INFORMED CONSENT: DOES MY PATIENT UNDERSTAND WHAT I AM ABOUT TO DO? A BRIEF OVERVIEW OF THE LAW ON INFORMED CONSENT

"Had I known that this could have happened, I would have never agreed to the procedure."

Lawyers who defend healthcare professionals have heard this phrase from plaintiffs on countless occasions. In medico-legal actions, allegations that a plaintiff has not provided an informed consent to the procedure that ultimately caused or contributed to his/her injuries are common.

As healthcare providers, sonographers have a legal duty to ensure that prior to carrying out any type of procedure with a patient, the patient has consented to that procedure. Failure to confirm consent from a patient exposes you to a potential civil claim and/or proceedings before your provincial regulator.

For consent to treatment to be considered valid, it must be "informed" consent. The patient must have been given an adequate explanation about the nature of the proposed examination or procedure and its anticipated outcome as well as the significant risks involved and alternatives available. The information must be such as will allow the patient to reach an informed decision.

The healthcare practitioner who has requested the investigation is responsible for ensuring the patient has provided their informed consent. While the sonographer should be able to rely on the informed consent obtained by the physician/authorized health professional, you should still understand the informed consent process and your obligations to the patient, as circumstances may arise that will require you to ensure that informed consent has been obtained.

While there are general principles that underlie the doctrine of informed consent, provincial regulatory bodies (if in place) will have their own policy guideline and/or practice direction on informed consent. Additionally, some provinces have imposed a statutory obligation to obtain informed consent (i.e. Health Care Consent Act in Ontario or Health Care Consent and Facilities Admission Act in British Columbia). Finally, in addition to practice directions or statutory responsibility, there is a common law duty to obtain an informed consent to treatment. As a result, the information in this article is general in nature and does not represent an exhaustive list of a sonographer's legal responsibilities, nor is it a substitute for legal advice regarding obligations. It is strongly recommended that you consult with the applicable College website, where one is in place. You are also encouraged to seek the advice of legal counsel via the Sonography Canada pro bono legal advice hotline.

There are numerous criteria that apply for patient consent to be valid in Canada:

1. The patient must have capacity to consent to the procedure.
2. The patient must receive proper disclosure of information from the health practitioner proposing the procedure.
3. The authorization should be specific to the procedure to be performed.
4. The patient should have the opportunity:
    a. To ask questions
    b. To receive understandable answers
5. The authorization obtained should be free of undue influence and coercion.
6. The authorization obtained should be free of misrepresentation of material information.

1. THE PATIENT MUST HAVE CAPACITY TO CONSENT TO THE PROCEDURE

Consent can only be valid if the person providing it has the capacity to do so. The question of legal competency typically arises in situations where you are treating someone who is under the age of 18 or persons who may have some type of mental illness. However, these factors alone should not determine competency (i.e. someone under the age of 18 or who has cognitive decline and impairment can provide a valid consent to treatment).

When determining capacity, the healthcare practitioner who has requested the intervention must be confident that the person consenting to treatment has the ability to appreciate the nature and consequences of the consent discussion. If there is doubt, they must seek consent from the parent, guardian, or substitute decision maker. If there is any question as to whether the patient may not appreciate the nature and consequences of the consent discussion due to a language barrier, the healthcare practitioner requesting the intervention must ensure that someone is present that can provide translation.

2. THE PATIENT MUST RECEIVE PROPER DISCLOSURE OF INFORMATION FROM THE HEALTH PRACTITIONER PROPOSING THE PROCEDURE

Your patient must understand the nature of the procedure and why it is being proposed. The patient must be advised of the risks associated with the procedure. The question that typically arises is to what extent the healthcare practitioner has to advise the patient of risks. In Canada, the healthcare practitioner proposing the

procedure is required to advise a patient about attendant, material and special risks. Attendant risks are those that are more common. Material risks are those that are less common, but serious should they occur. Material risks can differ between patients, so the healthcare practitioner should take into account the patient's particular health and condition when considering what risks are material. Finally, specific risks include those that are possible with respect to the specific patient.

The test in Canada as to whether the patient provided informed consent is whether the average reasonable person, in the same position as the patient, would have consented to the treatment knowing the attendant, material and special risks.

In addition to the above, the patient should be advised of the procedure's impact on lifestyle, and any economic considerations of receiving or refusing the proposed procedure. The patient must be provided with any alternative treatments available and what the risks and benefits of each would provide. Finally, the patient needs to be informed as to the risks of refusing/not proceeding with treatment.

3. THE AUTHORIZATION SHOULD BE SPECIFIC TO THE PROCEDURE TO BE PERFORMED

The consent that a patient provides must relate to the specific treatment/procedure that the healthcare practitioner is proposing or recommending.

The healthcare practitioner does not have to obtain a patient's consent for every single step of a treatment plan. If the method of treatment that is being proposed for a patient consists of a course of treatment over a period of time, it is not necessary to obtain a separate consent for each stage of the treatment. However, the entire course of treatment should be discussed with the patient.

If the healthcare practitioner is including other individuals in the administration of the procedure to a patient (i.e. sonographers, student sonographers, etc.), then they must ensure that the patient is advised of the fact that others will be involved in providing treatment and that the patient consents to their involvement.

4. THE PATIENT SHOULD HAVE THE OPPORTUNITY TO ASK QUESTIONS AND RECEIVE UNDERSTANDABLE ANSWERS

The discussion regarding consent to treatment should not be a one-way discussion. Ideally, the healthcare provider should have a conversation with the patient where they can ask questions and the healthcare provider can provide the information necessary to answer those questions.

5. THE AUTHORIZATION OBTAINED SHOULD BE FREE OF UNDUE INFLUENCE AND COERCION

It goes without saying that the healthcare provider must ensure that their patient does not feel pressured or obligated to proceed with the proposed treatment. Not only should they ensure that the patient does not feel pressured to proceed by another person, the healthcare provider must also ensure that they are not advocating the treatment plan or procedure in such a way that the patient feels they have no choice but to proceed.

6. THE AUTHORIZATION OBTAINED SHOULD BE FREE OF MISREPRESENTATION OF MATERIAL INFORMATION

While the healthcare provider is free to provide the patient with their opinion as to the best course of action, they should be as objective as possible when presenting the information to the patient. Accurate and impartial information on all treatment alternatives must be provided.

Your Responsibilities in the Informed Consent Process

When you are performing patient treatment under the order of a physician or other authorized health professional, you nevertheless retain certain responsibilities with respect to health care consent. These include:

1. Confirming that informed consent has been obtained;
2. Explaining to the patient what you are going to do and why; and
3. Proceeding with the treatment only if there is no doubt about the patient's capacity and consent.

Before beginning treatment, you should review the patient's record to ensure that the informed consent discussion has been documented. The physician or other authorized health professional should have documented this discussion, including the fact they spoke to the patient, identified the treatment plan/procedure, identified your involvement in the treatment, advised them of the risks and benefits, advised them of any alternatives, made a note of any questions that the patient had and whether the patient provided consent. The patient record may also include a signed treatment plan.

Take the time to talk to the patient and explain what you are going to do and why. If you suspect that the patient does not understand the treatment or if you have any doubt about the patient's capacity to provide informed consent, you should not proceed. Similarly, if the patient resists treatment or withdraws their consent, you should not proceed. Instead, refer the patient back to the physician/authorized health professional for a capacity assessment and/or consent discussion. You should also document your discussions and actions in the appropriate patient record.

In a medico-legal action where informed consent is an issue, the patient will claim that the healthcare provider proposing the treatment did not provide them with all of the necessary information to make an informed decision. The patient may also allege that the healthcare professionals involved in their treatment failed to ensure their on-going consent or respect their decision to withdraw consent. If you have documented your discussion, that will be helpful in corroborating your argument that you took reasonable steps to ensure that treatment was not done unless a valid consent was given.

You are not alone when navigating decisions related to informed consent and other complex practice risk questions. Sonography Canada members participating in the Professional Liability Insurance program have access to specialist support, including a pro bono legal hotline provided by Gowling WLG (Canada) LLP.

Gowling WLG pro bono legal advice: 1-888-446-4046.