Informed consent for surgery: risk discussion and documentation

Melissa Hanson, MD
Dennis Pitt, MD

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Correspondence to:
D. Pitt
Department of Surgery
The Ottawa Hospital
501 Smyth Rd, Box 202
Ottawa ON K1H 8L6
dpitt@ottawahospital.on.ca

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The Canadian Medical Protective Association reports that over a recent 5-year period, 65% of medical legal actions involving informed consent were surgical and only 21% of these cases were decided in favour of the surgeon. We examined the documentation of informed consent by general surgeons at the General Campus of the Ottawa Hospital and found it to be poor (Appendix 1, available at canjsurg.ca). We suspect this is not unique to our group.

The Consent to Treatment policy of the College of Physicians and Surgeons of Ontario, based on the Health Care Consent Act of the Ontario legislature, was updated in 2015 and delineates the requirements of informed consent. There is similar legislation and regulatory policy in all the Canadian provinces and territories.

Prior to obtaining consent for the proposed surgery, the surgeon must provide the patient with information about the nature of the surgery, the expected benefits, material risks and adverse effects, alternate treatments and the consequences of not having the surgery. Material risks include risks common to all surgery and risks specific for the proposed surgery, even if they are rare. Risks that may cause the patient to refuse surgery are especially important, and the specific circumstances for individual patients, such as work responsibilities, family issues, religious beliefs and insurance coverage, have to be considered. Because not all of the hundreds of conceivable risks for an operation can be discussed, surgeons have to use their clinical judgment in the discussion. Supporting documents can contribute to the discussion, but they are not a substitute for oral communication. Surgery without consent can be done only in emergency situations when the patient is not capable and no substitute decision-maker is available.

Challenges to obtaining informed consent may arise. Surgery produces anxiety in patients, and some display this stress more than others. Hearing their surgeon iterate a long list of things that can go wrong is frightening. Although patient autonomy includes the right to refuse necessary surgery and the “therapeutic privilege” of withholding information is outdated, we want to minimize patients’ fear and avoid anxiety-induced excess catecholamine release causing problems at administration of anesthesia. The surgeon’s calm, reassuring...
Demeanour goes a long way in relieving this stress. Family members can be helpful with the occasional patient who does not wish to hear about any potential complications.

Another challenge can be a language barrier when a friend or family member translates the surgeon’s explanations into brief sentences, with the patient receiving a fraction of the information provided. A hospital interpreter can be a valuable resource.

Part of the discussion requires surgeons to make reasonable attempts to answer the patients’ questions. The majority of these questions are straightforward, and a simple, clear response usually suffices to bring relief to the patient and their concerned family. With all the information available on the Internet, patients may wish to engage in an intensive, detailed discussion, and the surgeon must be patient while facilitating their understanding of the wealth of data they have acquired.

Proper documentation is the only objective measurement of what information was communicated to the patient and provides legal protection for the surgeon. The defence of “I cannot remember this particular patient but my usual practice is…” does not suffice. Although consent can be implied or expressed orally, consent for surgical procedures requires recorded documentation. The minimum recommended documentation is the date of the dialogue, who was involved, material and unique risks discussed, any special circumstances of the patient, the risk of not having the surgery and whether consent was obtained or refused. A frequent finding in our retrospective chart review was that the documentation of the informed consent discussion was found in the operating room (OR) report, dictated after completion of the procedure (Appendix 1). If a complication occurs in the OR, documentation after the fact about the discussion of that particular risk is of questionable value.

The following is an example of proper documentation of an informed consent discussion.

The patient was advised that laparoscopic cholecystectomy was indicated to prevent further episodes of pain and complications from the gall stones. The nature of the surgery and the risk of conversion to open laparotomy for unexpected bleeding, infection or injury to an organ during the operation was discussed with the patient and her husband. We talked about the postoperative course and potential complications, including wound infection and herniation. I advised them of common risks for all surgery, such as pneumonia and venous thrombosis. She understood and wished to proceed with surgery. The surgery will be delayed until after her daughter’s wedding.

Templates may facilitate proper documentation and serve to remind the surgeon of important details to include in the discussion with the patient, although the discussion and documentation have to be individualized for each patient. Audiovisual recording of the consent process is common in the United States and could be useful in Canada if the surgeon anticipates a very difficult, contentious process. The assistance of an experienced colleague and a legal professional would be prudent in such a situation.

The dialogue and documentation of informed consent for surgery have evolved from a brief chat and a quick signature into a major and sometimes complex component of surgical practice. We can anticipate more changes in the future in response to patient expectations regarding communication and information. It is important to keep up to date with and fulfill the medical legal requirements in the policies of the provincial regulatory authorities.

Affiliations: From the Department of Surgery, The Ottawa Hospital, Ottawa, Ont.

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References