

Informed Consent: Examining the Patient and the Process

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Objectives

1. Discuss the ethical and legal aspects of informed consent.
2. Review the core elements of informed consent.
3. Learn what is considered “adequate” when disclosing information to patients.
4. Identify ways to properly document the entire process with case examples and enhancing strategies.



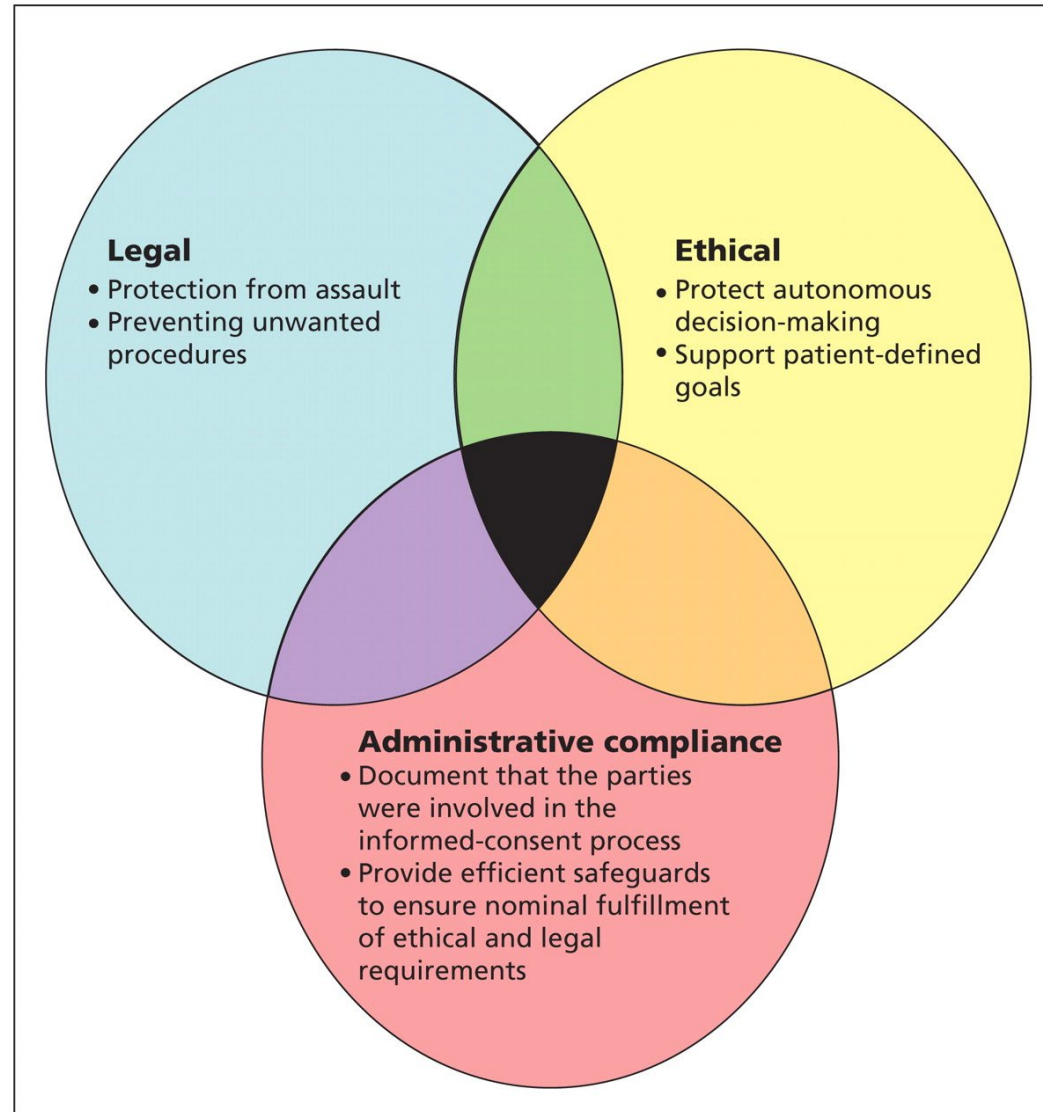
What is Informed Consent?



Informed Consent is the process by which the treating healthcare provider **discloses** appropriate information to a **competent** patient so that the patient may make a **voluntary** choice to accept or refuse treatment.

The consent form should not be confused with the consent process; the form merely documents that the process occurred.

The Multiple Overlapping Areas of Informed Consent



Hall, D. E., Prochazka, A. V., & Fink, A. S. (2012).

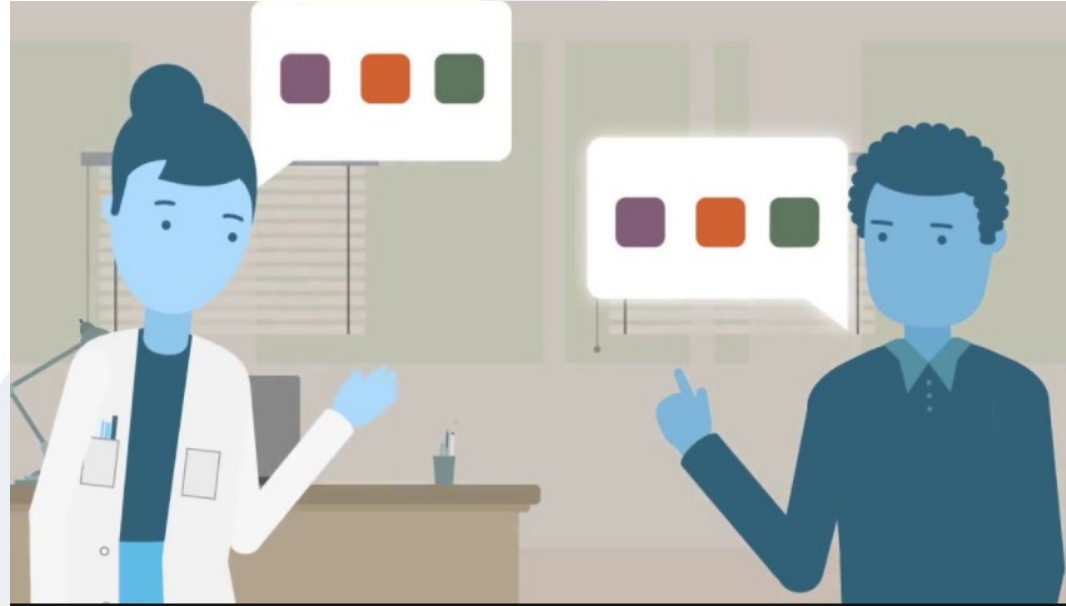
What are the Core Elements of Informed Consent?

Generally, the discussion includes the following:

- Nature of the decision/procedure
- Reasonable alternatives to the proposed intervention
- Relevant risks, benefits, and uncertainties related to each alternative
- Assessment of patient understanding
- Acceptance of the intervention by the patient



Always Strive for a Comprehensive Discussion



Decision-Making Capacity

A person has decision-making capacity if they can tell you the following:

- What the problem is
- What the recommended treatment is
- What alternatives are available
- What the expected outcome of each approach is



Disclosure

How much information is considered “adequate”?

There are three different standards of disclosure:

1. ***Reasonable Physician Standard:*** This standard allows the physician to determine what information is appropriate to disclose.
2. ***Reasonable Patient Standard:*** This standard focuses on considering what a typical patient would need to know in order to understand the decision at hand.
3. ***Subjective Standard:*** This standard is the most challenging to incorporate into practice since it requires tailoring information to each patient.

The ***Reasonable Patient Standard*** is probably the most commonly used legal and ethical standard.



Effective Consent = Understanding

To be effective, consent requires communication and understanding.

It is the portion of the discussion when the patient is able to demonstrate that he or she fully grasps all the information that has been disclosed.



Challenges to the Informed Consent Process



Health Literacy

Many patients do not know the meaning of basic medical terminology.

One colorectal study revealed participants did not know the meaning of common medical terms such as “polyp,” “tumor,” “lesion” or “blood in the stools,” and no participant knew what the colon or bowel was, or where it was located.



Medical Team Challenges

- Poor communication technique
- Lack of time for the informed consent process
- Inability to detect patient incomprehension
- Legal outlook toward consent process



Patient Challenges

- Anxiety and fear of new procedures
- Health status (terminal, debilitating diseases)
- Cognitive Impairment (neurological disorders, elderly)
- Denial of the disease state

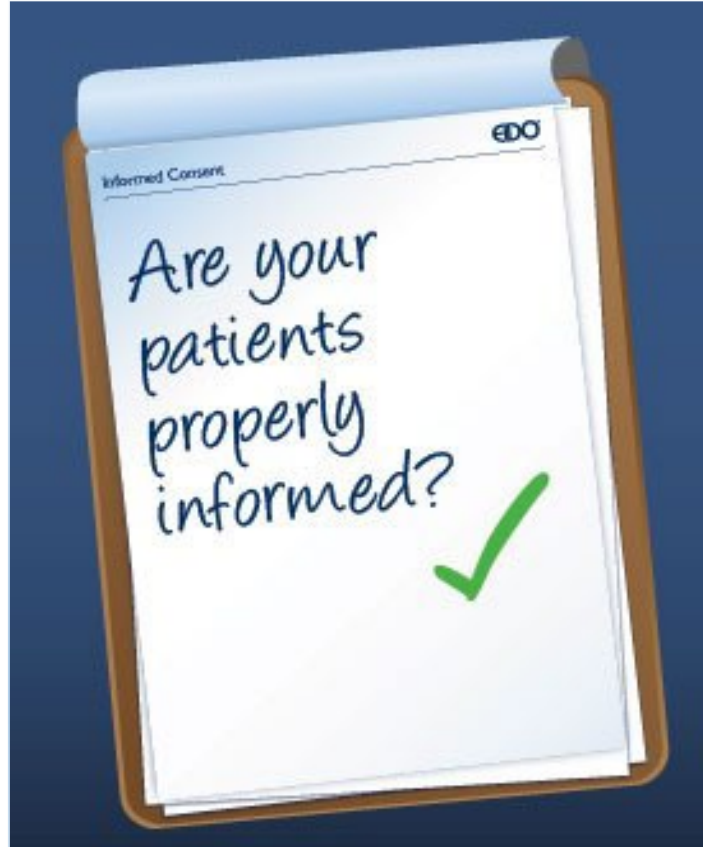


Consent Document Challenges

- Complex language
- Medical terminologies
- Legal nature
- Lengthy consent documents



Patients with Special Circumstances



Patients with Limited Capacity

Case: A 64-year-old woman with MS is hospitalized. The team feels she may need to be placed on a feeding tube soon to assure adequate nourishment. They ask the patient about this in the morning and she agrees. However, in the evening (before the tube has been placed), the patient becomes disoriented and seems confused about her decision to have the feeding tube placed. She tells the team she does not want it in.

They revisit the question in the morning, when the patient is again lucid. Unable to recall her state of mind from the previous evening, the patient again agrees to the procedure.

Is the patient competent to decide?

Patients Who Refuse Care

Case: A 55-year-old man has a three-month history of chest pain and fainting spells. You feel his symptoms merit cardiac catheterization.

You explain the risks and potential benefits to him, and include your assessment of his likely prognosis without the intervention. He is able to demonstrate that he understands all of this, but refuses the intervention.

Can he legally refuse? Should you leave it at that?



Patients with Surrogate Decision Makers

If the patient is determined to be incapacitated or incompetent to make healthcare decisions, a surrogate decision maker must speak for him or her.

If no appropriate surrogate decision maker is available, the physicians are expected to act in the best interest of the patient until a surrogate is found or appointed.

In rare circumstances, when no surrogate can be identified, a guardian ad litem may be appointed by the court.

Strategies that Enhance the Informed Consent Process



Use the Teach-Back Method

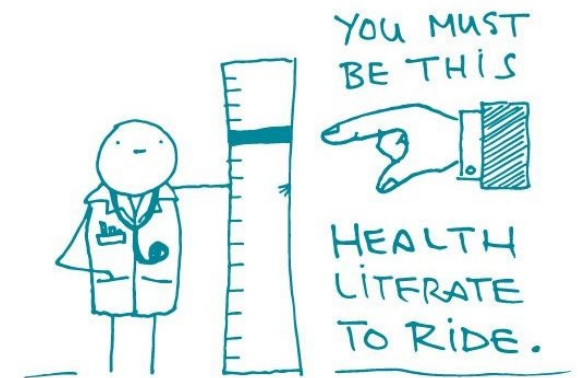
Teach-back is a great way to check patient understanding because you:

- Ask patients to explain in their own words what they were told during the informed consent discussion.
- Provide a chance for the clinician to check the patient's understanding and reteach information, if needed.
- Check on clarity or how well the clinician explained what the patient needs to know. You are not testing the patient.

Use Health Literacy Universal Precautions

When healthcare providers use this approach, they acknowledge:

- Professionals cannot accurately identify who understands and who does not.
- Even individuals with proficient health literacy skills may not attribute the same meaning to health terms and instructions as professionals do. These individuals can sometimes have trouble understanding health information. Especially, when they are sick, frightened or in pain.
- Health literacy can be situational. It may vary based on factors.
- Everyone benefits from clear, actionable information.



Simplify Consent Forms

Simplify the content, length and language of informed consent documents.

- Use words familiar to the non-medical reader.
- If possible, keep words to three syllables or fewer.
- Write short, simple and direct sentences.
- Present key information in bulleted texts, diagrams and graphics.



Shared Decision Making – Engage Patients, Families and Friends

Encourage your patients to have a trusted family member or friend with them during the informed consent discussion to support them as they get information and make decisions.

- Patients may be vulnerable due to the physical and emotional effects of their illness.
- A patient that is stressed out about their condition is more likely to misunderstand the information given.
- A support person can lower stress, help the patient to process the information, and ask questions.

Elicit Goals and Values

Not all patients want the same things.

- Treatments have different consequences, and some will matter more to one patient than another.
- Ask specific questions such as:
 - Is your goal to minimize pain?
 - Do you want to get back to work or school quickly?
 - Do you want to return to playing recreational sports?
- Patients may ask you, “What would you do?”



Show High-Quality Decision Aids

Decision aids provide information about:

- Various options available for a specific medical problem or screening procedure
- Expected outcomes for the various options
- Potential benefits, harms and risks

Examples: Interactive Media, Graphical Tools, Mobile Apps


Artificial Hydration
Decision Aid

COALITION for
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What is artificial hydration?
Artificial hydration is a medical treatment that gives water and sometimes salt for the body. This is done when a person is not able to drink enough on their own or when they have problems swallowing.

How is artificial hydration given?
It is given as a liquid through tubes such as:

- An **IV tube** (intravenous tube) under the skin.
- An **NG tube** (nasogastric tube) put through the nose into the stomach.
- A **PEG tube** (percutaneous endoscopic gastrostomy tube) or **G tube** (gastric tube) placed during surgery into the stomach or small intestine.



When do people need artificial hydration?
When they cannot drink normally by mouth. The problem may be short-term (temporary) or long-term (permanent).

Reasons for short-term artificial hydration may include:

- Serious illness, surgery, or a severe injury.
- Brief loss of alertness or awareness.
- To cope with special treatments like radiation.

Reasons for long-term use may include:

- Loss of the ability to swallow normally due to illness, stroke, or injury.
- Brain injury with a loss of alertness or awareness.
- Inability to drink enough fluid by mouth.

Who should use this guide?
This decision aid is for people with serious illness. It can be used to support medical decision-making and conversations about artificial hydration.

Explaining Benefits, Harms and Risks of Options

Acknowledge that there's often uncertainty regarding outcomes of the options.

- Share the limitations for the evidence.
Ex: “Some research shows this treatment is effective, and some shows it is not effective.”
- Some benefits and harms will have time limitations.
Ex: “You will not be able to drive for a month.”
- Be complete. Do not leave out little things.
Ex: “Your skin around the area we cut will be tender.”

Risk vs Benefit



Offer Choices and Help Patients Choose

It is important that the patient understand that there are always choices, even if the only alternative is to do nothing.

Also, keep in mind that patients may need your help to assess the feasibility of each option.

- How soon can the procedure be done?
- Who can do the procedure?
- How much will the procedure cost?
- What support needs will they have post-operatively?
- How much time will they likely need to take off from work?



Documenting Informed Consent



Be Thorough and Deliberate

Clinicians should document the content of the informed consent process to provide evidence of their good-faith efforts.

A chart note stating the patient gave his or her consent for the treatment or procedure is insufficient.



Proper Documentation of an Informed Consent Discussion

The patient was advised that laparoscopic cholecystectomy was indicated to prevent further episodes of pain and complications from gall stones. The nature of the surgery and the risk of conversion to open laparotomy for unexpected bleeding, infection or injury to an organ during the operation was discussed with the patient and her husband. We talked about the postoperative course and potential complications, including wound infection and herniation.

I advised them of common risk for all surgery, such as pneumonia and venous thrombosis. She understood and wished to proceed with surgery. The surgery will be delayed until after her daughter's wedding.

Surgical Safety Checklist

SURGEON'S CHECKLIST

What do I document?

- Date
- Who was involved?
- Material Risks
- Unique Risks
- Special Circumstances of the Patient
- Risks of Not Undergoing Intervention
- Consent Given or Refused?
- Findings of Incapacity and Identity of Substitute Decision Maker

Hanson, M., & Pitt, D. (2017).

Informed Consent Malpractice Allegations

- Failure to explain the risks and adverse effects of surgery
- Failure to explain alternative treatment options



Final Takeaways



- Informed consent is an ongoing process, not a static event.
- The process builds trust and mutual respect between the patient and provider.
- Clinicians should focus on the true value of informed consent as an educational resource.
- The use of multimedia consent tools may be a valuable complement to traditional verbal conversations in the informed consent process.

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Any Questions?

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