

Making Informed Consent an Informed Choice

WHY DOES INFORMED CONSENT NEED TO BE IMPROVED?

- Informed consent is one of the top 10 most common reasons for medical malpractice lawsuits.
- Informed consent is often treated as a nuisance and a formality.
- Even after signing a consent form, patients often do not understand:

The benefits, harms, and risks of treatment

The possibility of poor outcomes

Their option to say “No”

AUTONOMY

The Principle of Autonomy gives patients the right to decide what happens to their body. Patients have the right to:

- Make care decisions
- Receive adequate disclosure
- Choose treatment options
- Refuse medical intervention
- Withdraw consent

CONSENT AND FORMS: IT'S NOT ABOUT THE FORM

CONSENT may be obtained ONLY by the one providing the intervention and MUST be obtained by that person specifically interacting with the patient and providing the appropriate information and options. IT CANNOT BE DELEGATED.

DOCUMENTATION OF CONSENT acknowledges that the patient has agreed to the procedure. This written acknowledgement is executed on a standard form (HCH127) by the patient and witnessed by an APRN, attending, nurse, PA, or resident.

IT'S NOT ABOUT THE FORM

- Signed Form ≠ Informed Consent
- The consent form (HCH127) exists to document that the patient has been provided information, has understood the information, and has agreed to a particular treatment or procedure.
- Many patients sign informed consent forms even when they do not understand the procedure.
- Courts have held that providing information when the patient doesn't understand, does not constitute informed consent.

Recognizing Patient Capacity for Decision-Making

Most patients have the capacity for decision-making.

Capacity:

- Means the ability and the right to make a decision.
- Can change over time and can vary depending on the decision to be made.
- Every person should be assessed for capacity.
 - If there is lack of capacity → legal designee should be identified.

Key criteria for patient capacity:

- Ability to make and communicate a choice.
- Ability to understand key information about his or her condition, options for treatment, and benefits, harms, and risks of treatment.
- No law or court order requiring treatment.

WHAT IS LACK OF CAPACITY?

Incapacity ≠ Disagreement

Patients may refuse treatment even if it puts their lives in jeopardy. The following conditions *do not automatically* mean patients lack capacity:

- Inability to speak
- Intellectual disability
- Physical disability
- Mental illness
- Cognitive impairment
- Intoxication

Incapacity ≠ having conditions that make it harder to communicate or make decisions.

Authorized Representative

Family and friends often help patients make decisions, but in most cases, **the final decision rests with the patient.** Except for:

- When the patient lacks decision-making capacity
- Most minors
- When the patient requests not to be informed
- When life-or health-threatening emergencies allow no time to speak with an authorized representative

Minors: The decision is made by a parent or legal guardian.

Adults: The decision is made by someone designated by the patient (health surrogate), *or* the decision is made someone designated by someone other than the patient who has authority (Spouse → Adult Children → Siblings → Other Relatives)

ADEQUATE DISCLOSURE

“Adequate Disclosure” is a non-delegable duty of the clinician providing the treatment and must include an explanation of:

- The patient's proposed care, treatment, and services;
- Potential benefits, risks, and side effects of the proposed care, treatment, and services;
- The likelihood of the patient achieving his or her goals;
- Any potential problems that might occur during recuperation;
- Reasonable alternatives to the patient's proposed care, treatment, and services;
- The discussion encompasses risks, benefits, and side effects related to the alternatives;
- The risks related to not receiving the proposed care, treatment, and services.

The JDH policy on elements of consent contains specific information about our institutional requirements, including when consent must be obtained <https://health.uconn.edu/policies/wp-content/uploads/sites/28/2017/06/2015-03-Informed-Consent-Clinical-Obtaining-Documenting.pdf>

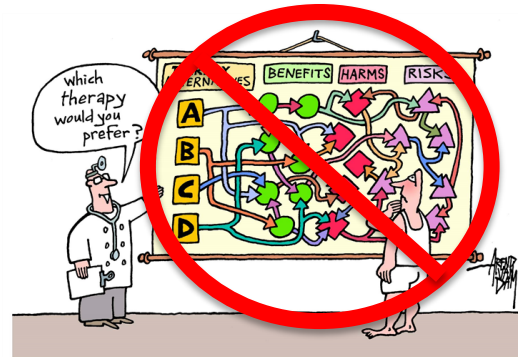
MAKING INFORMED CONSENT AN INFORMED CHOICE

Informed Consent requires clear communication about choices.



Informed choice requires:

- Clear, unbiased information about **all** treatment options
- An answer to the question: What if I do nothing?
- Knowing how the options align with the patient's goals and values.



informed consent

From Arend van Dam,
politicalcartoons.com

Of course, the information must be presented in a way the patient can understand

THE IDEAL PROCESS (elective procedure in this case)

Provider meets with the patient

- Including key family members is always good
- The procedure, risks, benefits, alternatives, etc. are explained
- Ample opportunity is provided for questions

Provider documents the conversation in writing and this note goes in the medical record. **If not documented, “it never happened”**

- Ample opportunity is provided for the patient to reflect
- Sometimes encouraging the patient to defer consenting for a few days is a strategy

At some point the patient must give written agreement to proceed. This permission is documented on a form and witnessed by Attending, resident, APRN, PA, or nurse

THE LESS-THAN-IDEAL PROCESS

- Provider meets with the patient on day of procedure
- No previous note documenting consent
- The procedure, risks, benefits, alternatives, etc. are explained at the time of signing
- Provider uses the HCH127 to document elements of consent as well as to witness patient's agreement. IF HCH 127 is used:
 - All elements must be there
 - The form must be executed by the provider performing the procedures

Federal Lawsuit Alleges UPMC Falsely Billed For Medical Procedures, Failed To Properly Obtain Patient Consent

By [Lindsay Ward](#) July 7, 2020 at 5:24 am Filed Under: [Federal Lawsuit](#), [Lindsay Ward](#), [Local News](#), [Local TV](#), [UPMC](#)

- Plaintiffs include the Department of Health and Human Services and the Centers for Medicare and Medicaid Services. Both accuse the University of Pittsburgh Medical Center of falsely billing CMS (Medicare/Medicaid) for procedures without proper informed consent.
- Investigation started after a whistleblower complaint by an employee to Federal government that UPMC physicians were **improperly delegating informed consent responsibilities to residents, fellows, NPs, and PAs** in violation of federal and state law and UPMC policy.
- Suit asks Court to fine UPMC treble damages, which could run into 7 figures (plus legal fees).
- Informed consent is a critical responsibility at the foundation of a physician-patient relationship **that can never be delegated.**