The importance of informed consent and disclosing harm

The following articles outline two key medical-legal principles that new physicians need to keep top of mind: informed consent and disclosing harm to patients. Informed consent is about letting patients know the nature of the proposed investigation or treatment and its anticipated outcome. It also involves discussing the significant risks involved in the procedure and any reasonable treatment alternatives. In the event that the treatment results in an adverse clinical outcome, it is important for the physician to discuss this unanticipated outcome with the patient or, with the patient’s permission, the family.

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ACTION for safe medical care: CMPA RISK FACT SHEET

Dr. Gordon Wallace, MD, CCFP(EM), FRCPC

INFORMED CONSENT
Allegations of inadequate consent and the failure to adequately document the consent discussion are recurring themes in CMPA medical-legal cases. The following information promotes practices that will help reduce risk and assist physicians to achieve valid and informed consent before treatment is administered to a patient.

CONSIDER THIS...
A gynecologist obtains consent for a tubal ligation from a 40-year-old woman who has a history of abdominal surgeries. The consent discussion includes the failure rate of the procedure and the risk of ectopic pregnancy. The patient expresses concern about scarring.

During the laparoscopic surgery, the gynecologist encounters difficulty in inserting one of the inferior ports for the creation of the pneumoperitoneum. So, a left flank port is created.

Post-operatively, the patient becomes hypotensive and is taken back to the operating room for an exploratory laparotomy. A laceration of the inferior epigastric artery is found and treated. The patient recovers well with no further complications.

The patient initiates a legal action for lack of informed consent. She alleges that the gynecologist did not discuss the risk of vascular injury or the possibility of a second incision which resulted in an unsightly scar. Although the experts question the physician’s choice of anatomical location for the inferior port, they are most critical of the consent
discussion. The gynecologist failed to disclose the risk of vascular injury as well as the possibility that the surgery might be converted to an open procedure, especially given the patient’s history of abdominal surgeries.

A settlement is paid to the patient by the CMPA on behalf of the gynecologist.

WHAT DOES THIS MEAN FOR CMPA MEMBERS?

If consent is to be considered valid, it must be “informed” consent. In other words, physicians must provide the patient with an explanation of the proposed investigation, procedure or treatment, the anticipated outcome, as well as the potential complications, risks, and reasonable available alternatives. The explanation should provide information which enables the patient to reach an informed decision.

Even if a risk is an unlikely possibility, if its occurrence carries serious consequences (e.g. paralysis or death), it must be regarded as a material risk requiring disclosure.

RISK REDUCTION REMINDERS

The process of informed consent plays a major role in the physician–patient relationship. The following points can assist doctors in managing risk:

1. Assess if the patient appears to understand the information being provided. Address any language, cultural, or cognitive barriers to effective communication.
2. Discuss the diagnosis with patients. When there is reasonable uncertainty about the diagnosis, share this uncertainty, the reason for it, and what possibilities are being considered.
3. Discuss the proposed investigation or treatment including the risks in clear and understandable language. Inform patients about other reasonable options for treatment and related risks.
4. It is prudent to discuss the limitations of an investigation or procedure (e.g. failure rate of a test to detect serious conditions such as cancer).
5. Inform patients about other health care providers who may be involved in their care, for example if part or all of a treatment is to be delegated to a trainee. Patients should also be reassured about the quality of that care and the measure of supervision which will be exercised.
6. Ask patients if they have any concerns. Give them the opportunity to ask questions. Answer the questions and assess that they appear to understand.
7. Even when patients waive aside all explanations or seem prepared to submit to the procedure or treatment without discussion, explain that the risks should still be discussed.
8. If patients refuse investigation or treatment, inform them about the actual or potential consequences of this decision.
9. Print material, videos, and other handouts can all support the consent discussion but do not replace it.

10. 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 patients and the answers given
- patients’ 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

Of all legal and College cases with a consent issue, 65% involved a surgical procedure. Of the surgical cases with a consent issue, 79% had an unfavourable medical-legal outcome for the member.

Statistics are based on a recent 5-year study of CMPA medical-legal cases.

Learn more by accessing these resources

**CMPA articles**
Consent and minor procedures — What physicians need to know
Is this patient capable of consenting?

**CMPA Good Practices Guide**
Informed consent

**CMPA eLearning**
Informed consent

**CMPA handbook**
Consent: A Guide for Canadian Physicians

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Disclosing harm from health care delivery

Dr. Gordon Wallace, MD, CCFP(EM), FRCPC

Despite the commitment to provide the best care possible, clinical outcomes may not be as originally desired or anticipated. Harm — a negative effect on the patient’s health or quality of life — most often results from the progression of a disease. Harm can also result from complications related to health care delivery itself, usually stemming from the risks inherent in clinical investigations and treatments. Biologic and physiologic variability may play a role. Unfortunately, harm from health care delivery may also result from harmful patient safety incidents. The reasons for patient safety incidents are failures in the processes of care or in the performance of providers, including provider error.
Physicians will want to and are obligated to communicate directly with patients whatever the reasons for clinical outcomes. Disclosure discussions serve to communicate to the patient the reasons why a patient safety incident occurred. Disclosure supports patients, families, organizations, and health care providers. Disclosure is the right thing to do.

**ATTEND FIRST TO THE PATIENT’S SAFETY AND CLINICAL CARE NEEDS**
- Seek to improve the patient’s existing clinical condition.
- Make the immediate clinical environment safe (e.g. remove malfunctioning equipment).
- Obtain informed consent for further clinical investigations, treatments, or consultations the patient needs.
- Consider whether it would be best for another physician to assume care of the patient.

**PLAN THE INITIAL DISCLOSURE**
- Schedule the initial disclosure with the patient as soon as reasonably possible.
- Gather the facts to gain a preliminary understanding of what happened.
- Speak to other health care providers who were involved in the patient safety incident.
- Confirm whether there will be a quality improvement review of the patient safety incident.
- Organize the main discussion points.
- Anticipate and prepare for emotional reactions and questions from the patient and family.

**INVITE PARTICIPANTS TO ATTEND THE INITIAL DISCLOSURE MEETING**
- Invite those individuals who have a direct role in providing clinical care and emotional support to the patient. Consider the patient’s wishes.

**CONDUCT THE INITIAL DISCLOSURE**
The most responsible physician, or an appropriate delegate, usually leads the initial disclosure meeting.
- Sit at eye level in a private area with the patient, free from interruptions.
- Begin the discussion with an expression of sympathy and compassion for the circumstances. Address the patient’s information and emotional needs.
- Explain what happened, focusing on the facts. Avoid jargon.
- Invite the patient to provide his or her perspective on what has happened.
- Avoid speculating or laying blame.
- Remain professional and take care not to appear defensive.
- Briefly outline the investigative process that will be followed and what the patient and family can expect to learn. If known, share specific timelines.
- Assess the patient’s level of understanding and satisfaction, and ask if there is anything further that can be done to assist the patient at this time.
- Provide the patient with the name and telephone number of a person whom they can contact. This person may also periodically touch base with the patient, even when there is nothing new to report.

**QUALITY IMPROVEMENT REVIEW**
Physicians should contribute to properly structured and conducted quality improvement reviews.

**CONDUCT THE POST-ANALYSIS DISCLOSURE**
In hospital settings, hospital leaders usually lead the post-analysis disclosure meeting, while the responsible physicians may have a more limited role.
- Explain the conclusive, factual reasons for harm to the patient as determined by the quality improvement review. The focus should be on key learnings and improvements being made that could benefit other patients.
- Apologize to the patient, as appropriate. The nature of an apology for a poor clinical outcome will depend on the reason for the outcome. It is always appropriate to say you are sorry for the circumstances or condition of the patient.
- Avoid statements that express or imply legal responsibility, such as negligence or fault. Legal responsibility is not usually clear, and courts and medical regulatory authorities (Colleges) make these determinations.

**DOCUMENTATION**
- Document all relevant details of disclosure meetings in the patient’s medical record, including meeting dates, matters discussed, and expressions of empathy.
- Document the patient’s clinical condition, including any informed consent discussions.

For more information see *Disclosing harm from health care delivery: Open and honest communication with patients*, 2015. Visit [www.cmpa-acpm.ca](http://www.cmpa-acpm.ca).

CMPA physicians are available to provide advice and support. CMPA members are encouraged to contact the CMPA at 1-800-267-6522.

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1. The Canadian Patient Safety Institute (CPSI) and the CMPA have adopted certain terms from the World Health Organization (WHO). **Harmful Patient Safety Incident**: A patient safety incident that resulted in harm to the patient. In Québec, the term “accident” means “an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personnel member, an involved professional, or a third person.” As the CMPA interprets the Québec legislation, the term “accident” would align with the WHO term “harmful incident”.

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