Principles of Consent

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Does My Patient Understand What I Am About To Do?

About the Authors

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Introduction

A 17-year old patient walks into your office for an ultrasound exam of their abdomen.

- Do you, as the sonographer, need to obtain consent prior to performing the procedure, or was it the responsibility of the patient's referring physician to get consent?
- Can a 17-year old patient give consent?
- What qualifies as informed consent in this situation? What are best practices for obtaining informed consent?

This article will help you, as a sonographer, answer the above questions and provide you with a broad understanding on the principles of consent.

Overview: What is Consent to Treatment?

Generally, the following elements are required for a patient to provide consent, either expressly or impliedly,[1] to treatment or medical care:

- the patient must be *capable* to consent;
- consent must *relate to the specific treatment or procedure*;
- consent must be *informed*;
- consent must be given *voluntarily*; and
- consent must not be obtained through *misrepresentation or fraud*.

While these broad principles underlie the doctrine of consent, provincial regulatory bodies, certain provincial legislation and common law (i.e. case law or judge-make law) impose specific requirements related to informed consent.[2] Thus, 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 obtaining legal advice.

Broad Principles of Consent

The term 'treatment' is broad, and includes anything that is done for a therapeutic, preventative, palliative, diagnostic, cosmetic or other

[1] *Health Care Consent Act*, section 11(4).

[2] See: *Health Care Consent Act* in Ontario or *Health Care Consent and Facilities Admission Act* in British Columbia.

health-related purpose, such as a procedure.[3] There are a number of criteria that apply for patient consent to treatment to be valid in Canada:

The Patient Must Have the Capacity to Consent

Consent can only be valid if the person providing the consent has the capacity to provide it. Sonographers and other health professionals can rely on a presumption of capacity, unless it is not reasonable in the circumstances to do so. For example, questions relating to capacity typically arise in situations where a patient is a minor, or where an individual has been diagnosed with cognitive impairment or disability. However, these factors alone do not determine capacity, which may fluctuate with time or depending on the treatment/procedure. A minor or someone with cognitive decline and impairment can still provide a valid consent to a treatment/procedure in certain circumstances. It is the healthcare professional's responsibility to assess the individual's capacity to provide consent.

Although it is the responsibility of the health professional obtaining consent to determine capacity, capacity is a legal test. For example, Ontario's *Health Care Consent Act* provides that a person is capable with respect to a treatment if the person is able to understand the information that is relevant to making a decision about the treatment … and able to appreciate the reasonably foreseeable consequences of a decision or lack of decision. In the leading case on this issue, the Supreme Court of Canada noted it is the *ability* to understand and appreciate that is important in making this determination, rather than actual understanding or appreciation.[4] As long as the person is able to appreciate the nature and consequences of a medical procedure, he or she may give a valid consent. There is no specific age at which an individual can give consent. The ability of a young person to provide consent will depend upon the individual's level of maturity and intellect as well as the seriousness and complexity of the treatment involved.

If there are concerns about capacity, refer to your province's practice guidelines or legislation to determine who the patient's substitute decision maker may be. 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 an interpreter is involved.

Consent Must Relate To The Treatment

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.

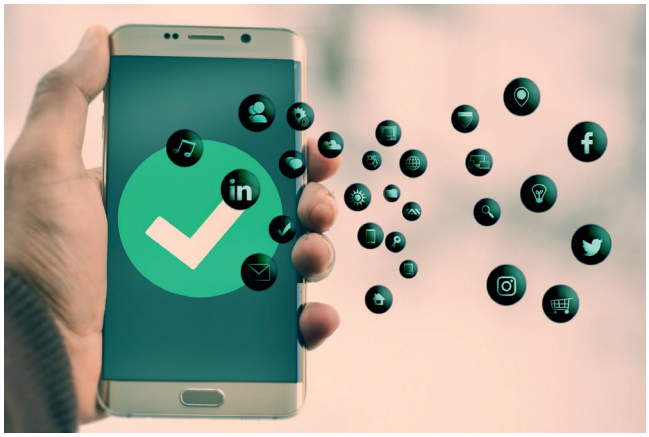
If the healthcare practitioner is including other individuals in the administration of the procedure to a patient (i.e. sonographers, student sonographers, etc.), then they must ensure that the patient is advised of the fact that others will be involved in providing treatment and the patient consents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

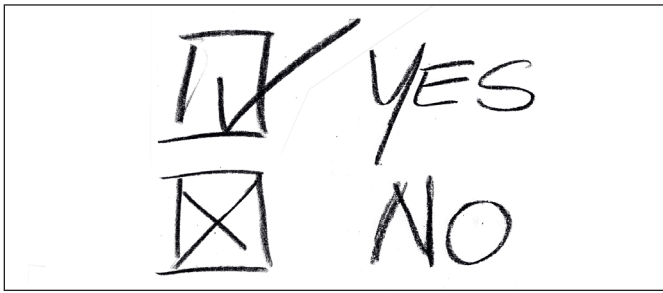
Consent Must be Informed

This is a major component of consent in a healthcare setting. For consent to a treatment/procedure to be considered valid, it must be **"*informed*" consent.** In order to be informed:

- The patient must have been given an ***adequate explanation*** about the ***nature*** of the proposed examination or procedure. This means that the person must receive the information that a "reasonable person" in the same circumstances

[3]See for example, Ontario's *Health Care Consent Act* at section 2.
[4]See for example, the Supreme Court of Canada decision in *Starson* v. *Swayze* [2003] S.C.R. 722





would require in order to make a decision about the treatment.

- The patient must understand the examination or procedure's ***expected benefits or anticipated outcome***;
- The patient must understand the ***material risks and material side effects*** involved and ***alternatives available***.

To be clear, while providing a patient with an explanation of the treatment/procedure, as a healthcare professional you should touch on the nature of the treatment/procedure, the expected benefits, risks and side effects of the treatment/procedure, and the likely consequences of having or not having treatment.

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 health and condition when considering what risks are material. Finally, ***specific risks*** include those that are possible with respect to the specific patient.

Healthcare professionals are expected to listen, too. In order for consent to be informed, the patient must be given the opportunity to ask questions, and to receive understandable answers prior to undergoing treatment. Ultimately, the information provided must permit the patient to reach an informed decision about ***whether or not*** to undergo the treatment/procedure. Importantly, consent to the treatment/procedure also includes the right for an individual to ***refuse*** treatment.

Consent Must Be Given Voluntarily

The consent obtained should be free of undue influence and coercion. The patient must not feel pressured or obligated to proceed with the proposed treatment/procedure. Not only should the healthcare professional 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.

Consent Must not be Obtained Through Misrepresentation or Fraud

Consent cannot be properly obtained where there has been a 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.

Consent can be Implied or Express

Informed consent may be implied or express. Implied consent occurs either by the words or behaviour of the patient or by the circumstances under which treatment is given. An example of implied consent could be a patient arranging and

attending an appointment with a healthcare professional, and answering questions related to their medical history.

Express consent is directly given, either orally, in writing, or by gesture. Where consent is given orally, the sonographer should document the patient's verbal consent in the health record.

Where there is doubt, it is preferable that consent be express. It is prudent for a sonographer to obtain express written consent if the exam is related to a patient's breasts, genitals or rectum.

A Sonographer's Obligations Related to Consent

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 ensure informed consent has been obtained may expose you to a potential civil claim and/or proceedings before your provincial regulator.

The healthcare practitioner who proposes the investigation or treatment is ultimately responsible for ensuring the patient has provided informed consent. While the sonographer *should* be able to rely on the informed consent obtained by the physician/authorized health professional, it is still important to verify the individual's consent and to understand the consent process and your obligations to the patient. There is no protection from liability for a health practitioner who acts in reliance upon an apparently valid consent or refusal, and thus circumstances may arise that will require you to ensure that informed consent has been obtained.

In addition, the healthcare facility in which the treatment/procedure is provided may also have responsibility for ensuring that there are policies and procedures in place as well as quality assurance monitoring to ensure that all of the rules governing informed consent are complied with on a consistent basis. The healthcare facility may have its own requirements that sonographers must follow when providing treatment. For example, a healthcare facility may have a policy that requires patients to sign a written consent prior to receiving any treatment. Note that while a consent form will provide evidence of consent, it is not consent itself. Ensuring that your workplace has policies on informed consent in place will help to mitigate legal liabilities.

Responsibility Checklist

Confirm that Informed Consent Has Been Obtained: Before beginning the treatment/procedure, 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. You may also have a discussion with the patient to ensure that they have provided informed consent.

Explain to the Patient What You are Going to Do and Why: Take the time to talk to the patient and explain what you are going to do and why. Be confident that the person consenting to the treatment/procedure has the ability to appreciate the nature and consequences of the consent discussion. If you suspect that the patient does not understand the treatment/procedure or if you have any doubt about the patient's capacity to provide informed consent, you should not proceed. Similarly, if the patient resists the treatment/procedure 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.

Do Not Proceed With the Treatment/Procedure If There is Doubt About the Patient's Capacity or Consent: In a medico-legal action where informed consent is an issue, the patient will claim that the healthcare provider proposing the treatment/procedure 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.

Conclusion

Think back to the practice scenario in the introduction: can you answer each of those questions? Did any of your answers change?

Consent is an important practice point for all healthcare professionals, including sonographers. Make sure you are up to date with *specific provincial obligations* related to consent. 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 may have access to specialist support provided through the Miller Thomson On Call™ Berkley Support Program. Please contact us mtoncall@millerthomson.com or 1.800.387.4452.

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