
Name:

Block:

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Activity: Informed consent

Think-Pair-Share:

- What is consent?
- What are some situations when consent is required?
- How might “consent” connect to the healthcare and medical system?

Informed consent is one of the most important ethical and legal requirements within the medical system. When a patient understands the benefits, risks, and possible consequences of a medical intervention, and voluntarily agrees to this medical intervention, informed consent has been obtained.

Informed consent has three (3) requirements:

1. **Informed consent must be voluntary:** patients cannot be forced, coerced, or manipulated into providing consent to a medical intervention. This would not constitute “consent”. The patient must freely give consent. Consent is an active and ongoing process—this means that a “yes” can become a “no” at any time during a medical intervention (in other words, patients can change their minds).
2. **Informed consent must be “informed”:** Maybe this one is a bit obvious, given the name “informed consent”, but essentially what this means is that patients must be provided

with any relevant information relating to the proposed medical intervention. This includes a description of the intervention or treatment; its expected benefits, risks, and side effects; the possible consequences of **not** receiving the treatment; and any possible alternatives to the proposed intervention. In other words, the patient needs to be provided with information about what they are agreeing to.

- 3. The patient must be capable of giving their consent:** In order for a patient to give consent, they need to be able to *understand* the information about the medical intervention and *make a judgement call* for themselves. Healthcare providers need to be confident that their patients can understand the consequences of a medical intervention, and that they are able to make decision that is right for them.

This information was adapted from the following video:

WTH is Bioethics? (2019, August 25). *Informed Consent* [Video]. YouTube.
<https://youtu.be/xTIdmv2VzNs>

Case study activity

Watch the following video, or read the accompanying script, which outlines an interaction between a patient and a healthcare provider.

Video: <https://www.ecfmg.org/echo/dozen-consent-video.html>

Script: <https://www.ecfmg.org/echo/dozen-consent-script.html>

The patient is lying on an examination table wearing a hospital gown and covered with a sheet. The physician enters the room 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?

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 spinal 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?

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.

Think-Pair-Share:

- After watching the video or reading the script, do you think that “informed consent” has been obtained in this situation?
- Have the three requirements for “informed consent” been met?

Informed consent and organ donation

The concept of **informed consent** might make a lot of sense when thinking about situations where people are able to make their own decisions about medical treatments and interventions. You might be able to imagine someone explicitly saying “yes” to a life-saving surgery, or saying “no” to taking a particular medication. However, the situation is a bit different when it comes to organ donation specifically.

In the case of organ donation through BC Transplant, a potential organ donor is typically being maintained by a ventilator. Usually, they are not showing any signs of brain function, and they are not breathing on their own. **In these circumstances, it is not possible to obtain informed consent from these patients directly (because they do not have the brain function to communicate with others and make decisions about their health).** Therefore, BC Transplant must obtain informed consent from the patient’s family or legal next of kin (LNOK), who will make a decision on the patient’s behalf.

The “Human Tissue Gift Act” very clearly sets out a patient’s LNOK as their substitute decision maker for organ donation. The Act states that consent may be given by the following people in this order:

- 1) The person’s spouse of any age
- 2) If none, any of the person’s children who have attained the age of majority
- 3) If none, any of the person’s parents
- 4) If none, any of the person’s siblings who have attained the age of majority
- 5) If none, any of the person’s next of kin who has attained the age of majority

Registering your decision about organ donation (“yes” or “no”) through BC Transplant allows your loved ones to be certain about what you would like them to do if you ever happen to be in this situation.

Think-Pair-Share:

- With informed consent in mind, why is it important to register your decision about organ donation through BC Transplant’s Organ Donor Registry?
- What other action can be taken to help provide informed consent in this situation?

Because organ donation typically happens when someone cannot explicitly consent to the donation, registering your decision about organ donation through BC Transplant is the primary way to make sure that your decision about organ donation is known. This ensures that there is a clear record of your “yes” or “no” in the BC Organ Donor Registry.

If you have not registered your decision, then your LNOK will need to make the decision on your behalf, keeping in alignment with what they think you would have wanted for yourself. Therefore, even if you have not registered your decision, or don’t know if your family members have, it is important to discuss with your family what you would want in this situation, so that your decision can be followed.

Take action: register your decision about organ donation

If you would like to, log on to <https://register.transplant.bc.ca/> and register your decision about organ donation (“yes” or “no”). You can specify which specific organ(s) you would like to donate. If you are under the age of 19, you will also need your parent or guardian’s signature—this could be a good way to start a conversation about organ donation with your family.

After registering your decision about organ donation through BC Transplant, it is a good idea to have a conversation with your loved ones about this decision. This will help them know what to expect if they are ever in this situation—where they would be the ones providing **informed consent** on your behalf.