CMPA.
Empowering
better healthcare

ACTION for safe medical care: CMPA RISK FACT SHEET

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.

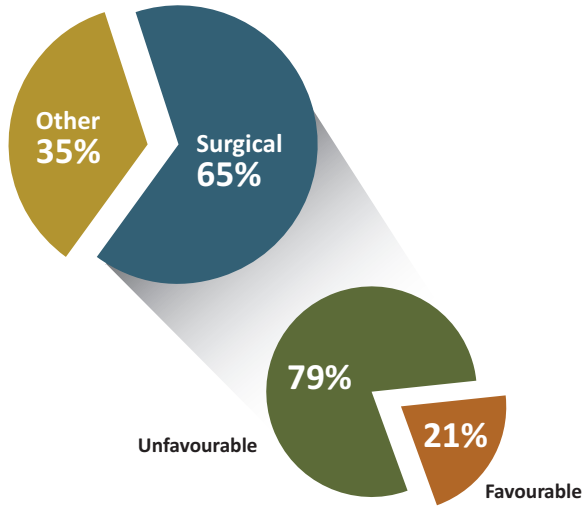
During the laparoscopic surgery, the gynecologist encounters difficulty in inserting one of the inferior ports for the creation of the pneumoperitoneum. So, a left flank port is created.

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.

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.

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.

continued

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 healthcare 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

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

CMPA consent form template
Consent to use electronic communications [pdf]