

Informed Consent

Related Standard of Practice: Informed Consent

The College of Physicians & Surgeons of Alberta (CPSA) provides advice to the profession to support physicians in implementing the *CPSA Standards of Practice*. This advice does not define a standard of practice, nor should it be interpreted as legal advice.

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Scope

This document provides advice on all aspects of consent, recognizing the primacy of consent in any physician-patient relationship.

There are instances where the rigorous obtaining and documenting of consent requires an even higher standard of procurement, disclosure and documentation. These instances include consent for:

- patient participation in research
- any type of medical or surgical work which might be regarded as less than entirely necessary to the physical health of the patient, but presents significant and life-altering consequences (e.g., cosmetic surgical procedures and gender alteration treatments)
- treatments and/or procedures for which there is divisive (such as abortion), evolving and/or uncertain social consensus (see Appendix A: The Special Case of Physician-Assisted Death)



Advice

General Principles of Consent for Adults

The College accepts and recommends as foundational the Canadian Medical Protective Association (CMPA) publication entitled Consent: A Guide for Canadian Physicians.

The voluntariness of consent, understanding, scope of information sharing and context must all be considered in a consent discussion.

- Voluntariness: Consent must be voluntary and without coercion. Voluntary consent means consent can be withdrawn by the patient throughout a course of treatment, providing s/he has capacity to do so. To ensure there is no coercion to consent, the physician must consider the capacity of the patient to participate in a consent discussion. Capacity is a continuum varying from a comatose patient, through a patient who may be confused intermittently, to one who is fully competent. Capacity can vary over time.
- **Understanding:** Beyond basic capacity, the physician needs to consider whether or not an individual truly understands what is being discussed. Often the best way to assess understanding is to have the patient outline the reasoning s/he used in making an informed decision on the course of action to ensure the logic and the postulates applied are reasonable within the patient's context.
- Scope of information sharing: It is often impossible and usually unreasonable to outline every possible risk. Relevant risks can be identified to a(n):
 - o professional standard (what other physicians would disclose)
 - subjective standard (what the patient would want to know)
 - o objective standard (what a reasonable person in similar circumstances would want to know)

Information should be shared to an objective standard for disclosure and a subjective standard for understanding.

A professional standard ignores patient individuality and unique context, while a subjective standard can only be determined in retrospect once the information has already been disclosed. Ideally, information should be shared to an objective standard for disclosure and a subjective standard for understanding. The legal environment applies an objective ("reasonable person") standard for consent (i.e., to disclose what a reasonable person would expect). The "reasonable person" standard also applies to the efforts a physician must make to ensure patient understanding; the Courts have said not to the point of "vigorous and inappropriate cross-examination."



- Context: Various contexts need to be considered when obtaining consent, including but not limited to:
 - Urgency. In an urgent situation where the patient is incapacitated, the patient's wishes are
 unknown and no alternate decision maker is available, the physician has a duty to proceed with
 care. If there is any doubt about the urgency, a second medical opinion is highly recommended if
 available.
 - Capacity of the patient, including for an incapacitated patient:
 - the timeliness and availability of substitute decision makers
 - information about the patient's known wishes (such as a Personal Directive)
 - Treatment decision, including:
 - expected consequences of proposed treatment
 - alternative treatments and their expected outcomes
 - consequences of no treatment (i.e., the natural course of the condition if untreated)
 - Individual patient's specific concerns.

Informed consent is therefore more of a process than an event, evolving over time, mirroring maturation of the patient-physician relationship and the progression of care. The patient's physical, social, spiritual and mental well-being should all be considered in decisions about care; developing a sense of common purpose and shared responsibility early in the course of the physician-patient relationship is the best way to ensure valid informed consent. Such a real relationship creates an environment where the risks and benefits of a proposed intervention can be shared in a meaningful way.

Oral and Written Consent

As part of good communication, even when there is implied consent, it is always good practice to have a conversation with the patient.

Either written consent or oral consent should be obtained and documented when any examination and/or treatment:

- is likely to be more than mildly painful;
- carries appreciable risk; or
- will result in ablation of a bodily function.

Important note: Elective procedures with serious potential for side effects require more thorough and complete discussion and carry increased expectation for written documentation.

Written consent is preferred, with the understanding that consent is much more than a signed piece of paper.



Appendix A: Informed Consent – The Special Case of Physician-Assisted Death (PAD)

Background

In its February 6, 2015 ruling *Carter v. Canada*, the Supreme Court of Canada (SCC) unanimously declared unconstitutional the Criminal Code prohibitions on physician-assisted dying as violating the individual's right to life, liberty, and security of the person (s. 7). Declared invalid were both Section 241(b) of the Criminal Code that says everyone who aids and\or abets a person in committing suicide commits an indictable offence, and section 14 that says no person may consent to death being inflicted on them.

The SCC decision establishes physician-assisted death (PAD) as a Charter right for "a competent adult person who (1) clearly consents to the termination of life; and (2) has a grievous and irremediable medical condition (including an illness, disease or disability) that causes suffering that is intolerable to the individual." The decision focuses on "physician-assisted" death. It is not clear how the decision will affect other members of the care team (such as a pharmacist dispensing a lethal medication or a nurse participating as a member of the team). The decision allows both assisted suicide, where the patient is provided assistance in intentionally ending his/her own life (e.g., a patient with ALS who is provided with a lethal dose of medication for self-administration) and euthanasia, where a physician directly administers a lethal dose of medication (or equivalent) in accordance with the wishes of the patient.

The SCC decision does not establish a regulatory regime or safeguards. This work has been left to the federal and/or provincial governments and/or medical regulators, who have until February 2016 to develop legislation and/or policy to regulate PAD, should they choose to do so. Several levels of government have suggested action is forthcoming, but in the interim significant public debate has ensued. Gaps that must be addressed include but are not limited to a definition of "grievous and irremediable medical condition," challenges faced by allied health professionals, reporting requirements and insurance protection for patients.

While it is not the role of the College to adjudicate such debates or fill the void left in the legislative environment, the College has a duty to advise the profession of its expectations of members.

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The College has taken a conservative approach in its interpretation of the Carter decision. For example, while "competent adult" was not defined by the SCC, the College has defined "adult" as an individual who is, by law, capable of giving consent. Minors are therefore excluded, including mature minors.

The College has further interpreted "competent adult" to mean the individual seeking PAD must be able to consent (or to rescind consent) throughout the process. By taking this position, the College has effectively excluded advanced directives as a possible consent mechanism.

Given the significance of a decision about PAD, there are additional, specific requirements for obtaining and documenting an individual's consent. The College's advice is based on an environmental scan of other jurisdictions that allow PAD and is an extension of general advice to the profession regarding informed consent.

Principles

The principles guiding the College's advice on PAD are:

- The College has an obligation to serve and protect the public interest.
- Physicians have a professional belief and value to provide respectful care for patients with diseases that
 cannot be cured, enshrined in precept 3 of the Code of Ethics: "Provide for appropriate care for your
 patient, even when cure is no longer possible, including physical comfort and spiritual and psychosocial
 support."
- Physicians have an obligation not to abandon their patients.
- Physicians are expected to practise medicine in keeping with their level of clinical competence to ensure they safely deliver quality health care.
- Physicians have an obligation to provide their patients with health information, referrals and health services in a non-discriminatory fashion to enable their patients to make well-informed decisions.
- The medical profession as a whole has an obligation to ensure people have access to the legally permissible and publicly-funded health services.
- Physicians have an obligation not to interfere with or obstruct the public's access to legally permissible and publicly-funded health services.
- Physicians should err on the side of caution during this time of legislative uncertainty.
- Physicians' right to freedom of conscience should be respected.

The College recognizes these obligations and freedoms may come into conflict.



Advice

- 1. Access to holistic care and palliative care Chronic disease management and palliative care by their nature and purpose are to ameliorate symptoms and optimize functioning. As noted above, the *Code of Ethics* states "physicians are required to provide appropriate care for patients, even when cure is no longer possible, including physical comfort and spiritual and psychosocial support."
- 2. Patient request for PAD Upon receiving a patient's request for PAD, the physician must have a complete and full discussion about PAD with the patient. Physicians are expected to provide patients with all the information required to make informed choices about treatment, including diagnosis, prognosis and treatment options, and to communicate the information in a way that is reasonably likely to be understood by the patient. Counseling patients on treatment options is part of the role of the physician; PAD might be the right option for a select few, but there are many other options that need to be part of the conversation.
- 3. Competent adult patient The SCC decision applies only to competent adults. PAD cannot be provided to incompetent patients, including when consent is given by alternate decision makers, is known by patient wishes or is provided through a personal advanced directive. At minimum, two physicians are required to independently document that the patient is competent and able to consent. A request for PAD is contextual to the patient's medical condition, its natural history and prognosis, treatment options and risks, and the benefits associated with such options. The physician is responsible to ensure the patient understands such factors, and is able to communicate a reasoned decision based on that understanding. When it is unclear whether these criteria have been met, a psychiatric/psychological consult is required to examine the patient's decision-making capacity (or limitations) in greater detail.
- 4. **Accountable physician** Physicians offering a PAD option must have the appropriate qualifications and training to render a diagnosis and prognosis of the patient's condition, together with the appropriate technical knowledge and technical competency to provide PAD in a manner that is respectful of the patient's context and wishes. The physician must be willing and able to collaborate with others in providing such care.
 - Before proceeding with PAD, the College recommends physicians consult with the Canadian Medical Protective Association (CMPA) during this time of legislative uncertainty.
- 5. **Witnessed documentation** –A patient's decision to proceed requires formal documentation which may be oral and transcribed by another party, or written by the patient. The written request must be dated, signed by the patient and include the signature of two witnesses who can attest the patient is capable, acting



voluntarily and free from coercion. One of these witnesses must be someone who is not: a relative; entitled to any portion of the estate; an owner, operator, or employee of a health care facility where the patient is receiving treatment; or the attending physician.

- 6. **Medical opinion** –While the SCC decision acknowledges the right of a competent adult to identify intolerable suffering, the physician's role is to determine from a medical perspective whether or not the condition is "grievous and irremediable" (i.e., impossible to cure or put right). Making this determination will involve counseling the patient about other options for treatment and care to identify what is in the patient's best interests. In some cases, the physician and patient will have a different understanding of whether PAD is in the patient's best interests; ultimately, case law will assist in reconciling these situations, recognizing that reconciliation through the courts is likely to be a prolonged process. To be explicit: in some situations, a physician may offer the opinion the patient does not suffer from a grievous and irremediable condition, in which case physician-assisted death should not be offered.
- 7. **Referral for psychiatric/psychological assessment** If the patient's physician has reason to believe the patient may be suffering from a psychiatric or psychological disorder or depression causing impaired judgement, the patient must be referred for assessment and possible treatment. PAD should not proceed unless the psychiatric or psychological assessment demonstrates the patient is not suffering from a treatable psychiatric or psychological disorder or depression causing impaired judgement. While chronic depression or any other mental illness may itself represent a "grievous and irremediable condition," the additional assessment is to ensure the illness itself does not impair the patient's ability to make an informed and reasoned decision.
- 8. **Second opinion and waiting period required** A second consultation and waiting period of at least 15 days are mandatory. If the patient still wishes to proceed, the physician must review all aspects of the PAD process with the patient and remind the patient of his/her ability to rescind the request at any time.
- 9. **Ongoing capacity** A patient must maintain mental capacity for PAD to proceed. If at any time during the progression of a patient's condition, the patient loses the mental capacity to rescind his/her decision, PAD ceases to be an option.

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- 10. **Required information** The patient must be informed of the following, this information must be included in the patient record, and a copy must be provided to the patient:
 - a. patient's diagnosis and prognosis;
 - b. feasible alternatives (including comfort care, hospice care, and pain control);
 - c. option to rescind the request for PAD at any time;
 - d. risks of taking the prescribed medication;
 - e. probable outcome/result of taking the medication; and
 - f. life insurance implications.
- 11. Individual medical record The following documents must be added to the patient's medical record:
 - a. all written and oral requests made by the patient for PAD;
 - b. physician's diagnosis, prognosis and statement that the patient is competent and is making an informed and voluntary decision;
 - c. second physician's diagnosis, prognosis and statement that the patient is competent and is making an informed and voluntary decision;
 - d. if performed, a report of the outcomes of the psychiatric/psychological assessment and treatment, including counseling;
 - e. physician's offer, after the 15 day waiting period and following completion of all required documentation, to rescind the request; and
 - f. a note from the physician stating that all of the requirements have been met, indicating the steps taken, and the medication prescribed.
- 12. **Notification of death to the Medical Examiner** Until advised otherwise, PAD must be reported to the Medical Examiner under the *Fatalities Inquiries Act*.
- 13. **Notification of death to an oversight body** The CPSA believes a provincial multi-disciplinary committee should receive and review all PADs, as in other jurisdictions.

Pending the establishment of such a committee in Alberta, physicians are required to notify the CPSA when a death involves the assistance of a regulated member, and to provide all documents identified in (12) above with the notification.

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The collection of this information will ensure appropriate procedures and documentation, to enhance the provision of professional services as per Section 50(2)(a) of the Health Professions Act.

14. Conscientious objection – Physicians may decline to provide PAD if doing so would violate their freedom of conscience, as per the CPSA standard of practice Moral or Religious Beliefs Affecting Medical Care. The right of the individual physician to make a conscientious decision on end-of-life care including PAD must be respected. This is reflected in paragraph 132 of the SCC Carter decision that says "In our view, nothing in the declaration of invalidity which we propose to issue would compel physicians to provide assistance in dying," and further "we underline that the Charter rights of patients and physicians will need to be reconciled."

The College's expectation and belief is that physicians and other caregivers who support PAD as an option will make their services available either directly or through a third party provider, giving patients the opportunity to self-refer.

A physician who declines to provide PAD must not abandon a patient who makes this request; the physician has a duty to treat the patient with dignity and respect. The physician is expected to provide sufficient information and resources to enable the patient to make his/her own informed choice and access all options for care, even if providing such information conflicts with the physician's deeply held and considered moral or religious beliefs. This means arranging timely access to another physician or resources, or offering the patient information and advice about all the medical options available.

Physicians must not provide false, misleading, intentionally confusing, coercive or materially incomplete information, and the physician's communication and behaviour must not be demeaning to the patient or to the patient's beliefs, lifestyle choices or values. The obligation to inform patients may be met by delegating this communication to another competent individual for whom the physician is responsible.

- 15. Complaints arising In such an evolving environment, PAD-related complaints may be brought to the College. The College will manage these complaints as it does all complaints, with a focus on ensuring appropriate patient care, fairness and improving medical practice. In the experience of the College, inadequate communication is the root of most complaints. Whether participating in, providing or conscientiously declining to provide PAD, physicians should take extra care to ensure communication and documentation of these discussions is optimal.
- 16. Challenges of allied health professionals The College recognizes PAD will touch other healthcare professionals. Patients seeking physician-assisted death will typically have many different healthcare

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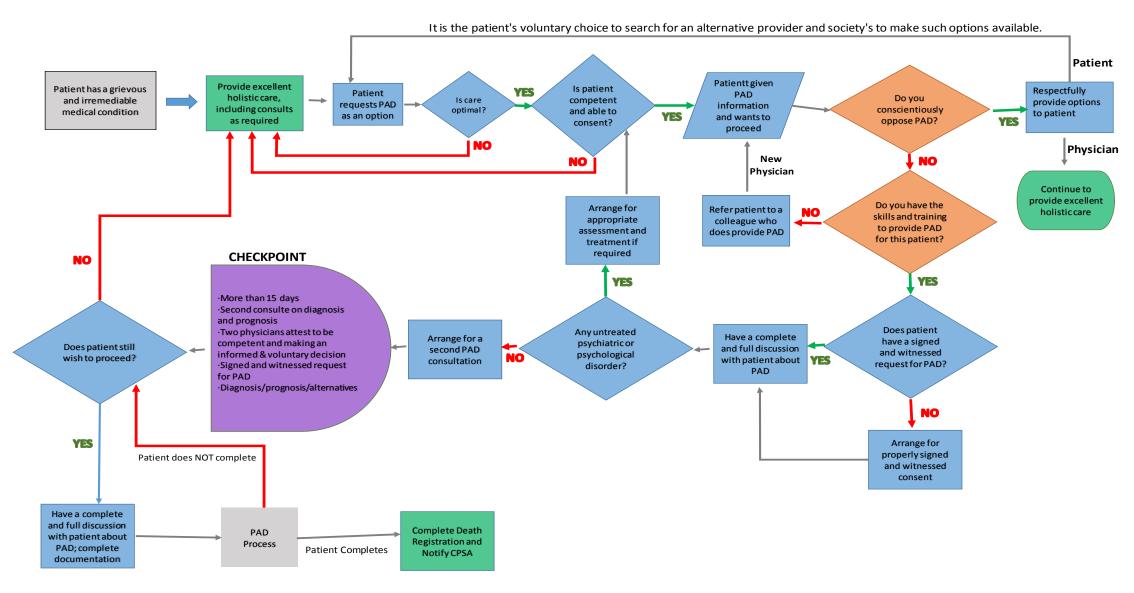
providers; for example, patients with disabling neurologic conditions will often receive care from physiotherapists, occupational therapists, social workers, nurses, patient care aides, and nutritionists as well as their primary care physician, neurologist and other physician providers.

In addition, the process of PAD, whether self-ingestion of medication by the patient (assisted suicide) or physician-administered medication (euthanasia) will require participation by pharmacists, nurses, palliative care team members and others.

Physicians need to be sensitive to the impact of PAD on other members of the healthcare team, including their concerns about legal liability. (The SCC Carter decision addresses only the role of physicians; other healthcare provider roles are not addressed). Other members of the healthcare team may have the same moral or religious objections when a patient seeks PAD.

17. **Social dialogue** – The College will continue to actively participate in the social dialogue examining how best to guide physicians in the care of patients who have "grievous and irremediable medical condition (including an illness, disease or disability) that causes suffering that is intolerable to the individual." The treatment provided must reflect the World Health Organization definition of health as much more than disease management, but treatment of the patient in their own context. The College believes such holistic care is best provided through well-functioning teams, and all options for chronic disease management and palliative care need to be part of the wider conversation.

DECISION FLOW CHART FOR PHYSICIAN-ASSISTED DEATH



Note: In this flow, holistic care means treatment of the entire person extending beyond their disease process to the social, spiritual and cultural determinants of health.



Appendix B: Alberta Laws Specific to Consent

1. Adult Guardianship and Trusteeship Act

Section 2 (Principles) states:

This Act is to be interpreted and administered in accordance with the following principles:

- (a) an adult is presumed to have the capacity to make decisions until the contrary is determined;
- (b) an adult is entitled to communicate by any means that enables the adult to be understood, and the means by which an adult communicates is not relevant to a determination of whether the adult has the capacity to make a decision;
- (c) where an adult requires assistance to make a decision or does not have the capacity to make a decision, the adult's autonomy must be preserved by ensuring that the least restrictive and least intrusive form of assisted or substitute decision-making that is likely to be effective is provided;
- (d) in determining whether a decision is in an adult's best interests, consideration must be given to
 - (i) any wishes known to have been expressed by the adult while the adult had capacity, and
 - (ii) any values and beliefs known to have been held by the adult while the adult had capacity.

Section 87 (Authority to select specific decision maker) says:

- 87(1) Where a health care provider has reason to believe that an adult may lack the capacity to make a decision respecting the adult's health care or the adult's temporary admission to a residential facility, the health care provider may assess, in accordance with the regulations, the adult's capacity to make the decision.
- (2) Subject to section 88, a health care provider may, in accordance with this Division, select a specific decision maker to make a decision for an adult respecting
 - (a) the adult's health care, or
 - (b) the adult's temporary admission to or discharge from a residential facility where the adult has been assessed, under subsection (1), as not having the capacity to make the decision.
- 2. <u>Adult Guardianship and Trusteeship Regulations</u> Outlines capacity assessment, co-decision making (Guardianship and Trusteeship) and specific decisions.
- 3. <u>Health Information Act</u> Section 104 outlines the exercise of rights by other persons as it relates to providing health information.
- 4. Mental Health Act This act covers the ability of a physician to issue admission certificates (Section 2) and asses persons detained under the criminal code (Section 3). Also Part 3 of the Act considers "Treatment and Control". Section 26 says "For the purposes of this Part, a person is mentally competent to make treatment decisions if the person is able to understand the subject-matter relating to the decisions and able to appreciate the consequences of making the decisions." Sections 27 through 30 outlines decision making options for individuals not deemed mentally competent.
- 5. <u>Personal Directives Act</u> If a patient has a personal directive, Section 9 of this Act outlines how it comes into effect. The agent's authority when the personal directive is enacted is:

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Agent's authority

- 14(1) Unless a personal directive provides otherwise, an agent has authority to make personal decisions on all personal matters of the maker.
- (2) An agent must follow any clear instructions provided in the personal directive that are relevant to the personal decision to be made.
- (3) If the personal directive does not contain clear instructions that are relevant to the decision to be made, the agent must
 - (a) make the decision that the agent believes the maker would have made in the circumstances, based on the agent's knowledge of the wishes, beliefs and values of the maker, or
 - (b) if the agent does not know what the maker's wishes, beliefs and values are, make the decision that the agent believes in the circumstances is in the best interests of the maker.

<u>Limitation on authority</u>

- 15 Despite section 14, an agent has no authority to make personal decisions relating to the following matters unless the maker's personal directive contains clear instructions that enable the agent to do so:
- (a) psychosurgery as defined in the Mental Health Act;
- (b) sterilization that is not medically necessary to protect the maker's health;
- (c) removal of tissue from the maker's living body
 - (i) for implantation in the body of another living person pursuant to the Human Tissue and Organ Donation Act, or
 - (ii) for medical education or research purposes;
- (d) participation by the maker in research or experimental activities, if the participation offers little or no potential benefit to the maker;
- (e) any other matter prescribed in the regulations.

Providing emergency medical services

- 24(1) If a person who appears to lack capacity has made a personal directive but
 - (a) the personal directive has not been located,
 - (b) the agent designated in the personal directive to make the personal decision with respect to the matter is unable or unwilling to make the decision or cannot be contacted after every reasonable effort has been made and the personal directive does not contain any clear and relevant instructions, or
 - (c) the personal directive does not designate an agent and the personal directive does not contain clear and relevant instructions, a health care practitioner may provide emergency medical services, without consent, to the person.
- (2) If a health care practitioner has provided an emergency medical service under subsection (1), the health care practitioner must as soon as practicable make a reasonable effort to contact any one of the following for the purpose of informing that person that an emergency medical service has been provided under this section:
 - (a) the agent or guardian, if any, of the person to whom an emergency medical service has been provided;
 - (b) the nearest relative if there is no agent or guardian;
 - (c) any other individual described in the regulations, if there is no nearest relative.

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- 6. <u>Personal Directives Regulations</u> Expands on Section 9 of the Act as it relates to assessments.
- 7. Supreme Court of Canada decision <u>Carter v. Canada (Attorney General)</u>, 2015 SCC 5. Date: 20150206 Docket: 35591

