INFORMED CONSENT

When a ☑ is not enough – What is informed consent?

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This column seeks to translate the legal requirements of informed consent to provide members some key practical steps towards compliance. It is not meant to override or contradict the standards of the College of Pharmacists of BC or applicable legislation. It does not constitute legal advice.

Consent. Informed consent.
Express consent. Implied consent. Inferred consent. What’s the difference? Just as long as the patient signs the form, you’ve got the consent, right?

Not so fast. When it comes to consent, we are fielding a lot of questions, in particular regarding its documentation. So we’ve put together this little primer to help you distinguish between these concepts and understand your obligations. There are four key take-aways from this article:
1. Informed consent is always required for the provision of health care services.
2. The words “express”, “implied” and “inferred” all describe the way the consent is given, not whether it is informed.
3. It is the pharmacist’s responsibility to ensure the patient has given informed consent, no matter how it is communicated.
4. Keeping a record of the encounter is recommended.

What is “consent”?
Basically, consent is agreement. If a patient consents, the patient agrees. The law says that a health care provider must not provide any health care to an adult without the adult’s consent (except in certain very limited circumstances).

That same law also explains the elements of consent. This is important, because consent to health care will only exist if all the elements of consent exist. When all the elements exist, we say that the patient has given informed consent to receive health care. There are slightly different elements of consent for adults and for minors or people of lesser capacity who are incapable of providing informed consent.

What is informed consent?
There are four basic elements that make up an adult’s informed consent to health care:
1. It must relate to the proposed health care, be given voluntarily, and not be obtained by fraud or misrepresentation.
2. The adult must be capable of making a decision about whether to give or refuse consent to the proposed health care. The law allows providers to presume that an adult is capable of giving or refusing consent until the contrary is shown.
3. The provider must give the adult the information a reasonable person would require to understand the proposed health care, including information about the condition, the nature of the proposed health care, its risks and benefits and alternative courses.
4. The adult must be given an opportunity to ask questions and get answers about the proposed care.

For people under the age of 19, the requirements are slightly different. The health care provider must:
1. Explain to the individual and be satisfied that he or she understands the nature and consequences and the reasonably foreseeable benefits and risks of the health care and
2. Make reasonable efforts to determine and must conclude that the health care is in the individual’s best interest.

The parent or guardian cannot overrule the individual’s decision and is not entitled to disclosure of the information.

In short, no matter how old they are, the patient has to have been told – and the pharmacist must be satisfied that the patient understood – the information that is relevant to the patient’s decision whether or not to consent.

The capable patient (adult, mature minor or parent of infant) – and no one else – makes the decision.

Only when the patient makes an informed decision, can he or she give informed consent. Informed consent is always required for the provision of health care.
Duty to communicate clearly

Providers have a duty to communicate clearly when seeking consent or deciding whether an adult is not capable of consenting. This means providers must communicate with the adult in a manner appropriate to the adult’s skills and abilities, and may allow the adult’s spouse, or any near relative or close friend who accompanies the adult to help the adult to understand or show an understanding of the relevant information.

How do I judge whether the patient is capable?

When deciding whether an adult is incapable of giving, refusing or revoking consent to health care, a health care provider must base the decision on whether or not the adult demonstrates that he or she understands the information given, and the information applies to his or her situation.

Okay, so what is express, implied or inferred consent?

The terms express consent and implied or inferred consent describe the way in which consent is communicated: the patient may expressly communicate informed consent verbally, or by signing a form, or checking a box. The patient impliedly communicates consent when his or her behaviour implies that they consent, such that you can infer from their behaviour that they consent.

Is the consent process to be documented for every pharmacy service?

It depends, and here is why. Pharmacy practice is overseen by the College of Pharmacists of BC under the authority of BC and federal laws. The College prescribes pharmacy practice rules, requires informed consent be obtained and leaves it to the registrants’ judgement regarding documentation.

Government and other pharmacy benefits payers require that pharmacy comply with the College rules. However, some payers may also require that informed consent be documented in a particular way as a prerequisite for payment.

Even if the College or payers do not require documentation, it is recommended to do so. Documentation establishes accountability and will support how you exercised your professional judgement when questioned by your peers. It can also support your defense in a negligence legal case and against payer-audit recoveries.

Regardless of whether the consent is communicated expressly, or inferred from conduct, the elements of consent must exist in order for the consent to be informed, as required by law.

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How does the pharmacist document informed consent?

Any form of documentation is acceptable provided it documents that the four elements of consent existed and that it is documented in compliance with the applicable standards of care. The documentation must also comply with payers’ requirements if the payer requires documentation as a pre-requisite for payment.

Some organizations use standard forms that may require the patient to indicate by signature their expressed consent. Others make notes on the paper or the digital patient file. Whichever way you document, these two critical steps must be taken in sequence:

**Step 1:** Obtain informed consent fulfilling the four elements of consent. Communicate with the patient.

**Step 2:** Document your communication process with the patient as required for that service by CPBC and payer.

By doing both of the above, you have obtained and documented informed consent, performed your professional obligation and protected your service fees.

**Adaptation:** The College provides a recommended documentation and notification template that may be used by the provider for documenting a patient’s informed consent, in which the pharmacist attests that he or she obtained informed consent fulfilling the four basic elements (see PPP-58 Adapting a Prescription - Appendix D).

The Ministry/PSD has not specified a format. Patient signature to evidence informed consent not required.

**Immunizations:** The College has not specified a format. The Ministry/PSD has not specified a format. The College has specific consent requirements described under Part 4 of the Health Professions Act - Bylaws, Schedule F. Patient signature to evidence informed consent not required.

There is no legislation that precludes pharmacists from exceeding existing standards and obtaining the patient’s signature to evidence informed consent. The key is that consent was obtained using the four basic elements and using the two-step process.

What about later? Can a patient change her mind?

Yes. Re-visit patient consent if you are ever in doubt as to the patient’s wishes, or when the treatment plan changes. Refusal or revocation of consent should be documented. It is advisable to have a process in place to handle such requests.

Is consent for health care reasons different than for privacy reasons?

Yes. Consent for privacy reasons is about consent to the collection, use and disclosure of the patient’s personal health information, not about the provision of health care.
A detailed discussion is beyond the scope of this article, but the basic principle is that patient consent may be implied for the collection, use, and disclosure of the patient's personal information, within the circle of care, for the purposes of ongoing care and treatment. Hospital pharmacies and government agencies are covered by the Freedom of Information and Protection of Privacy Act (the FOIPPA), but community pharmacies are covered by the BC Personal Information Protection Act (PIPA), and the HPA Bylaws, Part VII. See those laws for more detail about the requirements.

Implied consent must be “informed and knowledgeable” so under the PIPA, community pharmacies are permitted to rely on written notices about the pharmacy’s information handling practices to communicate to patients the reasons for the collection, use and disclosure of patient information and the ways in which the pharmacy respects patient privacy.

Remember, this applies only to consent for the collection, use and disclosure of personal information. For health care, you must communicate with the patient and ensure the four elements exist. This is a key difference.

If the pharmacist wishes to collect, use or disclose the patient information for some purpose not consistent with direct patient care (a “secondary purpose”), the pharmacist should obtain express consent, which involves fully informing the patient of the secondary purpose. There are certain legal exceptions to this requirement – see HPA Bylaws Part VII.

Informed consent for health care requires that the patient have the information that is relevant to the health care, the treatment and the risks and benefits. This requires the pharmacists to exercise professional skill and judgment, and to communicate with the patient.

Informed consent for the collection, use and disclosure of personal information requires that the patient have the information relevant to the information handling practices. This requires the pharmacist to, at minimum, have appropriate notices posted.

Informed consent for one is not sufficient for the other.

A pharmacy’s obligation to personal information is also described under HPA, PODSA and the PSA, which have additional requirements. These are not discussed here. Please refer to those laws to ensure your understanding and compliance.

Most organizations already have a Privacy Policy statement detailing how they will handle personal information. Those who do not are well advised to do so. The Office of the Information and Privacy Commissioner for British Columbia provides very good resources.

References
1. Health Care (Consent) and Care Facility (Admission) Act
2. Health Professions Act (HPA)
3. Pharmacy Operations and Drug Scheduling Act (PODSA)
4. Pharmaceutical Services Act (PSA)