



Medical law

Chapter 5

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Two key medico-legal issues new physicians should keep top of mind are those of informed consent and disclosure of adverse events.

Taking the time to obtain informed consent from a patient before treatment has shown to be good medicine indeed. Patients need to know the nature of the proposed investigation or treatment and its anticipated outcome, as well as the significant risks involved and any reasonable alternatives to the treatment. In the event the treatment does not go as anticipated and the patient experiences an adverse clinical outcome, it is important for the physician to discuss the unanticipated outcome with the patient or, with the patient's permission, the family.

Note: a related publication is available on the CMA website at: https://op1frpd5.cma-acpm.ca/documents/10179/24891/com_medico_legal_handbook-e.pdf/a603321b-0721-4574-b216-4fe5b5701c8e

In addition, the CMA *Good Practices Guide* found at www.cma-acpm.ca/gpg is an extensive collection of patient safety resources and related cases.

The basics of informed consent

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The process of informed consent plays a major role in the physician–patient relationship. For consent to serve as a defence to allegations of either negligence or assault and battery, it must meet certain requirements. The consent must have been voluntary, the patient must have had the capacity to consent and the patient must have been properly informed.

Physicians may wish to consider the following points when obtaining informed consent from patients:

- Address any language, cultural or cognitive barriers to effective communication. Assess if the patient appears to understand the information being provided.
- Discuss the diagnosis with the patient. When there is reasonable uncertainty about the diagnosis, share this uncertainty, the reason for it and what possibilities are being considered.
- Discuss the proposed investigation or treatment, including the risks, in clear and understandable language.
- Inform the patient of other reasonable options for treatment and related risks. There is no obligation to discuss what might be clearly regarded as unconventional therapy; however, the patient should be made aware of other accepted alternatives and why the recommended therapy is being offered.
- Be alert to a patient's concerns about the proposed treatment and address them appropriately. A particular patient's special circumstances might require disclosure of potential (although uncommon) hazards of the treatment when these might not ordinarily be seen as material. The duty of disclosure extends to what the physician knows (or should know) the particular patient would deem relevant to a decision about whether or not to undergo treatment.
- Do not guarantee results. Encouragement about optimistic prospects for the results of treatment should not allow for misinterpretation by the patient that results are guaranteed.
- Inform the patient about the consequences of leaving the medical condition untreated. Although there should be no coercion by frightening patients who refuse treatment, a physician has an obligation to inform the patient about the potential consequences of refusal.
- Do not fall into the "don't ask, don't tell" trap. Although a patient may wave aside all explanations, ask no questions and be prepared to submit to the treatment whatever the risks may be without any explanatory discussion, a physician must continue to provide sufficient information for informed consent.
- It is prudent to discuss the limitations of an investigation or procedure (e.g., failure

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- rate of a test to detect serious conditions such as cancer).
 - Pay special attention in obtaining consent for cosmetic procedures. When obtaining consent for cosmetic surgical procedures or for any type of medical or surgical work that may be less than entirely necessary for the physical health of the patient, take care to fully explain the risks and anticipated results. As in experimental research situations, courts may impose a higher standard of disclosure in such circumstances.
 - Be aware of Telehealth encounters. Telehealth can present a unique set of circumstances that may be novel to both the patient and the health care provider. In such circumstances, an explicit consent process may be prudent. Areas a physician might consider addressing in the consent process include the limitations of this assessment modality, alternative assessment options, roles and accountabilities of the participants, ongoing care responsibilities, and the capabilities and limitations of the technology (including backup plans) in the event of a technology failure.
 - Inform the patient about who may be involved in providing care; for example, if part or all of a treatment is to be delegated to a trainee. The patient should also be reassured about the quality of that care and the measure of supervision that will be exercised.
 - Ask the patient if there are any concerns. Give the opportunity to ask questions. Answer the questions and assess if the patient appears to understand.
 - If a patient refuses investigation or treatment, explain the actual or potential consequences of this decision.
 - Remember that print material, videos and other handouts can all support the consent discussion, but do not replace it.
 - Write it down! A written note documenting the consent discussion can later serve as important confirmation that a patient was appropriately informed, particularly if the note refers to any special points that may have been raised in the discussion. Document the consent discussion in the medical record in a timely manner. The note might contain the following:
 - Major risks discussed
 - Minor but important risks mentioned
 - Questions asked by the patient and the answers given
 - The patient's apparent understanding, especially if it is a young person, or one whose mental capacity or competency might be questioned
 - Any handout materials provided to the patient
- In Québec, 14-year-olds must consent to proposed treatments. Consent is required from a parent or tutor, or from the court, for treatments offered to minors under the age of 14 or for any patient considered incapable of giving consent. In other parts of the country, minors' capacity to consent must be established by determining the extent their physical, mental and emotional development will allow them to comprehend the nature and consequences of the proposed treatment and, specifically, of the refusal of such treatment. Generally, when minor patients are incapable of giving consent, parents or guardians are authorized to consent on their behalf and must be guided by the minors' best interest.
- The Canadian Medical Protective Association (CMPA) posts a number of risk management resources on its website. CMPA's current online medico-legal resources include articles on documentation and consent. For more information, visit www.cmpa-acpm.ca
- Alternatively, member physicians can also contact CMPA at 800-267-6522. If members do so, they will be placed in contact with a

medical officer who can provide them with confidential medico-legal advice.

EMERGENCY TREATMENT

The general rule that consent must be obtained before treatment is administered comes with an important exception — in cases of medical emergency when the patient (or substitute decision maker) is unable to consent, a physician has the duty to do what is immediately necessary in the interests of the patient, without consent. For the physician to declare any clinical situation an emergency for which consent is not required, there must be demonstrable severe suffering or an imminent threat to the life or health of the patient. It cannot be a question of preference or convenience for the health care provider; there must be a clear and certain need to proceed at the time. Further, in medical emergency situations, treatments should be limited to those necessary to prevent prolonged suffering or to deal with imminent threats to life, limb or health.

Even when the patient is unable to communicate in medical emergency situations, the patient's known wishes must be respected. Before proceeding, the physician will want to be satisfied there has been no past indication, by way of an advance directive or otherwise, that the patient does not want the proposed treatment. Further, as soon as the patient is able to make decisions and regains the ability to give consent, a proper and informed consent



must then be obtained for additional treatment. In some provinces, legislation permits the designation of a substitute decision maker to provide or refuse consent on behalf of the incapacitated patient. If the substitute decision maker is immediately available, emergency treatment should proceed only with the consent of that individual.

In urgent situations, it may be necessary or appropriate to initiate emergency treatment while steps are taken to obtain the informed consent of the patient or the substitute decision maker or to determine the availability of

advance directives. However, the instructions as to whether to proceed or not must be obtained as quickly as practically possible.

When an emergency dictates the need to proceed without valid consent from the patient or the substitute decision maker, a contemporaneous (at the time) record should be made explaining the circumstances that forced the physician's hand. If the circumstances are such that the degree of urgency might be questioned at a later date, arranging a second medical opinion would be prudent if possible.

THE BOTTOM LINE

When the patient or substitute decision maker is unable to consent and there is demonstrable severe suffering or an imminent threat to the life or health of the patient, a physician has the duty to do what appears immediately necessary without consent. Emergency treatments should be limited to those necessary to prevent prolonged suffering or to deal with imminent threats to life, limb or health. Even when the patient is unable to communicate, any known wishes must be respected. ❓

THE CANADIAN MEDICAL PROTECTIVE ASSOCIATION

CMPA is a not-for-profit, physician-owned medical liability protection organization that provides education, advice and legal assistance to physicians in Canada. CMPA also assists physicians in identifying and managing risk in promoting safer medical care. Any physician licensed to practice in Canada (including medical residents) is eligible for CMPA membership.

Note: a publication on consent is available on the CMPA website at: <https://oplrpd5.cmpa-acpm.ca/en/web/guest/-/consent-a-guide-for-canadian-physicians>





Disclosing adverse events to patients

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ADVERSE EVENTS AND LITIGATION

Patients and families litigate for a variety of reasons. While financial need is certainly a factor, disappointment and anger over poor clinical outcomes or unfulfilled expectations also play significant roles. Surprise at unanticipated outcomes or the incidental discovery of important undisclosed details in and around an adverse event are also strong motivators. Patients and families sometimes state that litigation is an attempt to find out what happened after other attempts at communication and inquiry have not successfully answered their questions. Litigation

may also be an attempt to change the system so that similar events do not recur.

Physicians react to unexpected complications and poor clinical outcomes for their patients in a variety of ways. Most want to understand what went wrong. Moreover, most physicians experience a great sense of personal responsibility and are self-critical when an adverse event affects a patient. There is sometimes a tendency to attribute the cause of the harm to others before all of the contributing circumstances and facts are even known. All physicians are motivated to prevent, to the extent possible, the adverse event from happening again.

WHAT IS AN ADVERSE EVENT?

Patients deserve to know the reasons for unexpected clinical outcomes. The term "adverse event" refers to unintended harm from health care delivery, rather than the patient's underlying medical condition. The World Health Organization uses a different terminology focused on "patient safety incidents" that is being introduced to Canada. Whatever the terminology used, many of those charged with improving patient safety dislike the term "medical error" because it carries a sense of blame or fault that may be

inappropriate, especially when it is used before all the circumstances and facts about a case are known.

Although an undesired outcome may represent the progression of disease, sometimes care is at fault. Harm from health care delivery may unfortunately occur, despite the best of care. Such harm results most frequently from a recognized complication — an inherent risk of an investigation or treatment. For example, a patient with no previously known allergy to penicillin may suffer anaphylaxis from the drug. Harm may also result from failures in the structure and process of care, including issues in individual provider performance. The patient with a known allergy to penicillin reacting to the drug given by mistake would be an example.

Adverse clinical outcomes are not usually caused by negligence or fault.

In the courts, the medical standard of care to determine a physician's negligence or fault is not one of perfection, but rather the standard of care that might reasonably have been applied by a colleague in similar circumstances. The courts rely heavily upon the testimony of other physicians working in a similar specialty in the same kind of practice to help establish the applicable standard of care.

DISCLOSURE OF ADVERSE EVENTS TO PATIENTS

It is an ethical, professional and legal obligation to disclose to patients the occurrence and nature of adverse outcomes as soon as is reasonable to do so. Ideally, the communication of adverse events should be done in a gentle, non-rushed manner in a private setting. It is important to formulate a plan of communication before approaching the patient and family. But remember — before communicating directly with patients who have commenced legal action against them, members should consult the Canadian Medical Protective Association (CMPA) or legal counsel.

Note: a related publication is available on the CMPA website at: <https://opllfrpd5.cmpa-acpm.ca/en/web/guest/-/communicating-the-disclosure-of-harm-with-patients-after-an-adverse-event>

TIPS FOR DEALING WITH ADVERSE EVENTS

1. Deal with any emergencies and immediate health concerns.
2. Residents involved in an adverse event should report it to their supervising physicians and are encouraged to be present to observe the disclosure discussion as a learning experience. If time allows, CMPA members may wish to seek telephone advice from CMPA before communicating with the patient, family or hospital involved.
3. Give the patient factual clinical information about what has happened and the clinical nature of his/her condition as it now exists. Avoid speculation about what may have happened if a different course of action had been followed. Avoid attribution of blame, particularly concerning the care provided by others.
4. Provide recommendations to deal with the medical condition as it now exists, including alternate treatments and the risks and benefits of any other investigations and treatments. This is an informed consent discussion on how to move forward. Answer the patient's questions about the proposed treatments.
5. Maintain close communication with the patient and the family (with the patient's consent) about the ongoing clinical condition and any further plans for treatment.
6. Facilitate any necessary treatments and consultations.
7. Transfer care to another physician if the patient requests or prefers it or if the condition requires care that you cannot provide.
8. Express feelings of empathy, sorrow and concern as appropriate. Sharing sincere regret about what has happened, or wishes that the event had not occurred, is an entirely acceptable and desirable response. Sometimes, if the outcome is indisputably due to your improper care, you may acknowledge your responsibility.
9. Inform the patient about any process through which the event may be investigated, but be aware that there may be limitations on what information may be made available from further analysis.
10. Document the care and the discussions that occurred in a factual way after the adverse event. Never alter the record or change what had been written previously in any way.
11. Call CMPA if you are concerned about potential medico-legal problems as a result of what has happened.