

INFORMED CONSENT:

What You May Know and What You
Did Not

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Conflict of interest

- None

Objectives

- At the end of this session, participants should be able to:
 - Distinguish between a signed consent form and the process of obtaining informed consent
 - List the elements of informed consent generally required under law
 - Define medical battery and explain the elements of avoiding being charged with it

Focus of presentation

- Medicolegal perspectives on informed consent
- Emphasis on practice considerations

The basics

- Elements of the negligence tort
 - Duty
 - Breach
 - Injury
 - Causation
 - Damages

Negligence

- **Injury** (harm)
 - Physical
 - Emotional/psychological
 - Financial
 - Other

Medical Malpractice Elements

- Duty
 - Duty to the patient (general)
 - Adhere to *standard of care (SOC)*
- Breach of duty
 - Deviation (departure) from standard of care
- Injury
 - Harms are generally the same as in any tort

Medical Malpractice Elements

- Damages
 - Generally the same as in other torts

Informed consent and negligence

- Failure to obtain informed consent as the basis for a medical malpractice claim
 - Rarely viable as the only claim unless
 - Represents a striking example, or
 - Involves medical battery
 - Often added to other counts (claims of other deviations from the standard of care)

What must be included?

What must be included?

- AMA CODE OF MEDICAL ETHICS OPINION
2.1.1
- (a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.

What must be included?

- (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

What must be included?

- 3. The burdens, risks, and expected benefits of all options, including forgoing treatment

[Ignore physician references. This means you.]

What does “all options” mean?

What must be included?

- NJ Model Civil Jury Charge 5.50C:
 - 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**.

[Of course, this doesn't only apply to physicians]

What must be included?

- NJ Model Civil Jury Charge 5.50C:
 - The purpose of this legal requirement is to protect each person's right to self-determination in matters of medical **treatment**.

Patient elements

- Can a clinician express a preference or make a recommendation?

Patient elements

- What if the patient doesn't want what you prefer or recommend?

Patient elements

- What if the patient is unreasonable?

Informed consent FAQ

- What is the role of “consent forms” in obtaining informed consent?
- What is the role of charting?
- Who can obtain informed consent?
- Who is responsible for assuring that informed consent was given?

Consent forms

- What is the role of “consent forms” in obtaining informed consent?

Documentation

- What is the role of charting in the consent process?
 - In case of a lawsuit, your charting is likely to be more helpful than just a signed “consent form...” as long as it’s accurate.

Roles

- Who can obtain informed consent?
- Who is responsible for assuring that informed consent was given?

When to obtain informed consent

- When is informed consent required?
 - Surgery? Invasive treatments? Invasive diagnostic procedures? Contrast studies? Blood transfusions?
 - What about prescribing an antibiotic or casting a fracture?
- Why?

Informed Consent - Documentation

- Prudent practitioners document the informed consent process in the patient record irrespective of the presence or absence of a “consent form.”

Informed Consent for Medical or Surgical Treatment. Bergé P. JLNC Vol 30
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The “prudent patient” standard

- The “objective” standard of the “prudent patient.”

Canterbury v. Spence, 150 U.S.App.D.C. 263, 282

The “prudent patient” standard

- EXAMPLE

The “prudent patient” standard

- 48 y/o woman sent to surgeon for mass in left axilla
- Surgeon sends her to pathologist for FNA of lymph node
- Path report: malignant cells consistent with breast carcinoma metastatic to lymph node

The “prudent patient” standard

- MRI: abnormal cluster of calcifications
suspicious for cancer in light of positive FNA
- Surgeon to patient: you have breast cancer.
We must remove your breast or you will die.

The “prudent patient” standard

- In OR, surgeon sends a tissue sample from area where the MRI abnormality was probably located
- Report: no tumor found in the sample
- Performs mastectomy

The “prudent patient” standard

- Pathology:
 - No tumor in breast
 - “Lymph node” that was thought to be enlarged, and was the subject of the FNA was simply benign breast tissue

The “prudent patient” standard

- Deviations?
 - Pathologist?
 - Surgeon?
 - **Informed consent issues:**
 - Options at the time of the negative intraoperative pathology report?

The “prudent patient” standard

How to apply the “prudent patient” standard in a case such as this?

What would a prudent/reasonable patient decide under these facts (i.e., possibly no cancer)?

Informed consent: standard of care

- Who decides what is INFORMED CONSENT?
- The standard of care regarding informed consent 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 final decision is made by the jury.

Implied consent

- American Medical Association CODE OF MEDICAL ETHICS OPINION 2.1.1
- 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.

Implied consent

- American Medical Association CODE OF MEDICAL ETHICS OPINION 2.1.1
- 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.

Lack of capacity/competence

- **Capacity** refers to the patient's ability to make a particular decision based primarily on mental status. Capacity can be assessed clinically.
- **Competence** is a legal determination made by a court, usually with input from one or more appropriate professionals. People who have been deemed incompetent usually have a guardian empowered to make decisions.

Lack of capacity

- What do you do if in your assessment the patient lacks the capacity to make a particular decision?
 - What is the law in your jurisdiction?
 - What are the established policies and procedures in your institution?
 - Is there an emergency that immediately threatens the life or well-being of the patient?

Refusing life-extending treatment

- Refusing life-extending treatment does not equal incapacity.
- In general, patients have the right to self-determination and to choose to refuse treatment even if such refusal will endanger their lives.
- Assessment of capacity and documentation of such assessment is important.

Informed consent as a defense

- Consent as a defense against a claim of *malpractice*?
- Consent as a defense against a claim of *medical battery*?

Defense against malpractice

- Explaining a risk and/or including it on a “consent form” is not a defense if the injury was preventable

Medical battery

- Battery claims (civil, sometimes criminal)
 - Patient denies having given permission to be touched in a particular way, or
 - for a particular procedure to be performed, or
 - to be touched or have a procedure to be performed by a particular person, OR
- patient *withdraws consent* for the touching, procedure or examination, which is not then stopped.

Medical battery

- In *Levin v. United States*, 2016 Guam 14,
 - Patient gave informed consent orally and in writing for cataract surgery in Navy hospital
 - Saw equipment in the OR and withdrew consent
 - Withdrew consent again after eye was anesthetized, but procedure continued
 - Suffered corneal clouding, a risk he had been informed of

Medical battery

- Brought lawsuit for medical negligence and for battery
- Negligence claim dismissed due to a technicality (could not sue the Navy due to sovereign immunity)
- U.S. Supreme Court held that his medical battery claim could continue despite sovereign immunity

Medical battery

- U.S.S.Ct. 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,

Medical battery

(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)

Medical battery

- Avoiding medical battery claims
 - Thoroughly document the informed consent process
 - Include in documentation anybody who may be involved performing a procedure or examination
 - If there is any doubt that the patient may be withdrawing consent, stop if it is medically feasible (“no” means “no”)

References

- *Canterbury v. Spence*, 150 U.S.App.D.C. 263, 282
- American Medical Association CODE OF MEDICAL ETHICS OPINION 2.1.1 available at <https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-2.pdf>

References

- California's Medical Battery–Conditional Consent charge available at <https://www.justia.com/trialslitigation/docs/caci/500/530b/>
- Informed Consent for Medical or Surgical Treatment. Bergé P. JLNC Vol 30 No.1 Spring 2019

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- 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>
- *Matthies v. Mastromonaco*, 733 A.2d 456, 160 N.J. 26, 1999

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- *Levin v. United States*, 2016 Guam 14
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Thank you!

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