Informed Consent

Informed consent (IC) is the process by which a patient that has been fully informed can participate in choices about his health care. This concept originates from the right of autonomy, and that the patient has to direct what happens to his body. This is first and foremost a legal concept, but there is a strong overlay of ethics as well. The provider MUST fully inform the patient under the law, but it is also fair ethically to allow patients to determine their own destinies.

The provider is obligated to give the patient the following elements in the discussion:

- The 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

Most students (and many medical staff) believe the informed consent is the signed form. This is a most important concept to get straight. The discussion with the physician is the “informed consent,” whereas the form and the signature merely documents that an IC discussion took place. Do NOT confuse the signing of the form and the consent discussion. They are two separate events. This bears repeating:

THE INFORMED CONSENT IS THE **DISCUSSION**, NOT THE SIGNING OF THE FORM.

Informed consent means the provider gives the patient unbiased information about his condition. It is not a legal means of coercion. Thus, the provider’s job is not to try and convince the patient he needs a procedure. The role of IC is to merely present the facts. The patient must decide whether to undergo the proposed treatment/procedure and may opt to decline. The provider may highly recommend the procedure, but may not use fear or control tactics to get the patient to do what the provider wants. That would defeat the purpose of being “informed.” Courts have consistently rendered the opinion that patients may “determine their own destiny, even at their own peril.” What that means, for example, is that the provider may want a patient to undergo chemotherapy treatment for cancer; but the patient has the option of not going through it if he doesn’t want to. This may result in an earlier death for the patient. The provider may not agree with that decision, but it is the patient’s decision to make, not the provider’s. The provider must respect the patient’s ultimate decision, even if the provider disagrees with it.

Types of Informed Consent

- **General:** This is the form a patient signs when they first get into the office or emergency department. Although it says “Consent to Treat” at the top of the form, it is really more consent to bill. This form covers only basic care such as vital signs and general exam. Expected x-rays and lab tests would be covered. Any invasive, risky, or advanced radiology procedures require additional and specific consent.
- **Implied:** This occurs without written or verbal acknowledgment by the patient. Sometimes just signing in at the ER is implied consent you wanted basic interaction, although you wouldn’t perform surgery off that consent. When you stick your arm out to get your blood pressure checked, you have just given implied consent. If you are unconscious, the medical staff can presume you would have wanted treatment had you been conscious; this also represents implied consent.
- **Express:** Here you have verbally indicated your assent to a procedure. You may also have signed a form indicating your agreement, which is also express consent. However, express consent means you understand what you are signing. There is no consent if no consent discussion took place. Then it is merely your name on a piece of paper and consent can be nullified by the courts. Remember, the informed part of IC is the discussion.

Who Can Provide Information

Which provider(s) can hold the consent discussion is outlined by state law and varies from state to state. It is also position-specific. Thus, the state law may indicate a nurse can give the consent discussion, but only for starting IV’s or certain catheters that fall under nursing duties. The physician must give the consent discussion for advanced procedures such as spinal taps, surgery, biopsies, etc. The physician may delegate this to a midlevel provider who is performing the procedure in his place, such as a physician assistant or nurse practitioner. Non-professional individuals may NOT provide a consent discussion.

You must look up the specific state law that outlines who may have the consent discussion with a patient. General documents or websites may not get your particular state law correct. Additionally, the hospital is allowed to create rules that are more stringent than the state guidelines, but not less stringent. So, a hospital could say only physicians may give all consent discussions. They couldn’t say the janitor may give the discussion to the patient, because that would be a policy weaker than the state minimum standard.

Who Can Grant Consent

In order for the patient's consent to be valid, he must be mentally competent and have capacity. Competence is a legal decision decided by the court, whereas capacity is a medical decision determined by the physician. If you are declared by the court to be mentally insane, then you are incompetent. If you are drunk, you have lost capacity. Incompetence is permanent, but capacity is temporary. So a physician who says he determined a patient to be incompetent is incorrect. He may not make that determination; only a court of law can. He can only determine capacity. Neither incompetent nor incapacitated patients may contract for themselves. Therefore, neither may give medical consent. Patients such as Alzheimer's dementia patients may have lucid days. On those days they possibly could be deemed capable of consenting to certain procedures.

In general, minors may not consent, but there are numerous exceptions. Again, the age of consent is outlined by state law, and therefore varies by state. The general age of majority may be 18 in one state, 16 in another. Also the type of consent determines what age you can consent. In some you may be able to consent to marriage at age 15, but consent to neurosurgery may require you to be at least 18. Most states have a concept of "mature minor." These are individuals who are younger than the age of majority, but show remarkable maturity. In those circumstances the court may allow a younger individual to consent in certain circumstances. Individuals who have gotten married, or had children early (just being pregnant doesn't count) are generally considered "emancipated minors" and may then consent to treatment for both themselves as well as their children.

Who May Witness Consent

Again, the consent is the discussion; the form merely memorializes the discussion took place and the patient had opportunity to ask questions. Only a couple of states require a witness signature on the form by law. However, many if not most hospitals require a witness. Therefore it is the desire of the hospital that these documents be witnessed, but that is not a legal requirement. Since these witness boxes are so common, many students mistakenly believe a witness signature is required by law. In most states, it is not. It merely represents best practices.

Who can witness the patient signing the form? Legally it can be anyone. No state requires it be the nurse. It merely needs to be an adult, and someone who witnessed the discussion with the physician. The witness signature does NOT mean they are sure the patient understood the IC discussion or made the right decision. It merely means a discussion took place. Therefore, legally the witness may be a family member, or the janitor who happened to be in the room at the time. It does not need to be a healthcare professional since they aren't attesting that the patient understood or the physician statements were correct. Many hospitals require a witness signature on their form, but this is rarely a state law requirement.

Consent for Clinical Trials

This type of consent is **completely different than consent for treatment as discussed above.** There are whole courses and degrees dedicated to protections of individuals giving informed consent for experimental treatments in clinical trials. The protections, age of consent, documents that must be signed, etc. are vastly different as there are enhanced protections during experiments.

Case Study:

What are the possible ethical issues in this situation?

A 32 year old woman was admitted to the Trauma Intensive Care Unit following a motor vehicle accident; she had multiple injuries and fractures, with several complications which continued to develop over the first couple of weeks. The patient rapidly developed Adult Respiratory Distress Syndrome, was on a ventilator, and was continuously sedated. Shortly after the patient's admission, her parents were contacted and remained vigilant at her bedside. The parents reported that the patient was one month away from having her divorce finalized. The patient's husband was reportedly physically and emotionally abusive to her throughout their five years of marriage. The parents had not notified this man of the patient's hospitalization, and reported that a visit by him would be distressing to the patient if she were aware of it. The patient's soon to be ex-husband is her legal next of kin.

What are possible ethical dilemmas in this situation?

Informed consent is the process or receiving approval to diagnose and treat. While the concept is simple, there is much more to informed consent than agreeing to treatment. Cases that include ethical dilemmas, power of attorney, conflicting notions between family members, and perhaps a patient's inability to participate in actual informed consent, do create challenges for health care professionals. Most organizations have policies and procedures to follow in these cases. Also, health care organizations also have ethics committees that may be consulted for situations that arise where there may be questions about patient competence or other problems with clear informed consent. These decisions are not made by one person. You would not be expected to determine outcomes. You could be part of a committee discussion. Check with your local health care facility about how their ethics committee operates. You may find an avenue to learn more and perhaps participate.