Written Informed Consent

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"Pro/Con" Section Editor:
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PRO

Obtaining consent from a patient prior to a medical procedure is a modern concept. For example, the American Medical Association published its position on informed consent in 1981.[1] Historically physicians have been reluctant to promote full disclosure to patients. This reluctance was likely related to the limited therapeutic options available and the widespread use of placebos in past centuries and is probably as ancient as the practice of medicine itself. Hippocrates specifically advocated concealing most things from patients.[2]

The doctrine of informed consent has come into medical practice largely as a result of the medical profession's responses to a series of decisions by various courts. In 1914, Justice Benjamin Cardozo wrote (in *Schloendorff v. Society of New York Hospital*):[3] "Every human being of adult years and sound mind shall have the right to determine what shall be done with his own body." In 1908, Mary Schloendorff had been anesthetized and operated on against her clearly expressed protests.[4]

The term "informed consent" is believed to have first appeared in Justice Bray's decision in *Salgo v. Leland Stanford, Jr.*, in 1957.[5] The concept was further elucidated in *Natanson v. Kline* in 1960[6] and *Canterbury v. Spence* in 1972,[7] wherein the decision included the following:

"[I]t is evident that it is normally impossible to obtain a consent worthy of the name unless the physician first elucidates the options and the perils for the patient's edification."

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CON

A written consent form for regional anesthesia (RA) ideally represents an attestation by the patient that he or she has made an informed choice regarding the proposed regional anesthetic and has accepted the risks associated with said technique in the absence of undue duress. While attractive in theory, a consent form for RA is fraught with obstacles and may ultimately be counterproductive.

Informed consent hinges on accurate, up-to-date risk disclosure. Fortunately serious complications following RA are rare. Unfortunately prohibitively large numbers of patients are required for study to capture the incidence of such rare events. The American Society of Anesthesiologists (ASA) Closed Claims Project database provides the most contemporary and comprehensive collection of adverse events associated with RA in the United States[1]; however, the lack of a denominator prevents the calculation of incidence. Most other large studies are dated[2] or restricted to retrospective reviews of charts[3] or insurance claims[4] and self-reporting by anesthesiologists,[5,6] all of which lead to inaccuracies.

The heterogeneity of these studies undermines consensus of risk, which varies depending on the patient's health, the anesthesiologist's skill and the block performed. Increasingly prevalent patient-related risk factors for nerve injury (e.g., obesity,[7] diabetes,[8] potent anticoagulants[9]) affect complication rates. Differences in nerve localization methods, needle types and local anesthetics prohibit comparisons between studies. Differences in sample sizes and surgical procedures confound further. The presentation, investigation and diagnosis of anesthesia-related nerve injury is complex[10,11] and inconsistent among studies, resulting in under-reporting in some investigations and over-reporting in others. The questionable

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It was not just the courts that drove the issue of informed consent. Overlapping the same timeline, the concept was furthered by the attention given to research practices. In 1966, Henry K. Beecher, M.D., an anesthesiologist who made many important contributions to the field of medicine, published an article in the *New England Journal of Medicine* in which he documented failures to adhere to accepted standards of protecting research subjects by some of the most renowned researchers of the time.[8] Among the most egregious protocols cited were infecting retarded children with hepatitis virus and injecting nursing home patients with cancer cells.

The right of self-determination of patients in dealings with their physicians became convincingly clear in light of changes overtaking our society as a whole, such as the civil rights movement and the many challenges to authority of the Vietnam War generation.

Ethicists have suggested that informed consent has certain requirements.[9] A synthesis of these recommendations might be as follows[10]:

1. Capacity (the ability of a patient to understand);
2. Voluntariness (circumstances that minimize undue influences);
3. Information (data for and against a proposed treatment in a setting where the patient can think and discuss with family, friends or other care providers); and
4. Consent.

It also is suggested that physicians help patients decide on therapeutic options by being mindful of each patient's own particular set of values. This may be one of the most important concepts for anesthesiologists because the patient has already decided on what is usually the more fateful decision of having surgery. Anesthesiologists may see the consequences of anesthesia with a hierarchy that may differ significantly from what a patient may see. For us a patient's numb finger may be very unfortunate, but it is a vastly preferable outcome compared to what might transpire following an airway disaster during general anesthesia. It is the patient's right, however, to be included in that calculation of risks and benefits. For example, to someone who relies upon a super-human sense of fine touch, such as a concert violinist, a major league baseball pitcher or a safecracker, the rarity of airway problems may make general anesthesia sound greatly preferable over a nerve block. It is ethically unsound to assume that one knows so much about the benefits of regional anesthesia

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validity of the available literature limits its role in guiding discussions with patients and forming the basis of written documentation regarding risk and consent.

Discussions regarding anesthetic risk in the immediate preoperative period are controversial given the potential to exacerbate patient anxiety.[12] Pursuing the patient's signature for an RA consent form may further heighten anxiety. Moreover previous studies that examined which anesthetic risks patients would like to know about are conflicting.[13-18] Many patients prefer simple explanations about the main risks, while others would like full disclosure.

A consent form for RA cannot exist in isolation. What if a block fails, the patient is converted to general anesthesia (GA) and, amid severe postoperative nausea and vomiting, the patient declares that he or she never consented to GA? Indeed the Canadian Medical Protective Association (CMPA) states that "physicians may be liable in assault when … the treatment went beyond or deviated significantly from that for which the consent was given."[19] A consent form for RA breeds more legal documents, beginning with a consent form for GA. What about written consent for "rescue" blocks? Conscious sedation? The possibilities are endless. Therefore:

The need for written consent for anesthesia is seen as limited because ordinarily it should be implicit in the documentation of the pre-anaesthetic examination by the anaesthetist that the patient was properly informed …. When informed consent is called into question, a doctor's note on the record may be of equal or even greater usefulness for defence purposes …. Such notations, particularly if they identify questions or special concerns expressed by the patient, can serve to validate the consent process better than any other documentation.[19]

Accordingly there is little or no mention of a consent form for RA (or GA) in the ASA Guidelines for the Ethical Practice of Anesthesiology[20] or the Canadian Anesthesiologists' Society (CAS)[21] Practice Guidelines for Anesthesia. The ASA guidelines simply state that "anesthesiologists should provide preoperative evaluation and care and should facilitate the process of informed decision-making, especially regarding the choice of anesthetic technique."[20] Regarding RA in particular, a single sentence appears in the obstetrical subsection of the CAS guidelines and reads: "Informed consent should be obtained and documented in the medical record."[22] There is no mention of consent, either verbal or written, in the ASA guidelines for RA in obstetrics.[23] Why then do we need a consent form for surgical or chronic pain procedures? Perhaps we should eliminate these consent forms altogether and replace them with a handwritten note in the patient's chart detailing discussion of risks

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that it trumps one's moral obligation to respect a patient's right to self-determination.

To that end, a written consent form is useful in many ways. It is evidence that a careful discussion and deliberation has occurred, that a specific plan has been agreed to, that all questions have been answered and that risks and benefits have been described and alternatives explored. In a sense, it is a certificate affirming adherence to the modern ethical principles of the profession that dictates respect for the dignity of your patient and recognize specifically the patient's autonomy. Also it may well be that only during a discussion of risks generated by the presentation of a consent form that a patient's unique circumstances and legitimate concerns come to light. Even when the consent form is signed without a full discussion, as it unfortunately often is, it is a reminder each and every time of the expectations placed on your interaction with a patient. Ideals are capable of guiding us even from a distance.

We must be mindful that a consent form is not itself an informed consent. Informed consent is a process. A consent form is only a legal document. The advisability of having such a document as part of the permanent medical record is an issue that is best left to risk managers, hospital counsel and malpractice defense attorneys. This concern is largely governed by local litigation experience. If it is effective in protecting a practitioner from spurious claims by a patient that no discussion of risks, benefits and alternatives took place, then it is a reasonable use of time and effort for that reason alone. And insofar as the use of a written document establishes a ritual surrounding the interaction of an anesthesiologist and his/her patient, it also can be seen as a hard copy of our specialty's commitment to leaving behind us the dark ages of deciding what is best for patients without their input.

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and documenting informed consent. This interesting argument is beyond the scope of this article.

Many anesthesiologists do not provide RA for fear of medicolegal action.[24] Proponents of a consent form believe that such documentation will protect the provider in case of medicolegal action. This may not be the case, as explained by CMPA:

Consideration of a form of consent to be signed by the patient should not obscure the important fact that the form itself is not the "consent." The explanation given by the doctor, the dialogue between doctor and patient about the proposed treatment, is the all important element of the consent process. The form is simply evidentiary, written confirmation that explanations were given and that the patient agreed to what was proposed. A signed consent form will be of relatively little value later if the patient can convince a court the explanations were inadequate or, worse, were not given at all.[19]

Indeed a piece of paper bearing the patient's signature is not consent. We all recall instances where a patient was instructed by a physician or surgeon to "sign here" on a consent form without any discussion resembling the process of informed consent. The informed consent process is a conversation and exchange of information between the anesthesiologist and the patient culminating in a voluntary agreement to proceed with the proposed procedure.

I favour a patient-, provider- and situation-specific approach to risk disclosure for RA. I believe that the anesthesiologist must disclose the significant risks of RA and address all questions posed by the patient regarding risk. "Significant" risks are those that the anesthesiologist believes any reasonable patient would want to know about. "Significant" risks are those that happen relatively frequently (e.g., transient neuropathy) and those that happen rarely but are severe in nature (e.g., paralysis). "Significant" also depends, however, on the patient and circumstances as interpreted by the anesthesiologist during the preoperative interview. Discussions of risk and consent can then be documented in the anesthetic record by the anesthesiologist in the context of specific technical-, patient- and surgical-related risks factors.

Acknowledgments

I am grateful to David J. McKnight, M.D., F.R.C.P.C., for his expert commentary upon reviewing an earlier version of this manuscript.

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