HSSJ (2007) 3: 115–118
DOI 10.1007/s11420-006-9035-y

ETHICS

Nuances of Informed Consent: The Paradigm of Regional Anesthesia

Douglas S. T. Green, MD · C. Ronald MacKenzie, MD.

Published online: 3 January 2007

Informed Consent is the primary method employed in clinical practice by which patients and their physicians incorporate a patient's values, preferences, expectations, and fears in treatment decision-making [1]. Grounded in the philosophical concept of autonomy, it reflects a departure from the paternalistic tradition of western medicine, revealed first in the writings of Hippocrates and remaining dominant until recent times [2]. The practice of Informed Consent in the clinical arena evolved primarily through the medical profession's responses to various decisions by the courts. In this paper we review the concept of Informed Consent from a historical and ethical perspective and, in so doing, provide a context for a discussion of these considerations to a specific clinical domain, that of regional anesthesia.

Historical considerations

That a medical procedure could be performed without including the patient in the decision-making process will seem inconceivable to the physician of today. Nonetheless, the modern practice of Informed Consent is just that—modern—with a history not yet a century old. Indeed. the American Medical Association's position paper on this practice was published in 1981 [3]. When viewed from a historical perspective, a reluctance to promote full disclosure from patients has been the dominant posture of the medical profession. Such non-disclosure is probably as ancient as the practice of medicine and for most of recorded medical history what is now considered a primary obligation was seen as antithetical to one of the dominant ideas of practice. Even the venerable Hippocrates advocated concealing most information from patients [4]. This reticence likely arose as a consequence of the limited therapeutic options available to physicians in earlier times and the widespread use of placebos. However, the extraordinary advances made in medical practice over the last 50 years have produced a fundamental change in this long-enduring belief and established an attitude of disclosure.

What has now become the doctrine of Informed Consent has arisen in response to a number of decisive legal judgments beginning in 1914 with *Schloendorff v. Society of New York Hospital* (although other cases in American and English courts had established the concept that performing a procedure on a patient without consent was a form of common battery—a tort—the Schloendorff case is notable for its potent influence on subsequent decisions). This case involved a patient named Mary Schloendorff who had been subjected to surgery against her expressed wishes and vociferous protests. She successfully sued the surgeon and the hospital and in so doing began an inevitable erosion in medicine's attitude of paternalism. A quotation from the opinion of Justice Benjamin Cardozo in the Schloendorff case is rooted in the principle of autonomy: "every human being of adult years and sound mind shall have the right to determine what shall be done with his own body ...." [5]. Despite its historic significance, Justice Cardozo's opinion did not immediately alter medical practice and for years the courts remained reluctant to impose rules of practice on the medical profession. In fact, it took decades and a series of other relevant cases before the doctrine of Informed Consent became the professional standard as we know it today.

The term "Informed Consent" is of relatively contemporary origin, first appearing in Justice Bray's decision in *Salgo v. Leland Stanford Jr. University Board of Trustees* in 1957 [6]. This case involved a patient named Martin

The authors are Co-Chairs of the Bioethics Committee of The Hospital for Special Surgery

D. S. Green, MD (✉)
Department of Anesthesiology,
Hospital for Special Surgery,
535 East 70th St., New York, NY 10021, USA
e-mail: greendo@hss.edu

C. R. MacKenzie, MD
Department of Medicine,
Hospital for Special Surgery,
535 East 70th St., New York, NY 10021, USA

Salgo who awoke paralyzed after aortography, having never been informed that such a risk existed. The decision held that failure to disclose risks and alternatives was cause for legal action on its own, reaching further than a case of battery. The concept was further elucidated in *Natanson v. Kline* in 1960 [7], where the court held the medical profession responsible for a standard of disclosure of risks that a reasonable practitioner would provide a patient (Irma Natanson suffered severely disabling burns as a result of cobalt irradiation for breast cancer in spite of having been told that there were no risks associated with this treatment). Later, in *Canterbury v. Spence* in 1972 [8], that standard was rejected for one that would require practitioners to disclose the risks that a reasonable patient would want to know (Jerry Canterbury was partially paralyzed after thoracic spine surgery. His claim that he had not been informed that such a risk existed was confirmed in testimony by his surgeon). The decision of the court in the Canterbury case included the following admonition:

> "... the physician must seek and secure his patient's consent before commencing an operation or other course of treatment. It is also clear that the consent, to be efficacious, must be free from imposition upon the patient. It is the settled rule that therapy not authorized by the patient may amount to a tort—a common law battery—by the physician. And it 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."

In rejecting the notion that a physician was only legally responsible to divulge no more than what other reasonable practitioners would divulge, the court's decision also states:

> "Respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves."

This case may not have the drama of a Nuremburg tribunal or the public notoriety of the thalidomide tragedy. Nonetheless, this case, just one of thousands of torts decided around the country that largely went unnoticed, was a historic moment for medicine as a profession. If a profession is defined as a body of qualified persons who set and uphold standards of practice and ethics, this moment was notable for the display of the medical profession's failure and the capitulation of that responsibility to others. The courts had to define for the profession a level of disclosure that was neither onerous nor punitive in its breadth—it was merely reasonable. As we will discuss next, by the standard of its time, it was also clearly self-evident.

It was not just the courts that have guided the change in the current practices of informed consent. Superimposed on these evolutionary influences, the ethical norms for informing patients of risks and benefits of treatment have also been furthered by the analogous practices in the domain of clinical research. In 1966, Henry Knowles Beecher, a pioneering anesthesiologist at the Massachusetts General Hospital, published an article in the New England Journal of Medicine in which he documented failures to adhere to reasonable ethical standards for the protection of research subjects. Beecher presented 22 studies (his original, unrevised manuscript cited more than 50 such studies) published in mainstream academic journals by some of the most renowned researchers of the time. Among the most egregious protocols cited were studies involving the intentional exposure of retarded children to hepatitis virus and an investigation that involved injecting nursing home patients with cancer cells. As a consequence of this report, Dr. Beecher became a controversial figure but over time he and his paper have been afforded great historical significance.

It should be noted that these events took place during a tumultuous time in the history of our country. The Vietnam War generation saw a huge cultural shift in that many notions of authority were openly contested, and accepted social norms challenged. This was also the era of the civil rights movement that ultimately moved the nation towards acknowledging the freedoms and rights of all individuals. The notion of the right of self-determination of patients in dealings with their physicians was not a large leap in the light of the changes overtaking our society as a whole. The courts played a vital role in the advancement of the law in this regard. In the context of the evolution of the concept of Informed Consent, the courts, complemented by the input of members of a new discipline, bioethics, moved theory and practice forward.

Contributions stimulated and elucidated by the courts include:

1. Each person is considered to be master of his/her own body.
2. Doctors should describe the nature of the proposed treatment, the probability of success, the alternatives, and the risks.

The important elements of informed consent have been elucidated by medical ethicists who have held that for the process of Informed Consent to have moral authority it must meet certain requirements [9]. A synthesis of these recommendations might be as follows (Nancy Neveloff Dubler, personal communication):

1. Capacity (the ability of a patient to understand a diagnosis and the options for treatment)
2. Voluntariness (the consideration that the circumstances surrounding the process should minimize the undue influences of others)
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)
4. Consent

It is also suggested that physicians help patients decide on therapeutic options by being mindful of the need to address each patient's own particular set of values. This may be one of the most important concepts for anesthesiologists in helping their patients choose between anesthetic

options because the patient has already decided on what is usually (although not always) the more fateful decision—that of having a surgical intervention.

Regional anesthesia as a paradigm of nuanced informed consent

The use of regional anesthesia (as opposed to general anesthesia) where regions of the body are anesthetized by nerve blocks or neuraxial techniques (such as spinal and epidural anesthetics) has grown substantially in recent years [10]. Regional anesthesia techniques have evolved to include the placement of catheters for use in postoperative pain control and have had a significant impact on the entire perioperative experiences of patients [11]. There may be improvements in morbidity and mortality when some regional techniques are used [12, 13]. The preferences of orthopedists and anesthesiologists for regional anesthesia have been documented [14], and some practice guidelines recommending the use of regional anesthesia have begun to emerge [15].

Regional anesthesia may offer some important perspectives on the process of Informed Consent. In considering what information to give to a patient to adhere to the recommended elements of an informed consent, and what the ultimate recommendation for an anesthetic plan will be, a practitioner should be aware of the results of well-conducted outcome studies. For example, in recommending a regional anesthetic technique for an operation on an upper extremity, an anesthesiologist may be impressed with a large outcome study that showed no cardiac arrests, no episodes of respiratory failure, and no deaths following upper limb blocks in over 23,000 anesthetics performed [16]. The incidence of peripheral neuropathy complications was very low, ranging from a rate of zero to less than three per 10,000 anesthetics depending on the particular technique used. These are impressive numbers and may justifiably influence the recommendation for an anesthetic plan that the anesthesiologist may give to a patient. But when opinions favor a particular technique over another, there is a danger that strong personal preferences of an individual doctor or a more widespread institutional culture may afford a subtle paternalistic influence in the recommendations given to patients. The anesthesiologist may tend to see the risks and benefits with a hierarchy that may differ significantly from what a patient may see.

For an anesthesiologist the rare occurrence of a complication such as a patient's numb finger following a nerve block may be very unfortunate, but it is a vastly preferable outcome compared to what might transpire following an airway disaster on induction of general anesthesia. There are complications associated with all therapies and procedures, and the complications of regional anesthesia seem to be of a less catastrophic nature than those of general anesthesia. In comparing general anesthesia to regional anesthesia, problems of oxygen delivery leading to mortality, though rare, appear to be measurably more common for general anesthesia in some populations [17]. These are not mere value judgments as there is a clear quantifiable difference between loss of sensation of a fingertip and loss of everything. It is nonetheless the patient's right to be included in that calculation of risks and benefits, and important issues specific to the patients themselves may need to be considered. For example, the rarity of airway problems may make general anesthesia sound greatly preferable over a nerve block to a patient who has developed and relies upon a superhuman sense of fine touch, such as a concert violinist, a major league baseball pitcher, or a safecracker. To patients such as these the very low incidence of nerve injury that may result from a small needle injecting a local anesthetic near a nerve may still be preferable to the risks or discomforts of general anesthesia, but the idea of a large needle used to pass a catheter to achieve only a day or two of improved postoperative pain control may not be worth any further risk at all, if one exists. It is ethically unsound to assume that one knows so much about the benefits of a technique that it trumps one's moral obligation to respect a patient's right to self-determination. That right can only be respected by a thorough elucidation of alternatives and an exploration of the details of each patient's unique circumstance. It is the duty of anesthesiologists to explore these issues with a patient so that they may contribute what they can to the noble cause of self-determination, and to continue their specialty's well-recognized commitment to the protection of patient rights.

In considering the elements of an Informed Consent as outlined above, it is important to recognize that which is conspicuously absent from the list—a consent form. Informed Consent refers to a process; a consent form is only a document. In a recent editorial debate, one of the authors (DSTG) advocated for the use of written consent forms, but an opposing view was also expressed [18]. Some of the issues raised warrant repeating here. A written consent form is useful in many ways. It is formal and palpable documentary evidence that a careful discussion and deliberation has occurred, that a specific plan as been proposed and agreed to, that all questions have been asked and answered, that risks and benefits have been described, and alternatives explored. In a sense, it is a certificate affirming adherence to the ethical principles of the profession, which dictate respect for the dignity of the patient and the patient's autonomy and right to self-determination without undue influence. 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. In addition, even when the consent form is signed without a full discussion, as they unfortunately often are, it is a reminder each and every time of the expectations placed on the interaction with the patient. Ideals are capable of guiding us even from a distance.

There is a distinction between a moral obligation and a legal one and if the legal standard of disclosure includes informing patients of the risks that a reasonable person would want to know is also ethically sound, then we are

clearly obligated to uphold that standard. But what would a reasonable patient want to know? Let us return briefly to considering the patient who is about to have surgery on an upper extremity. What should the patient be told about the risks and available alternatives by an anesthesiologist who is convinced that a nerve block is safer than a general anesthetic?

If a well-designed outcome study suggests that the risk of nerve injury from an upper extremity block is on the order of zero to two or three per 10,000 cases, then they should be told that. They should also be informed of the calculation that the practitioner is making wherein those risks are being weighed against the graver risks of oxygen mishaps of general anesthesia as described above. It may well be that it is only at this point, long after the completion of a history and physical, that the physician discovers the patient's unique circumstances that need to be included in the calculation of risks and benefits. The patient that you knew as a schoolteacher or stockbroker may turn out to have a second and to them a more important life as a concert violinist. By exploring the nuances of a particular patient's life, a practitioner can achieve a level of professionalism that is morally superior to that which is required by law. We reaffirm the standing of our profession in its proper place in society when we make the effort to answer the question, not just of what a reasonable person would want to know but what, in our best judgment, would this unique human being need to know to more fully exercise the right of self-determination.

A paradigm that includes the nuances derived from a detailed discussion with a patient prior to an anesthetic can offer insights for other specialties. The details of a patient's life circumstances are likely to affect many or most medical plans once an effort is made to flesh out the unique circumstances of the individual. As argued above, we must remain mindful that Informed Consent is a process, not simply a form to be completed before treatment can begin. Yet insofar as the use of a written document establishes a ritual surrounding the interaction of a physician and his/her patient, it addresses not just legal concerns but also serves to document our profession's commitment to our patients and reminds us all of the need to explore the unique details of a patient's life, particularly those that have an impact on the advice that we offer them.

References

1. Coleman CH, Menikoff JA, Goldner JA, Dubler NN (2005) The ethics and regulation of research with human subjects. LexisNexis, Dayton, Ohio
2. Institute of Medicine, National Academy of Sciences, Responsible Research (2002) A Systems Approach to Protecting Research Participants, pp 120–121
3. America Medical Association (1997) Code of medical ethics. Current opinions with annotations. Council on Ethical and Judicial Affairs 1996–1997 edition. American Medical Association, Chicago, pp 120
4. Katz J (1995) Informed consent in the therapeutic relationship: law and ethics. In: Arras JD, Steinbock B (eds) Ethical Issues in Modern Medicine. Mayfield Publishing Company, Mountain View, pp 87–97
5. Schloendorff V (1914) Society of New York Hospital. 105 N.E. 92 (N.Y. 1914)
6. Salgo V (1957) Leland Stanford Jr. Univ. Bd. Trustees. 154 Cal. App. 2d 560, 317 P.2d 170
7. Natanson V (1960) Kline, 186 Kan. 393, 411, 350 P. 2d 1093
8. Canterbury V (1972) Spence, 464 F.2d 772 (DC Cir. 1972)
9. Beauchamp TL, Childress JF (2001) Principles of biomedical ethics, 5th edn. Oxford University Press, New York, pp 77–83
10. Neal JM, Kopacz DJ (2005) Needle placement and beyond ... teaching regional anesthesia to residents and fellows. American Society of Anesthesiologists Newsletter 69(5), May 2005
11. Liu S, Carpenter RL, Neal JM (1995) Epidural anesthesia and analgesia: Their role in postoperative outcome [Review article]. Anesthesiology 82(6):1474–1506, June 1995
12. Rodgers A, Walker N, Schug S, et al (2000) Reduction of postoperative mortality and morbidity with epidural or spinal anaesthesia: results from overview of randomised trials. BMJ 321:1493–1497
13. Yeager MP, Glass DD, Neff RK, Brinck-Johnsen T (1987) Epidural anesthesia and analgesia in high-risk surgical patients. Anesthesiology 66:729–736
14. Oldman M, McCartney CJL, Leung A, Rawson R, Perlas A, Gadsden J, Chan V (2004) A survey of orthopedic surgeons' attitudes and knowledge regarding regional anesthesia. Anesth Analg 98:1486–1490
15. Hawkins JL, Arens JF, Bucklin BA, Caplan RA, Chestnut DH, Connis RT, Dailey PA, Gilstrap LC, Grice SC, Oriol NE, Zuspan KJ (1999) Practice guidelines for obstetrical anesthesia: A report by the American Society of Anesthesiologists Task Force on Obstetrical Anesthesia (Special Article) developed by the Task Force on Obstetrical Anesthesia. Anesthesiology 90(2):600–611
16. Auroy Y, Benhamou D, Bargues L, Ecoffey C, Falissard B, Mercier F, Bouaziz H, Samil K (2002) Major complications of regional anesthesia in France. The SOS Regional Anesthesia Hotline Service. Anesthesiology 97:1274–1280
17. Hawkins JL, Koonin LM, Palmer SK, Gibbs CP (1997) Anesthesia-related deaths during obstetric delivery in the United States, 1979–1990 (Clinical Investigation). Anesthesiology 86(2):277–284
18. The Newsletter of the American Society of Regional Anesthesia and Pain Medicine, August 2006. Park Ridge, IL