Informed Consent for Medical or Surgical Treatment

Peter I. Bergé, JD, MPA, PA-C Emeritus

WHAT IS INFORMED CONSENT FOR TREATMENT?

"Did you check to see if there is a 'consent' in the chart?"

"Was the patient consented?"

These questions seem like useful items for a checklist which might help to protect a patient's rights. In fact, they reflect misconceptions that serve as a barrier to efforts to assure that a patient has given informed consent for a particular course of treatment or procedure.

The history of a patient's right to give informed consent for medical or surgical care goes back at least to the late 1800s (Walter 2012) and remains a modern concept. New Jersey's Model Civil Jury charge says

> A doctor must obtain the patient's informed consent before the doctor may treat or operate on the patient. The doctor has a duty to explain, in terms understandable to the patient, what the doctor intends to do before subjecting the patient to a course of treatment or an operation. The purpose of this legal requirement is to protect each person's right to self-determination in matters of medical treatment. (NJ Model Civil Jury Charge 5.50C)

If the reader finds "treat or operate on" to be very broad, that is understandable. In discussing informed consent, I embrace that expansive wording, while cautioning that informed consent must be obtained by any clinician treating the patient, and not only (as implied by the jury charge) by physicians. Further, the basic concept of informed consent applies to any treatment, not just surgical procedures.

A review of the basic elements of the negligence tort may be helpful in uniting the components of an informed analysis in context. The plaintiff in a civil tort claim such as personal injury generally has the burden to prove the case with a preponderance of the evidence, i.e. more than 50%, and must prove all of the elements: duty, breach of that duty, injury, causation (but for the breach of duty the injury would not have occurred), and damages (nature and quantity of compensation reasonably expected to make the injured party whole).

In medical malpractice, "duty" translates both to a general duty to the patient, and the obligation to adhere to the standard of care (SOC, the nature of which would involve a separate and lengthy discussion). "Breach of duty" is a deviation from the standard of care in the medical malpractice context. SOC and deviation are, in most cases, determined by the trier of fact (usually a jury) after presentation of expert testimony in court.

The standard of care regarding informed consent, however, is often established as a matter of law, whether by legislation (e.g., New York State [PBH § 2805-d]) or case law (e.g., New Jersey, see *Matthies v. Mastromonaco*, 733 A.2d 456, 160 N.J. 26, 1999).

The American Medical Association (AMA) Code of Medical Ethics Opinion 2.1.1, describing the informed consent process, appears in figure 1. [SEE FIGURE 1]

American Medical Association

CODE OF MEDICAL ETHICS OPINION 2.1.1

Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making.

The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decisionmaking capacity or declines to participate in making decisions), physicians should:

(a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.

(b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about:

1. The diagnosis (when known)
2. The nature and purpose of recommended interventions
3. The burdens, risks, and expected benefits of all options, including forgoing treatment

(c) Document the informed consent conversation and the patient's (or surrogate's) decision in the medical record in some manner. When the patient/surrogate has provided specific written consent, the consent form should be included in the record.

In emergencies, when a decision must be made urgently, the patient is not able to participate in decision making, and the patient's surrogate is not available, physicians may initiate treatment without prior informed consent. In such situations, the physician should inform the patient/surrogate at the earliest opportunity and obtain consent for ongoing treatment in keeping with these guidelines.

https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-2.pdf

Figure 1

While the law varies among jurisdictions, the core elements usually required are:

1. The reason for the proposed course of treatment (including diagnosis and goals), the intended benefits, and the known, significant risks. Some jurisdictions do not require explanation of commonly known risks, or those with both insignificant clinical impact and low incidence.

2. The risks and benefits of reasonable, accepted alternative courses of treatment, including no treatment.

3. Implicitly, the information is presented to the patient in such a way that the patient has sufficient understanding to make an informed decision regarding which course of treatment the patient wishes to pursue.

Note that a "consent form" is not generally an element required by law, although some jurisdictions may additionally require signing a form under some circumstances. The form, regardless of details, serves only as one element of evidence that the treater has obtained informed consent or, in some cases, of the failure to properly do so. In other words, if the consent form is the only documentation of obtaining informed consent, and the information presented there does not meet the standard of care, the form may inculpate potential defendant or defendants. Still, it is common for institutions, such as hospitals, to require that a signed "consent form" appear in the patient record when surgical or otherwise invasive procedures are to be performed.

A form indicating consent for treatment in general is usually signed prior to admission to a hospital or to an outpatient unit. Prudent practitioners document the informed consent process in the patient record irrespective of the presence or absence of a "consent form." LNCs who review patient records for medical malpractice claims, particularly those involving surgical or other invasive procedures, will often see discussions of the consent process both in progress records and in procedure or surgical notes. While there is no universal legal requirement for such documentation, local or institutional rules may mandate it.

To prove a deviation from the standard of care in obtaining informed consent, a plaintiff must prove that the clinician did not perform all the elements discussed. Even if the risks of the proposed treatment were explained, the standard is not met without discussion of alternatives, including the choice of taking no action, if that is a reasonable option. The patient's consent is not informed without being able to compare the risks and benefits of reasonable alternatives to those of the proposed treatment.

Causation is established not only by linking the treatment actually performed to the claimed injury, but also by comparing the probable results of alternatives, including forgoing any treatment, to the injury resulting from the treatment elected by the clinician. This is critical in jurisdictions that use the "objective" standard of the "prudent patient," i.e., asking if an imaginary reasonable, prudent patient would have elected one of the alternatives if presented with the risks and benefits. (see *Canterbury v. Spence*, 150 U.S.App.D.C. 263, 282). Under that standard it is irrelevant if the plaintiff says, "if I had known, I wouldn't have gone ahead with that treatment." The jury must decide if a prudent patient would have made that decision.

The patient's consent is not informed without being able to compare the risks and benefits of reasonable alternatives to those of the proposed treatment.

Implicit in this analysis is comparing the likelihood of harm from an alternative course, whether it be a different treatment or no treatment. This is essential to determine whether or not the patient would be in the same, better or in a worse position having elected a different course of treatment from the one performed.

It is also insufficient to stop at the point of asking, "if the surgery had not been performed, would that vessel have been cut?" Rather, one must look at the available, reasonable alternatives and their risks and benefits. If the risk of no treatment would likely have been death, then a jury would likely find that a reasonable patient would have elected that surgery despite the risk of cutting the vessel, and the case fails on causation. This is why analysis of the available alternatives is necessary, both for legal and for factual reasons. The plaintiff may not be, or may not have been, reasonable.

Regarding injury and damages, as with any personal injury case, the potential damages must be sufficient to cover the high costs of litigation and still properly compensate the plaintiff for the injuries sustained and the attorney for the investment of time, expertise and expenditures in the management of the case. If they are not, an otherwise meritorious case will likely not be pursued.

CONSENT AND LIABILITY

Some clinicians think that listing a potential complication on a consent form serves as a defense should the complication occur. Defense counsel also attempt to perpetuate that misconception. On deposition, the defense attorney will show plaintiff the signed consent form and ask, "Is that your signature?" And then, "Do you see where it the list includes, 'amputation of the wrong leg'?" as if inclusion of that event somehow absolves the physician of liability. It does not, and defendants will usually acknowledge that they have a duty to take all reasonable precautions to prevent known complications. In fact, inclusion of an event on a consent form, or in a discussion that occurs in order for informed consent to be obtained, highlights the fact that the treating clinician is aware of the potential complication, and has the obligation to take the accepted measures that would reduce the risk of the complication occurring, and to take the actions indicated to mitigate its severity once the complication has been discovered.

Some clinicians think that listing a potential complication on a consent form serves as a defense should the complication occur. It does not.

A signed form indicating consent for treatment may, under some circumstances, serve as a defense against a claim of medical battery. A battery claim is typically distinguished from negligence when the patient denies having given permission to be touched in a particular way, or for a particular procedure to be performed. Battery is a civil (and sometimes criminal) offense distinct from failure to obtain informed consent, a type of negligence (Bradley v. Sugarbaker). Initially obtaining informed consent, however, is not sufficient to forestall a claim of battery. In *Levin v. United States*, 2016 Guam 14, the court cogently discusses the circumstances under which a patient may withdraw consent, adopting the test in *Mims v. Boland*, 138 S.E.2d 902 (Ga. Ct. App. 1964),:

> We hold that in the context of a medical procedure in which consent was previously given by the plaintiff, to constitute an effective withdrawal of consent, (1) the plaintiff must have used language that unequivocally revoked his or her consent and was subject to no other reasonable interpretation, and (2) stopping the treatment or examination must have been medically feasible. (*Levin v. United States*, 2016 Guam 14 at 21)

In *Levin*, plaintiff gave informed consent orally and in writing for cataract surgery. However, he claimed that once he saw the equipment in the operating room of the Navy hospital he withdrew his consent, and did so again once the eye was anesthetized. Then he suffered corneal clouding, a known risk purportedly discussed with him before the surgery. He sued for medical malpractice and for battery. The negligence claim was dismissed on legal technical grounds having to do with sovereign immunity (it was a Navy surgeon and a Navy hospital). Levin appealed, claiming that the relevant cause of action was medical battery due to his allegation that he had withdrawn consent, and the United States Supreme Court held that the government was not shielded from a claim of medical battery by a Navy doctor acting within the scope of his employment. *Levin v. United States*, 568 U.S. 503 (2013)

Absent an unusually compelling claim of battery (medical/civil, or criminal), informed consent claims are rarely sufficient to stand on their own as a cause of action. Typically, the defendant is sued for otherwise deviating from the standard of care, and a count of failing to obtain informed consent appears as an additional claim.

Obtaining informed consent is a process, which involved bilateral communication, assuring that the patient understands the options available, and that the patient still agrees to the course of action discussed if conditions have changed.

WHEN IS INFORMED CONSENT REQUIRED?

Informed consent is required for medical treatment, and not simply for surgical or invasive procedures. That does not mean that a patient must sign a form. A patient prescribed a fluoroquinolone and is not given the option of another class of antibiotic, nor is informed of the black box warnings published for that class of drugs, may have a valid claim should the medication cause one of the serious and permanent injuries associated with its use. The prudent prescriber will not only have such a discussion, in terms that the patient can understand, but will document it in the patient's record for future reference.

SUMMARY

So, what is wrong with those two sentences beginning this discussion? They perpetuate the misconceptions that informed consent consists of having a patient sign a form, and that obtaining informed consent happens at a given moment. Obtaining informed consent is a process, which involved bilateral communication, assuring that the patient understands the options available, and that the patient still agrees to the course of action discussed if conditions have changed. A patient may withdraw consent for treatment, and if that withdrawal is expressed clearly and unequivocally while it is still medically feasible to withhold or stop the treatment, it may be considered medical battery for the clinician to continue.

FURTHER READING

For those seeking a more in-depth discussion on informed consent, I recommend these articles:

Medical Informed Consent: General Considerations for Physicians

DOI: https://doi.org/10.4065/83.3.313 https://www.mayoclinicproceedings.org/article/S0025-6196(11)60864-1/fulltext

Informed Consent - Israel National Commission for UNESCO

The International Center for Health, Law and Ethics http://unesdoc.unesco.org/images/0014/001487/148713e.pdf

To see how jurors are instructed to deliberate informed consent claims, which serves as a lay language explanation, I again refer to NJ Model Civil Jury Charge 5.50C: https://njcourts.gov/attorneys/assets/civilcharges/5.50C.pdf?cacheID=lFksCv8

and also refer to California's Medical Battery–Conditional Consent charge at https://www.justia.com/trials-litigation/docs/caci/500/530b/

Model jury charges in the jurisdiction where you work can be an excellent resource for a basic understanding of legal issues where you are assisting with the analysis.

An in depth discussion of *Levin v. United States* is found in Kels CJ. Liability for Medical Battery in the Military Health System. MILITARY MEDICINE, 179, 1:1, 2014

REFERENCES

Bradley v. Sugarbaker, No. 16-2405 (1st Cir. 2018), available at http://media.ca1.uscourts.gov/pdf.opinions/15-1128P-01A.pdf

Retrieved November 14, 2018

NJ Model Civil Jury Charge 5.50C. Available at: https://njcourts.gov/attorneys/assets/civilcharges/5.50C.pdf?cacheID=lFksCv8

Retrieved November 12, 2018.

NYS PBH § 2805-d. New York Consolidated Laws, Public Health Law - PBH § 2805-d. Available at https://codes.findlaw.com/ny/public-health-law/pbh-sect-2805-d.html

Retrieved November 12, 2018.

Walter 2012. Patients have had to give consent to medical treatment since 1880.

See *State v. Housekeeper,* 16 A. 382, 384 (Md. 1889) (noting that surgeon is justified in performing operation with consent of patient), cited in Walter, Paula (2012) "The Doctrine of Informed Consent: To Inform or Not To Inform?," St. John's Law Review: Vol. 71: Iss. 3, Article

2. Available at: http://scholarship.law.stjohns.edu/lawreview/vol71/iss3/2

Retrieved November 12, 2018.

Peter I. Bergé, JD, MPA, PA, is a New York State licensed physician assistant, with over 30 years of wide-ranging healthcare experience, and an attorney admitted to the bar in New Jersey since 2004. As a partner in a New Jersey litigation firm until June of 2016, his practice concentrated in representing patients in medical malpractice claims. Now working independently between New York, Pennsylvania and balmy Mexico City, he provides consultation to attorneys and other professionals on complex issues relating to medical malpractice and medically related litigation. He continues to give lectures to professional and in universities on medical malpractice and medicolegal and related topics, and to publish in those areas.