Informed Consent - Overview

Before they are asked to provide consent, patients in the United States have the legal and ethical right to receive all relevant information about possible outcomes and complications of proposed studies, interventions, or surgeries. In order to constitute informed consent, the potential risks, benefits, and alternatives to a proposed procedure must be discussed, and any patient questions or concerns must be addressed. Situations where emergencies preclude proper consent, or those involving unaccompanied minors and others who are not “competent” to make informed decisions, require special procedures in accordance with state law and hospital protocol. In some cases, a relative or other person may have the legal responsibility (e.g., Power of Attorney or legal conservatorship) to provide consent on behalf of the patient when he or she is unable to do so. When a patient is unresponsive or unable to make informed decisions, an attempt should be made to locate the patient’s Advanced Directives. An Advanced Directive is a legal document that specifies the care a patient may or may not wish to receive in the event that he or she becomes terminally ill or unresponsive and cannot participate directly in the decision-making process. Consultation with family members, social workers, the hospital ethics team, or other staff can be helpful in these situations. When in doubt regarding informed consent, ask for help!

A special situation that is frequently seen in U.S. medicine relating to informed consent involves the “Do Not Resuscitate” (DNR) order. When these orders are legitimately in place, advanced resuscitative techniques must **not** be employed, and intervention should be aimed at comfort measures rather than heroic efforts to resuscitate the patient.

Informed Consent - Scenario Script

The patient is lying on an exam table in a hospital gown and covered with a sheet. The physician enters the room and while making his opening remarks.

Doctor: OK, Mr. Hartman, let me tell you what I'm thinking based on the tests we've done so far and what needs to be done next.

Patient: Doc, did the CAT scan show what's causing my headache?

Doctor: No, but unfortunately CAT scans don't show everything, particularly the things I'm most concerned about. The good news is there are no signs of increased pressure, at least for now.

Patient: So what are the things you are concerned about?

Doctor: With a severe headache coming on so suddenly in a healthy guy, I am concerned that you may have had a small bleed in your brain. We call them "subarachnoid hemorrhages." Those represent an area of weakness in one of the blood vessels around the brain. Kind of like a bubble on an inner tube tire. And if that's the case, the neurosurgeons would need to go in and put a clip on that area to prevent any further bleeding.

Patient: That sounds serious…

Doctor: It is, and I have to tell you that sometimes it can be fatal. So it's really important that we find out what's going on.

Patient: [rolling onto his side and facing away from the doctor] How are you gonna do that?

Doctor: [walking around to take a seat in front of the patient] Well, the first thing we need to do is called a spinal tap. There is a fluid that surrounds your brain that connects to the lower part of your back where your spinal cord is. We can go into that area, into the spinal canal area and get some fluid out of that. It's much safer than going into the brain area. If there is bleeding we should either see some red blood cells or at least some chemicals that come from those cells breaking down.

Patient: Could it be anything else?

Informed Consent - Scenario Script (continued)

Doctor: The other thing that I would be most concerned about would be meningitis, which is an infection of the coverings of the brain. Actually, the spinal tap is also the best way to make that diagnosis. That fluid should have some white blood cells or pus cells in it; sometimes we even see bacteria. So the spinal tap is the best way to go to rule out both of the things I'm concerned about. And if we rule those out, we can relax a little bit.

Patient: So what does this spiral tap involve? Is it dangerous?

Doctor: It's actually a *spinal* tap; we call it a lumbar puncture, that's the medical term. We would kind of lie you on your back as you are now and put some numbing medicine in and around your low back, and go between two of your vertebrae and obtain some fluid out of there. Sometimes we can see red blood cells right away; that would indicate bleeding. But in any case we would send the fluid to the lab where they can look more closely and do the necessary tests.

Patient: But is it dangerous? What are the risks?

Doctor: There are risks with every procedure. The most common thing we see with this procedure is a severe headache but you are a guy who is already having a severe headache, and I don't think it's going to make it any worse. There's a very slight chance that some bleeding can occur around the spinal cord where we insert the needle but that usually is much more common in people that are on blood thinners or other medications and you're not on those. And then any time we introduce a needle into the body there's a chance of infection but we use very careful sterile techniques so that is highly unlikely also.

Patient: Is there anything else that we could do?

Doctor: Well, if the spinal tap is positive for blood, then we are going to need to do what's called a cerebral angiogram. That's where they take dye and shoot it into the arteries of your brain and then take some x-rays to identify the area of bleeding. That's obviously much more expensive and has many more risks than a spinal tap, so I think the spinal tap is the way to go.

Patient: Will my insurance cover it?

Doctor: Absolutely.

Patient: But it's going to hurt, right?

Informed Consent - Scenario Script (continued)

Doctor: We are gonna numb the area of your low back but it still involves a big needle. It should only take a few minutes to do though. So, do you feel ready to sign a consent?

Patient: Yeah.

Doctor: Do you understand what we want to do and why?

Patient: Yeah.

Doctor: Have I answered all your questions about risks?

Patient: Yeah, I guess… you really think we should do this?

Doctor: It would be very wrong *not* to…. [hands patient a form on a clipboard and a pen] I need you to read this, and sign it for me sir. Can you see it ok?

Patient: [reading the form] Yeah.

Informed Consent - Discussion Questions

1. Did the doctor present adequate information to allow this patient to give truly informed consent?
2. Did the doctor give the patient adequate opportunity to ask questions and address concerns?
3. What should be discussed before a patient is asked to sign a consent form?
4. Did the doctor use any medical terminology that the patient might not understand? If so, did the doctor adequately clarify the terms?
5. How comprehensive a list of possible complications and risks must be presented to the patient?
6. What strategies should be employed and what resources might be brought to bear when a patient refuses to give consent?
7. In what circumstances may a physician proceed in the absence of a consent?
8. How should the actual signing of a consent form be handled?

Informed Consent - Scenario Analysis

This scenario is meant to portray the proper way to obtain informed patient consent. The patient is being evaluated for a headache, has had a negative head CT, and the doctor feels the next appropriate step is to perform a lumbar puncture.

The doctor begins by interpreting and explaining the negative findings on the CT. He then goes on to explain the possible diagnoses that concern him the most. Although he does use a medical term, he immediately explains it in a way the patient can understand.

He explains the procedure, what information it may yield, and the possible risks and complications associated with it. In response to the patient's question about other alternatives, he indicates that there are other diagnostic options but explains why they would not be appropriate at this point. He very directly and honestly responds to the patient's concerns about the cost of the procedure and how painful it may be. He concludes by asking the patient if he understands what is happening and if his questions have been adequately answered. When he presents the patient with the consent form, he urges him to read it carefully before signing it. He also is considerate enough to be sure that the patient has adequate light to do so.

This physician's approach to obtaining informed consent is characterized by complete and clear explanations of potential diagnoses, results of studies done so far, and the rationale for pursuing further workup. He describes the proposed procedure in understandable lay terminology, acknowledging possible complications and risks. He also indicates other diagnostic options and explains why they would not be as appropriate.

The conversation is not rushed. The patient has ample opportunity to ask questions. Information is provided in a straightforward and clear manner. Before presenting the consent form, the physician checks the patient's understanding of the situation and what is about to be done and invites additional questions. Finally, he encourages the patient to read the consent form before signing it.

These are some of the hallmarks of properly obtained informed consent. Some might also suggest that the patient should articulate in his own words his understanding, but this may not be essential if it seems clear that he does understand.

Obtaining informed consent can be time-consuming and often requires a special effort to be sure information is being presented in a way that the patient can grasp. It may be particularly challenging in situations where the patient is in pain or urgent intervention is necessary, but, even then, proper consent must not be compromised.