

Seeking patients' consent in anaesthesiology: consent in clinical practice

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"I wish my life and decisions to depend on myself, not on external forces of whatever kind. I wish to be the instrument of my own, not other men's act of will. I wish to be a subject, not an object; to be moved by reasons, by conscious purposes which are my own, not by causes which affect me, as it were, from outside. I wish to be somebody, not nobody – a doer, deciding, not being decided for, self-directed and not acted upon by external nature or by other men".

Isaiah Berlin, 1969¹

Summary

The article explores the historical, legal and philosophical background and justification of informed consent. Anaesthesiologists have a responsibility to obtain separate informed consent, both to prevent litigation and to satisfy the requirement of rationality and respect for personal autonomy. The three-tiered model – competence, information, and consent – is described. The inherent nature and current practice of anaesthesiology problematizes proper informed consent. This includes timing, time-constraints, managed care, same-day surgery and emergencies. Wider use of pre-op clinics is advocated. There is a move towards written consent. Properly documented consent relieves the burden of proof, yet is neither a legal requirement nor confirmation of a proper interview. Authors generally advocate written consent in obstetric analgesic practice. Pre-printed forms do not replace an interview. The interview should be tapered to the needs and requirements of the particular patient. The reason why information is provided should be explained. Appropriate illustrative material and aids are advised. The uninformed patient cannot give consent. The supply of information empowers the patient to engage in an interactive conversation with the anaesthesiologist, and broadens the base for further discussions and questions. At least a full explanation of the procedure and techniques (particularly of all invasive procedures), information about the chances of success, incidence of complications, risks

involved, available alternatives, the relative risks and complications of alternatives, costs, and the role of the anaesthesiologist is required. Particular reference to the training of students is mandatory. Separate consent is required for all research purposes.

Introduction

The ethical motivation and justification of biomedical informed consent (the term "informed choice" underlines active patient participation in the process)², is respect for and promotion of patient autonomy – the right to make informed decisions about one's self. The "traditional" doctor-patient relation was paternalistic and asymmetrical; the power and authority of the doctor, based on his technical prowess, knowledge, and apparent control over life-and-death issues, trumped the vulnerability and ignorance of the patient. Patients merely assented to treatment, with little discussion. This aura of "secrecy", dating from Hippocratic times, was perpetuated in the first "modern" medical code of ethics – the 1847 AMA Code of Medical Ethics:

*"The obedience of a patient to the prescriptions of his physician should be prompt and implicit. He should never permit his own crude opinions as to their fitness, to influence his attention to them."*³

The recognition of the significance of respect for, and the inherent right of persons to personal autonomy, and an increasingly litigious societal ethos, have led to a revision of this professional relationship. The theory is that if sufficient information is supplied to empower patients to make informed decisions, the relationship becomes more symmetrical and contractual in nature. Contemporary notions on informed consent developed in civil suits in American law courts. These paradigm-changing cases form the basis of the contemporary notion of consent. Our legal system bases many of its own opinions on these decisions. Thus, in 1957, the difference between assent and informed consent was settled in the landmark Salgo case. After translumbar aortography Mr Salgo suffered permanent paralysis, a complication about which he had not been informed: "A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by a patient to a proposed treatment"⁴.

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The “paradigm” of informed consent

The most popular model of informed consent is a three-tier cascade; each step presupposes the previous:

1. Determination of subject competence to give consent: Competence is a pre-requisite to giving informed consent. A competent patient is able to grasp the essentials of what is explained, to think rationally and logically, and to come to an apparent rational decision. Competence can be limited by circumstances intrinsic to the patient (mental competence), and those extrinsic (imposed by some law or rule, relating, for example, to age, incarceration, or institutionalisation).
2. The supply of relevant information: Information forms the basis upon which the competent patient can make a decision. Rationality presupposes the possession and understanding of sufficient information; the uninformed patient cannot make an informed decision. Informed consent has elements of a contractual arrangement. Contracts are invalid if significant information is withheld. A full explanation of techniques, information about the chances of success, incidence of complications, risks involved, available alternatives, and the relative risks and complications of alternatives, costs involved, and the role of each member of the anaesthesiological team in the procedure. Risks include those inherent to the procedure and disease, compounded by host risks relating to underlying disease and co-morbidity, and boundary risks reflecting risks inherent to the particular environment where surgery is performed (e.g., procedures performed in an environment where such procedures are not usually undertaken, or by an inexperienced surgeon).⁵
3. Decision-making: Based on the information supplied, the patient, voluntarily and without coercion, makes a decision to undergo (or defer) treatment. He should be informed of the consequences of that decision and his right to withdraw consent at any stage, and of the right to a second opinion.

Consent in anaesthetic practice

Previously, anaesthesiologists have not deemed it necessary to obtain consent in this formal way. This position is currently not tenable, although, based primarily on the inherent nature of anaesthesiology, the paradigm of informed consent presents several problems:

1. Time and timing of consent: Ideally, the informed consent interview should take place a few days prior to surgery to facilitate an unhurried, un-coerced decision, to allow time to obtain more information if required, and to review decisions taken. This was specifically legislated (for anaesthesiology in all but emergencies) in France in 1994, and the experience has by and large been positive.⁶ This ideal has become virtually impossible in South Africa. Managed care and time-constraints limit doctor-patient contact. Increasingly, patients are admitted on the day of surgery. Anaesthesiologists may be pressurized to run through pre-op checks to start lists. “Real” informed consent is as “time-consuming and impractical” in South Africa as it is in the NHS.⁷ “Active, reciprocal and fluid discussion” is rarely possible; “it takes time to explain anaesthesia to patients, and time for them to reflect on this

information and ask for further questions”. However, if this practice is unacceptable, our unique knowledge implies a duty to correct it. For example, positive engagement with funders and managers can make them aware of our needs. We should also explore alternatives like pre-op clinics, which many anaesthesiologists run for major, complicated and problematic cases. Yet all of our patients are entitled to the same consideration. It stands to reason that patients cannot give acceptable informed consent in the operating theatre. This should be restricted to real emergencies.

2. Technology and complexity: Humankind’s interaction with the world results in constant extension and development of technology and pharmaceuticals. Anaesthesiology is often at the cutting edge, and is inherently complex; it is difficult for patients to grasp the complex and complicated nature of anaesthesiology, and to use related information in rational decision-making.

Given these difficulties, but recognizing the need for informed consent, how can we conceive of a realistic notion in anaesthesiology?

Firstly, we cannot ignore the significance of informed consent. No doctor may touch a person without express consent. Invasive treatment is unlawful without prior consent; “it constitutes the crime of battery and the tort of trespass to the person”.⁷ Patients should at least be fully informed of the scope and extent of procedures (e.g. all lines, tubes and catheters). Significant sequelae, as “potential but rare” consequences should be “discussed when gaining consent”.⁸ The court can form its own opinion on the relevance of particular risk information when it “was so obviously necessary that it would be negligent not to provide it” – irrespective of professional attitudes.⁹ Respect for the patient’s integrity and autonomy implies treating the patient as a subject, not an object. We should not do things “to”, but “with” the co-operation of the patient. Ignoring the necessity for informed consent implies a return to the paternalism of the “traditional” doctor-patient relationship.

Secondly, separate anaesthesiological informed consent must be obtained. As an independent specialty, we are accountable and responsible for our actions and omissions. The surgeon does not have the insight to obtain consent for us (though he can assist in the process); neither can he accept any responsibility on our behalf. Anaesthesia has its own unique ends, risks and consequences, independent from those of surgery.⁷ Booklet 15 of the Medical and Dental Professions Board of the Health Professions Council (<http://hpcsa.co.za>) entitled Seeking Patient’s Consent, states (3.1) that the doctor who provides treatment is responsible for discussing it with the patient. This obligation may be delegated to a competent person, meaning another anaesthesiologist or trainee, but the person administering the anaesthetic remains responsible. Booklet 13, the National Patients’ Rights Charter, states (2.2) that “everyone has the right to participate in decision-making on matters affecting one’s own health”; and (2.8): “Everyone has the right to be given full and accurate information about the nature of one’s illnesses, diagnostic procedures, the proposed treatment and the costs involved.” Ethicists conceive of rights as relationships in

which rights are balanced with corresponding obligations. The anaesthesiologist is obliged to honour these rights. The Health Professions Council judges the ethical nature of our actions and omissions against the ethical guidelines set out in these booklets.

Written consent and pre-printed consent forms

There is a general move favouring written consent. Booklet 15 (10.1.a) holds that written consent is required when “the treatment or procedure is complex or involves significant risks and/or side effects”, which describes anaesthesiology. A written and signed form does not guarantee that informed consent has been given. Legally, “written consent forms are neither necessary nor sufficient evidence that valid consent had been obtained”.⁷ “A signature on a consent form is of very little value in defending allegations of negligent counselling” although it is “useful documentary evidence that consent was indeed given”.¹⁰ An allegation of improper conduct can be better defended with documented evidence of an appropriate discussion of risks and side effects: “a doctor must be able to sustain a defence that he or she supplied the patient with adequate information about the nature and purpose of the procedure”.⁷ In an action brought years later, “a judge may prefer a patient’s evidence to that of a practitioner if a signed consent form cannot be produced.” Most authorities advise that informed consent should be documented in obstetric regional anaesthesia.¹¹ Preferably, a note should also be made about the nature of the complications discussed, and the consent should be signed and countersigned by the patient. The same applies to informed consent when the anaesthesiologist is the primary treating physician (treating chronic pain, for instance).

Concerns that the volume of information might imply spending an inappropriate time on writing notes are unfounded; it is not necessary to document every detail of the interview.

Pre-printed consent forms, particularly without an interview, are inadequate. Worthington warns that “clinicians can slip into the habit of asking patients to sign a piece of paper without any thought being given to either what is on the form or to its primary purpose.”² The ethical validity of consent hinges not on the written word, but on the nature and quality of the interaction between patient and clinician.” A similar comment appeared in the MPS Africa Casebook on patient information leaflets: “For elective or cosmetic procedures these are helpful in supporting the process but can never replace individual counseling”.³ In a study by Clark et al., printed information did not enhance the retention of specific risk-information. Two study groups were provided either with only an oral interview concerning five specific risks two weeks prior to surgery, or to an interview and a pre-printed anaesthetic consent form. Six weeks after surgery, the consent form group retained significantly less information than did the oral-only group.¹²

Standards of disclosure

Two paradigm cases in the USA are significant in this respect. In 1960, the Natanson case set the professional

practice or “reasonable doctor” standard; what needs to be disclosed is what the reasonable doctor would think necessary.⁴ (Ms Natanson developed radiation burns after radiotherapy, and had not been informed of the possibility.) In 1972 the Canterbury case set the “reasonable person (patient)” standard; disclosure should be based on the requirements of the reasonable patient. (Mr Canterbury became quadriplegic after cervical laminectomy.) A more recent development is the “subjective patient standard”; one should tailor information to the needs and requirements of the particular patient. So, what do patients want to know? Garden et al. offered CABG patients either one of three pre-operative information sheets, or all three: “full”, “standard” or “minimal” levels of disclosure.¹³ With only one leaflet, 64-73% of respondents thought the content was “just right”; when offered all three, 63% thought the “minimal” leaflet provided insufficient information. This confirms that ignorant patients cannot give informed consent. In a study by Farnill & Inglis in a suburban general hospital in Sydney, between 82-97% of respondents maintained that they would either “like” to, or see it as a “right” to be informed of the following categories of information (Table I):¹⁴

Table I: Information category	
When allowed to eat and drink	When allowed to get up
Common complications	All complications
Details of pain/pain relief	How long you will be anaesthetised
Where you will recover from anaesthesia	Drip or bladder catheter on waking
Alternative methods of anaesthesia	Details of premedicant drugs
Dangerous complications	Where you will be anaesthetised
Details of needles/drips used	

At the premed interview, Moores & Pace asked patients a standard list of general medical questions, ending with: Do you have any questions or would you like me to discuss any aspects of the anaesthetic?¹⁵ Only one third of respondents replied positively; two-thirds of their questions were anaesthetic-related, reflecting concerns about awareness, recovery, technique of anaesthesia and risk. It is clear that unless we raise particular issues, the patient may not. Merely asking: “Is there anything more you would like to know?” when the patient knows almost nothing, is insufficient. In fact, several authors (and HPCSA Booklet 15) emphasize our responsibility in promoting autonomous decision-making through proactive discussion between patient and doctor.¹⁶ Consequently, there is constant pressure on us to supply more rather than less information.

El-Sayeh & Lavies asked a study group of surgical patients what level of information they would like to receive.¹⁷ They were offered one of three option levels:

1. Full and detailed explanation of the anaesthetic, possible alternatives, with all the risks and benefits of each technique.
2. A simple description of the anaesthetic, with an explanation of main risks and benefits.
3. As little as possible; I expect that my best interests will be followed.

After surgery, they were re-interviewed to ascertain their satisfaction with information received. A surprising number (35%) opted for Level 3; about two thirds required Level 1 or 2 information. Yet, irrespective of the level of information requested, most patients (83-94%) were happy that they had received the required amount of information. Litman et al. found that 74% of parents wanted to know "all possible risks" with respect to anaesthesia for their children, 24% only "likely" risks.¹⁸ These data suggest that we can satisfy patients by trying to understand what they require. This is the route suggested by most authors, and in the HPCSA guidelines.¹⁹

Refusal to be informed

Rational decisions can only be made on the basis of particular knowledge; therefore, autonomy can only be satisfied with sufficient information. David Ost argues that a patient has an obligation to accept appropriate information, or at least a duty to know her fate.²⁰ Waiving the "right" to be informed denies the basis of personal autonomy. Yet, forcing unwanted information upon a patient might equate to psychological battery. When a patient adamantly refuses all information (in my own experience, a very rare occurrence) we should explain why certain information is crucial, and our legal and moral obligation. If the patient remains inflexible, yet seems competent, we should note it on the chart with the nature of the information withheld, and the reason. Providing more information does not increase stress or anxiety, only knowledge of anaesthesia.²¹

How much information should be supplied?

If the aim is informed consent, any information that a patient might need, or reasonably use in order to make a decision, is appropriate. If, on the other hand, the aim is legal defensiveness, then the level of information required is much higher (this is why the "full disclosure model" is generally advocated, though not necessarily practiced, in the USA). A general guideline is that the more serious and likely a risk or complication, the greater the incumbency to inform the patient. The Australian High Court ruled that "The more remote the contingency which a doctor is required to bring to the notice of a patient, the more difficult it may be for the patient to convince a court that the existence of the contingency would have caused the patient to decide against surgery".²² However, council has argued that even if knowledge of a complication that subsequently developed might not have led to a different decision, not knowing in fact caused mental anguish.

Risk disclosure

A very difficult question is how much of the risk involved in a procedure should be revealed. Jenkins & Barker recently published a comprehensive review of the literature on anaesthetic mortality and morbidity.²² The data overwhelms. For instance, the incidence of expected anaesthetic associated mortality is in the vicinity of 1:100000 in ASA1-2 patients and 1:50000 overall; peri-operative cardiac arrest is 0,5-1:10000; total peri-operative death within 30 days 1:200 (1:40 in emergencies; X2>60 years, X5>80 years, X7>90 years); aspiration 1:3000; failure to intubate 1:500; headache

1:5; cerebrovascular accident 1:100; awareness 1:300; anaphylaxis 1:10000; idiopathic deafness 1:10000, transient after spinal anaesthesia, 1:7; pain 1:3; postoperative nausea and vomiting (PONV) 1:4; sore throat 1:2 after intubation, 1:5 after laryngeal mask airway; total dental damage, 1:100.

Does it serve the interests of patients to fully disclose all of these complications? What should we disclose when specifically asked? A case can be made out either way. When specifically asked, we should have some basis to give an accurate answer. A possible solution is to have personal or institutional complication figures, which might be different from Jenkins' & Barker's. We cannot withhold this type of information because of discomfort in handling it.

As an alternative to quoting actual figures, which patients might have difficulty in conceptualising, Jenkins & Barker suggest the use of some form of scale to give the patient a practical sense of risk classification. Calman's verbal scale uses descriptives like very high (risk>1:10: PONV; sore throat), moderate (1:100-999: awareness without pain), very low (1:10 000-99 999: anaphylaxis), and negligible (1:1 000 000-9 999 999: spontaneous epidural haematoma). To these, Jenkins & Barker have added community groupings (e.g., respectively, siblings, street, small town, city). I have found similar contextual explanations useful.

A controversial issue is whether risks not directly related to anaesthetic risk, e.g., relative to the ability of the surgeon and the complication/mortality rate of the institution, should be conveyed to the patient. My opinion is that identifiable, real risks of this nature should be discussed with the patient.

The use of aids in informed consent

The HPCSA guidelines advocate the use of "up-to-date written material, visual and other aids to explain complex aspects of ... treatment where appropriate and/or practicable."²³ Agre et al. found that a pre-colonoscopy video, with or without an interview, significantly increased knowledge scores without affecting anxiety ratings, confirming the use of visual aids in pre-operative information transferral.²⁴ Guin & Donaldson found that making one's own videotapes can be both "fun and clinically helpful" for instruction and informed consent (in their office practice).²⁵ I have found a prepared information sheet helpful; this does not replace the informed consent interview, but broadens the basis for a discussion.

What is done in practice?

Watkins et al. conducted a postal survey amongst tutors of the Royal College of Anaesthetists; 218 (77%) responded.²⁶ Only 4, 5% of respondents used separate anaesthetic consent forms, and 72% thought them unnecessary, although oral consent is documented on the chart (70%). A point of particular criticism is that 70% do not obtain specific consent to use patients as subjects in student training, and 92% do not think this is required. Only 57% have a written departmental policy for antenatal explanation of anaesthetic techniques in labour; in 62%, this information was prepared in conjunction with an anaesthesiologist. In 80%, procedures allow for discussion of techniques with an anaesthesiologist.

Conclusion

A rational, ethically defensible and legally acceptable informed consent practice in anaesthesiology should be based on the following principles:

- Separate anaesthetic informed consent is mandatory;
- This need not be written but the process should be documented in some way;
- The HPCSA guidelines should be adhered to;
- It is generally accepted that written informed consent is mandatory in obstetrics;
- The nemesis of informed consent is the supply of information; when in doubt, it is better to supply more, rather than less information;
- The aim is not to impress or dominate, but to inform. Use understandable and down-to-earth language, tapered to the level of the patient, to discuss:
 - o All invasive procedures & those realistically expected;
 - o All common and serious complications;
 - o All options & alternatives;
- An ignorant patient has nothing to discuss and cannot give rational informed consent;
- Your discussion invariably leads to more discussion;
- Make a sincere attempt to come as close to the ideal given the limitations of time, language and cultural difficulties;
- Create an opportunity for discussion and questions;
- Note that particular consent should be obtained when patients are to be used for teaching students.
- Note also that these requirements are inadequate for informed consent for any form of research.
- Section 53 of the SA Health Professions Act requires service providers to provide details of fees charged when so requested by concerned persons, or when such fees exceed those "usually charged", though the definition of the latter is unclear.

As a trainee, I was taught that anaesthesiology is a science, but its practice an art; to my mind, obtaining adequate informed consent is at the heart of this art.

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"When providing information, you must do your best to find out about patients' individual needs and priorities. For example, patients' beliefs, culture, occupation or other factors may have a bearing on the information they need in order to reach a decision. You should not make assumptions about patients' views, but discuss these matters with them and ask them whether they have any concerns about the treatment or the risks it may involve. You should provide patients with appropriate information, which should include an explanation of any risks to which they may attach particular significance. Ask patients whether they have understood the information and whether they would like more before making a decision."
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