

Informed Consent Helps Avoid Lawsuits

Allegations of “lack of informed consent” and “battery” are common components of many medical malpractice lawsuits. The intention of this article is to provide legislative and risk management insight regarding issues of informed consent.

In 1971, as a result of *Cooper v. Roberts*, Pennsylvania rejected its traditional “professional or reasonable practitioner standard” and adopted the “reasonable person standard.” In the landmark case, Ms. Cooper sought damages for the perforation of her stomach during a gastroscopic examination. While the plaintiff signed a “blanket consent form” authorizing her attending physician to perform such medical procedures “deemed necessary or advisable”, there was no indication that the plaintiff was informed of the possibility of perforation or any other collateral risks of the examination.

The trial court initially granted a verdict in favor of the physician and the patient appealed. The Superior Court reviewed the appeal and granted the patient a new trial. The Court held that it was the duty of the physician to disclose those risks which a *reasonable* patient would consider material to his or her decision whether to undergo treatment. The adoption of the “reasonable person standard” placed the patient at the core of informed consent and the right to know all material facts no longer dependent upon the self-imposed standards of the medical profession.

The Law

In Pennsylvania, a claim for failing to obtain informed consent is considered a battery. A claim for lack of consent for surgery can be maintained even where there is no allegation of negligence in the actual performance of the procedure. Informed consent has been codified most recently by the 2002 passage of the MCARE Act which superseded all prior attempts to codify the doctrine. The MCARE Act does not apply retroactively, however, and does not address all of the details of informed consent that have been addressed by the courts up to the time of its passage. Consequently, common law decisions continue to be authoritative on some of the important aspects of the doctrine.

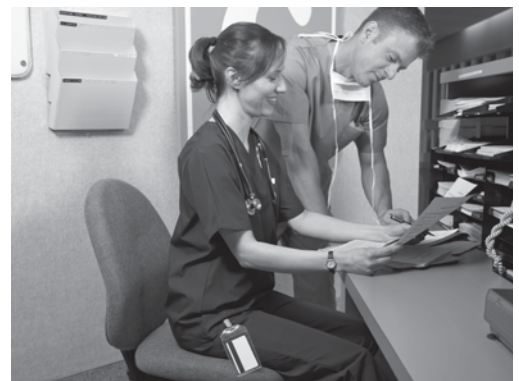
Unlike common law or prior legislation which required informed consent to be obtained only prior to performing surgical procedures, the MCARE Act requires that, except in emergencies, a physician is obligated to obtain informed consent prior to –

- performing surgery, including the related administration of anesthesia;
- administering radiation or chemotherapy;
- administering a blood transfusion;
- inserting a surgical device or appliance; and
- administering an experimental medication, using an experimental device, or using an approved medication or device in an experimental manner.

INFORMED CONSENT CHECKLIST

To make sure that you are adhering to accepted informed consent principles, remember the following:

- ✓ Obtain informed consent to avoid allegations of *lack of informed consent* and *battery*
- ✓ Avoid misrepresentation of your professional credentials, training or experience.
- ✓ Disclose the material facts, risks, possible complications, and alternatives that a “reasonable person” would consider significant.
- ✓ Document the consent discussion in the medical record.
- ✓ Discuss and document potential outcomes should a patient refuse treatment.
- ✓ Enhance the physician-patient relationship and improve patient satisfaction through the informed consent process.



The Act, unlike any prior law, will also hold a physician liable for failure to seek a patient's informed consent if the physician knowingly misrepresents to the patient his or her professional credentials, training or experience.

In obtaining informed consent, the patient must be advised of those material facts, risks, complications and alternatives that a reasonable person in the patient's situation would consider significant in deciding whether to undergo the procedure. Under the MCARE Act, the jury is permitted to take into consideration both what a reasonable patient would want to know and what the doctor is required by his profession to disclose. (Act 13 is available on the MCARE website at www.mcare.state.pa.us)

In order to succeed on an informed consent claim, a patient must establish that (1) the doctor failed to disclose all material facts before obtaining consent to a particular medical procedure; and (2) this undisclosed information would have been a substantial factor in the patient's decision whether to undergo [the] procedure. Although the patient does not have to prove that he would have chosen to forgo surgery had

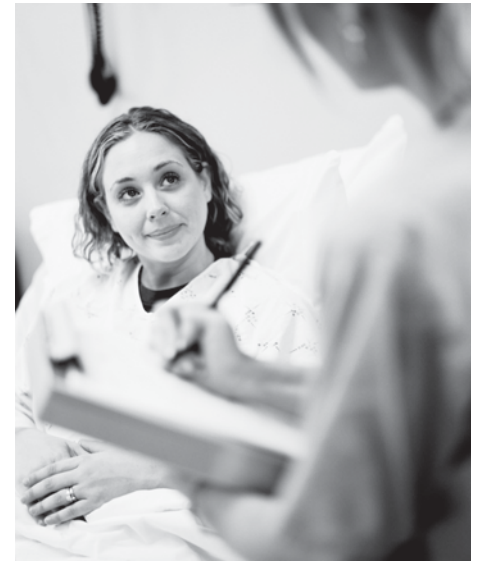
adequate consent been made, the substantial factor element requires the jury to speculate whether being fully informed would have played a significant role in the patient's decision.

To prove a claim that a doctor failed to obtain informed consent, a patient must establish that the procedure at issue is one that requires informed consent and must present expert testimony to establish 1) the existence of risks in the specific medical procedure; 2) the existence of alternative methods of treatment; and 3) the attending risks of such alternatives. Once these elements are established by expert testimony, it remains for the jury to determine the materiality of those risks and then decide whether the information and the probability of the type of harm in question is information which a reasonable patient would consider in deciding whether to undergo the procedure.

Consent is a Process

In a 2002 case, *Montgomery v. Bazaz-Sehgal*, the Pennsylvania Supreme Court addressed the consequences of battery. In this case, an adult male

consulted a urologist for treatment of a plaque blockage in his penis and a slight venous leak. The urologist initially treated the problem with injections.



When conservative treatment proved unsuccessful the urologist recommended surgical intervention. During the procedure the physician decided to implant an inflatable prosthesis into the patient's penis.

According to the patient, the doctor had recommended a revascularization procedure to increase blood flow to the



penis and never discussed a penile implant. After surgery the patient questioned the surgeon as to the need for the implant and the surgeon explained that he wanted to save him from a second surgical procedure.

Liability: The patient sued the surgeon arguing that he had committed a battery since he never consented to the placement of a penile prosthesis. Post-operatively he complained that he experienced pain and discomfort, loss of physical pleasure, mental anguish, and loss of consortium. The case proceeded to trial on lack of informed consent and battery claims.

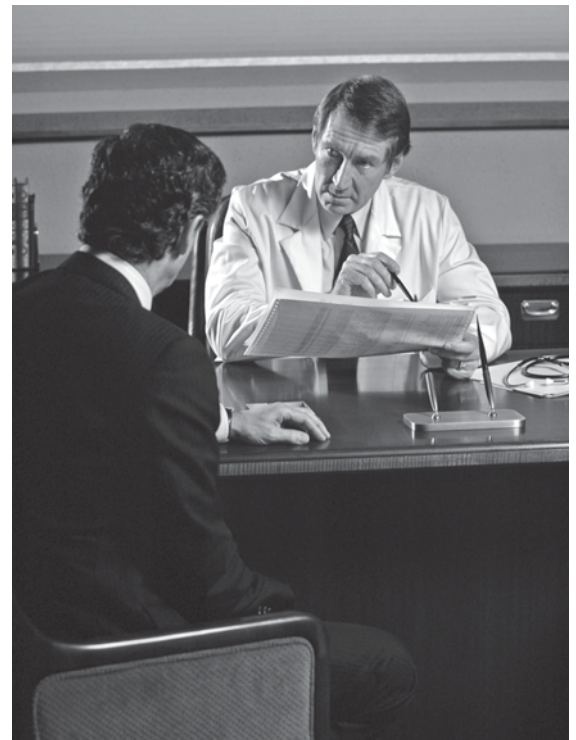
At the end of the trial, the defendant argued that the patient required a medical expert to sustain his claims and the trial court agreed and entered a verdict in the doctor's favor. The plaintiff appealed and the Supreme Court determined that a medical battery claim required only a showing of non-consensual contact to permit a jury to determine if the plaintiff's alleged emotional injury claims had validity. The plaintiff was granted a new trial.

Risk Management Commentary:

The successful defense of alleged battery cases relies on the language used on the informed consent form and any documentation referencing the informed consent discussion. Consent forms typically contain standard language as to alternative treatments or procedures, such as "I understand and consent to other treatments/procedures considered therapeutically necessary on the basis of findings or conditions found and judged by the doctor to require treatment during the course of this procedure." However defense attorneys warn that such standardized language applies to urgent and life-threatening conditions and does not typically apply to elective procedures where there is no eminent danger to the patient.

Remember, informed consent is a process and not merely a form. In order to ensure that patient rights are adequately honored, it is essential that a written protocol be developed to outline and describe your informed consent process. Include these four key components:

- **Consent Discussion** – The consent form should **never replace** a physician-patient discussion. The clinician or practitioner performing the procedure or administering the treatment is responsible for having the informed consent discussion with the patient and obtaining and documenting the patient's consent. Physicians must reveal all relevant information to the patient in allowing them to make a meaningful "informed" medical decision regarding the nature and purpose of proposed treatment, risks and benefits of proposed treatment, probability of success, alternative to proposed treatment, and the risks of foregoing treatment.
 - Detail the patient-specific items that were discussed and/or emphasized.
 - Has a consent form been signed?
 - Specify the educational handouts or information sheets provided to the patient.
 - Indicate whether the patient viewed any media-assisted programs, visual aids, or if internet resources were recommended.
 - Note the patient's language, if other than English, and the name and relationship of the translator.
- **Patient Education** – Provide educational pamphlets, written handouts and preoperative and post operative instructions for patients to better understand the possible complications involved in the proposed procedure and facilitate informed decisions. Document the materials used in educating the patient and record the fact that the patient received these materials.
- **The Consent Form** – Develop a consent form for those procedures requiring consent and obtain a patient's signature for consent. Do not delegate this important task. Provide the patient with a copy of the signed and dated consent form and keep one copy (if not the original) in the patient's chart.
- **Documentation** – In addition to the consent form, it is necessary to document the informed consent discussion in the patient's medical record to demonstrate the interactive nature of the consent process. Consider the following points when documenting the informed consent discussion:
 - Confirm that the consent discussion took place and the patient either consented or declined to consent.



Obtain Informed Refusal

A 36 female sought treatment from an orthopedic surgeon for a cyst on her right forearm. Over the course of 12 consecutive months the patient was seen in the office a number of times. At each visit the orthopedist advised her to have the tumor removed. After procrastinating an additional six months, the patient acceded to the doctor's recommendation for a biopsy. The tumor proved cancerous and the patient required subsequent amputation of her arm.

(continued on page 4)



Disclosure Statement

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- Name of the proposed treatment/procedure
- Benefits and risks of the proposed treatment/procedure
- Statement that the patient refused treatment/procedure despite the benefits and risks and the physician's recommendation
- Risks and expected or possible consequences of refusal
- Patient's (or legal representatives) signature, date and time
- Printed name and signature of the person who provided the information and obtained the patient's refusal

respect to the medical options proposed. Additionally, the MCARE Act requires physicians to not knowingly misrepresent professional credentials, training, or experience to a patient.

Although the law is strict, your efforts in obtaining consent will not only avoid the potential allegations of "lack of informed consent" or "battery", it affords the opportunity to enhance physician-patient relationships and improves overall patient satisfaction.

If you should require assistance in developing an informed consent or informed refusal document, please contact the Risk Management Department at Millennium Insurance Company at 610-848-7300.

At trial, the patient testified that had the doctor told her that she could have had cancer she would have, "rushed to have the biopsy!" The jury returned a verdict in the patient's favor.

Liability Issues: Allegations in this case involved a failure to timely perform the recommended biopsy and lack of informed consent with respect to the need for an immediate biopsy.

Risk Management Commentary: When discussing the nature of a suspected clinical diagnosis and the risks and alternatives to a proposed procedure or treatment, physicians should also disclose the potential outcomes if recommended treatment is not carried out. In the event a patient (or the patient's legal representative) declines the recommended procedure or treatment, their decision should be documented in the medical chart and an informed refusal form completed. Give the patient a copy of the informed refusal form. If the patient should refuse to sign it, note their refusal on the informed refusal form and in the patient's medical chart. Detail the following when documenting informed refusal:

Conclusion

Pennsylvania law relies on the "prudent patient standard" or what a reasonable patient would want to know about the recommended treatment. The primary theme emphasized throughout this law is to ensure that the patient is provided with all the material facts he or she needs to make an informed choice with

Millennium Insurance Company appreciates the efforts of Dan Ryan, Esq. of the Law firm of O'Brien & Ryan for his contributions to this article in explaining the obligations of physicians as specified by Pennsylvania law.

