parent or guardian must give consent.

Third, informed consent must be given voluntarily by the patient. That is, "it must be determined that the patient made her choice voluntarily and without coercion." *In re Farrell*, 108 N.J. 335, 354 (1987). For example, a terminally ill hospital patient may not want to undergo a certain treatment or procedure but feels pressure from a spouse or family member to consent. In this situation, removing all family members from the room before the informed consent discussion takes place will help ensure that the patient's decision is voluntary. "Society has an interest in ensuring the soundness of health care decision making, including both protecting vulnerable patients from potential abuse or neglect and facilitating the exercise of informed and *voluntary* patient choice." (emphasis added). N.J.S.A. § 26:2H-54 (d)

Expiration of Informed Consent

How long does informed consent last? New Jersey does not have a specific rule governing the number of hours or days informed consent remains valid. For example, informed consent for a specific surgical procedure, such as a tonsillectomy, lasts for the duration of the surgery. Generally, a patient's informed consent is good as long as circumstances do not change substantially. However, if an informed consent relates to a prolonged course of treatment — one that lasts weeks or months, the validity of the initial informed consent may come into question. For example, a cancer patient agrees to undergo a biweekly course of chemotherapy treatment for four months and gives informed consent at the first chemotherapy treatment. Is the consent valid for the entire course of treatment or should the patient give informed consent before each subsequent treatment? The answer will depend on whether circumstances surrounding the patient's treatment have changed over time. As a general rule of thumb, the longer the course of treatment, the more likely it is that circumstances will change and that the informed consent process should be repeated. When determining whether an

informed consent is still valid, consider the following issues:

Has the patient's condition changed? Using the cancer patient example from above, the patient has recently developed a new medical condition (high blood pressure) that did not exist when the treatment was originally commenced. Repeating the informed consent process at this point is necessary to address any new or increased risks of treatment. It will also increase the likelihood that this and any other new conditions will be revealed and considered when discussing future treatment options with the patient.

Have the risks and/or benefits of treatment changed? If a new study finds that the chemotherapy drug that the cancer patient is using causes a side effect or complication not previously known, this new information must be disclosed to and discussed with the patient before the next treatment and the informed consent process repeated.

Are new alternative treatments available? Similarly, in the event a new treatment alternative for the patient's type of cancer has been developed since the last treatment, the patient should be informed of this new treatment option, along with its risks and benefits and the informed consent process should be repeated.

How much time has passed since the last treatment? One additional consideration when treatment is extended over a long period (e.g., 30 days between treatments) is that memories will fade over time and the patient may not remember all of the risks and benefits initially explained to her at the outset of treatment. Therefore it is prudent to confirm the patient's understanding, and if necessary, repeat the informed consent process regularly. Because the informed consent process is time-intensive and requires a doctor's direct involvement, some doctors will be reluctant to engage in the informed consent process with the same patient repeatedly for the same treatment. However, repetition has the benefit of minimizing the chances that a procedure will be performed without an appropriate informed consent. Plus, a doctor's defense to an allegation of lack of informed consent may be bolstered if the patient's chart reflects that informed consent was given numerous times. ■