

Review

# Informed consent for anesthesia in ambulatory surgery: A South African perspective

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## Abstract

The nature and practice of anesthesiology problematizes informed consent, particularly in the ambulatory setting. Timing and time-constraints counter an interactive free flow of information; access to understandable, contextual information forms the basis of free choice by empowering the patient to engage in an interactive conversation with the anesthesiologist, and broadens the base for further discussions and questions. Separate informed consent in anesthesiology is philosophically mandated by the requirement of rationality in choice and respect for personal autonomy, and legally to prevent litigation. The paradigmatic cascade model of consent entails determining competence, supplying information and promoting free choice. Particular measures to counteract the difficulties of anesthesiological informed consent in ambulatory surgery include measures to increase anesthesiologist–patient contact time, and wider use of pre-op clinics. Pre-printed forms are useful but do not replace an interview, tapered to the needs and requirements of the particular patient. Appropriate illustrative material and aids are advised.

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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 . . .” Berlin [1]

## 1. Introduction

The 1847 AMA *Code of Medical Ethics* reflects the paternalistic and asymmetrical “traditional” professional relation dating from Hippocratic times: knowledge-based authority trumped the ignorance of the patient, who was expected merely to *assent* to treatment—“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.” [2] Paternalism was overcome by the recognition of the moral significance of respect for personal autonomy [3]. Information empowers patients to make informed choices which promote autonomy by promoting the ability to decide for oneself, and oppose paternalism, thus justifying biomedical informed consent [4]. The skewed professional relation therefore becomes more symmetrical and contractual. Informed consent has become “the hallmark of our health care system” [5], but is problematic in anesthesiology, particularly ambulatory care.

Although the requirements for and practice of informed consent vary, certain basic principles are, or should be, universal. Section 2 consists of a short review of the requirements and difficulties of informed consent in anesthetic practice as a background to Section 3, a short discussion of particular difficulties vis-à-vis ambulatory care, and remedies.

## 2. Consent in anesthetic practice

Formal informed consent is a relatively recent development in anesthesiology, following the development of anesthesiology as a separate and independent specialty. The complexity of anesthesiology, and constant technological and pharmaceutical development, make the contextual understanding and consequent application of information in rational decision-making difficult, particularly in multi-cultured, multi-language developing countries. Furthermore, once an intervention requiring anesthesia is indicated, the need for some form of anesthesia is self-evident; therefore, some anesthesiologists argue that informed consent is either unrealistic or superfluous in anesthesiology. It is tempting to use these difficulties as excuses to limit the informed consent process and deny our patients their due. Nevertheless, informed consent is mandatory. Complex information should be simplified to promote its utilization in decision-making.

### 2.1. The prototype informed consent model

Legal, regulatory, philosophical and medical literature favours a five-point analysis of the components of informed consent: competence, disclosure, understanding, voluntariness and consent [3]. These can be arranged in a useful and practical simplified three-tiered cascade, each subsequent level presupposing the former (modified from Beauchamp and Childress [3], p. 145):

1. *Competence*: A competent patient should be able to grasp the essentials of proposed treatment, to think logically and to come to a reasoned decision. There is some disagreement whether this includes an equal understanding of risks and complications [5]. To promote informed choice and limit paternalism, the requirements for competence should not be unreasonably high. Persons of limited intelligence, and young children, are often competent in the context of the situation, and should be involved in the process. Competence is often assumed, but can be judged on the basis of five possible standards: evidence of choice, understanding of the reasonable outcome of choice, choice based on rational reasons, the ability to understand and actual understanding [5]. Competence may be limited by circumstances intrinsic to the patient (cognitive and mental limitations, although these patients may have sufficient insight to make reasonable choices), or extrinsic (imposed by law, relating to age, incarceration or institutionalisation).
2. *Disclosure*: Only informed, competent patients are able to make rational choices, i.e. utilize particular information in a process of logical reasoning. Rationality therefore presupposes the possession and understanding of sufficient information. Decisions based on the exchange of information constitute contractual arrangements. Contracts are invalid if significant information is withheld; therefore, a full explanation of techniques and outcome, morbidity, alternatives and their risks and complications, costs and the role of each team member is mandatory. Risks include those inherent to the procedure and disease, host risks relating to underlying disease and co-morbidity, and risks related, for example, to the hospital environment and experience of operators (so-called boundary risks) [6]. Interviews should take place at a cognitive level commensurate with that of the patient. Although patients do not necessarily utilize the supplied information in the decision-making process, they nevertheless benefit in other ways [3].
3. *Decision-making*: Based on the information supplied, and a recommendation by the anesthesiologist as to the most suitable treatment and/or technique, the patient can make a voluntary and uncoerced (i.e. not under the control of another person [3]) decision to undergo (*consent to*), or defer treatment, and, in as far as possible, regarding the nature of that treatment. He/she should be informed of the consequences of that decision, his/her right to withdraw consent at any stage and of the right to a second opinion.

The handling of decisions which appear to be irrational or inappropriate would depend on particular circumstances (see also Section 2.5).

### 2.2. Separate informed consent is mandatory

Anesthesiologists should obtain informed consent in a well-structured manner, and not rely on implied consent or consent obtained by the surgeon. Firstly, anesthesiology is an independent specialty, and anesthesiologists are finally accountable and responsible for their actions and omissions. It is invariably invasive, and has unique ends, risks and consequences, of which others have limited insight [7]. All forms of treatment – even touching a patient without consent – are unlawful without prior consent, and may constitute “the crime of battery and the tort of trespass to the person” [7]. Any doctor who provides treatment is responsible for obtaining informed consent. When this obligation is delegated to a competent person (another anesthesiologist or trainee), the person administering the anesthetic retains responsibility for the validity of consent [8].

Secondly, respecting the patient’s autonomy implies treating her as a *subject* in the sense that Berlin uses the term in the introductory quotation: as a person with rights and interests [1]. We should not do things “to,” but “at the request of” or at least “with” the co-operation of the patient. Ignoring informed consent is a return to the morally unacceptable “traditional” paternalism.

Thirdly, the contract between doctor and patient implies a responsibility to inform. Without adequate information this contract is void. Inadequate information is a common basis for court action, although less commonly against anesthesiologists.

### 2.3. Written consent and pre-printed consent forms

Since anesthesiology is invasive, complex and involves significant risks and side effects, some form of written consent is advisable, though not universally mandatory [7,8]. Written consent does not guarantee valid consent [7]. A signed consent form may supply evidence that consent was given, not that counselling was necessarily sufficient, appropriate and not negligent [9]. An allegation of improper conduct can be better *defended* with documented evidence of an *appropriate discussion*—particularly in actions brought years later [7]. Although some documentation is advised (in many countries *required*) in all forms of anesthesia, particular attention has been advised in obstetric regional anesthesia [10], presumably due to the high risk of litigation, or when the anesthesiologist is the primary treating physician. Documentation need not be detailed, but should at least include the nature and extent of the interview, particularly the discussion of risks and complications, since *contemporaneous* notes may be useful in later actions.

Reliance on pre-printed consent forms without a structured interview is inadequate; “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.” The nature and quality of the interaction between patient and clinician determines its ethical validity [4]. Pre-printed forms and information sheets may support the process, but cannot “replace individual counseling” [2]. Individual counselling is more effective in promoting the retention of specific risk information than a combination of counselling and printed forms [11].

### 2.4. Standards of disclosure

Paradigm civil cases determined the evolution of two competing norms of disclosure: the *professional practice (reasonable doctor)* and the *reasonable person* standards [3,12]. A third, the individualized “*subjective patient standard*,” in which the requirements of the particular patient are taken as a guideline, is generally regarded as the preferable moral standard and best suited to contemporary practice and society [3,12]. Information should therefore be tapered to the requirements of the *particular* patient. These can only be determined during the interview. However, since inadequately informed patients cannot judge the adequacy of information supplied, exclusive reliance on this standard is neither legally nor morally acceptable, and there should be a reasonable connection between patient requirements and the professional standard [3,13]. Concerning the sort of information required by patients, 82–97% of respondents in a study by Farnill and Inglis responded that they would either “like” to, or that they saw it as a “right” to be informed of the following categories of information (Table 1) [14].

Inadequately informed patients may be unable to enter into an interactive discussion, to ask follow-up questions and to comprehend the scope of information which is available to them, and to which they are entitled [15]. Limiting the anesthetic interview to asking “Do you have any questions or would you like me to discuss any aspect of the anesthetic?” when the patient knows very little is inappropriate. We have a moral responsibility to promote autonomous decision-making through pro- and interactive discussion [8].

It is possible to satisfy the needs of patients by understanding their requirements. El-Sayeh and Lavies required a study group of surgical patients to choose one of three levels of information: a full and detailed explanation, a simple description or as little as possible (“I expect that my best interests

Table 1  
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 anesthetised
Where you will recover from anesthesia	Drip or bladder catheter on waking
Alternative methods of anesthesia	Details of premedicant drugs
Dangerous complications	Where you will be anesthetised
Details of needles/drips used	

will be followed”). At post-surgery re-interview, most subjects (83–94%) were satisfied with the level of information received, irrespective of the level requested [16].

The need and requirement to be informed is also evident in pediatric decision-making. Parents are the primary legal decision makers for their children, although most countries have legal procedures to override seriously inappropriate decisions. Litman et al. found that 74% of parents wanted to know all possible anesthetic risks, 24% only “likely” risks [17].

These data suggest that we can satisfy patients by understanding their needs. This is the route suggested by most authors [3,18].

### 2.5. Refusal to be informed—“waivers”

Since only informed individuals can make rational, autonomous decisions, patients have an *obligation* to accept appropriate information (at least a *duty* to know their fate) [19]. This is a reasonable demand since biomedical informed consent is mandatory to satisfy moral, legal and contractual demands. Although waiving the “right” to be informed may theoretically undermine personal autonomy, respect for personal autonomy may include respect for a wish *not* to be informed. Forcing information upon a patient might equate to psychological battery. Some studies indicate a majority of patients prefer to know very little about certain procedures and attendant risks, and only a small percentage may actually utilize information in decision-making [3]. There are primarily two ways of handling waivers: withhold the procedure until sufficient understanding is present, or accept that the waiver constitutes valid, if not informed, consent [3]. When, rarely, information is adamantly refused we should explain our obligations, and why information is crucial. If the competent patient remains inflexible, we should note the information withheld, and why. The concern that more information might increase stress or anxiety is unfounded (it only increases *knowledge* of anesthesia), and does not justify withholding information [20]. However, the way in which information is conveyed may influence the final results of treatment and even the healing process [21].

### 2.6. How much information should be supplied?

Any information that a patient might require, or reasonably use in order to make a decision, is appropriate. The level of information required may be much higher if the aim is legal defensiveness (justifying the “full disclosure model” in highly litigious societies). The more serious or likely a risk or complication, the greater is the requirement to inform since the likelihood of such knowledge influencing patient choice is increased [22].

Patients should be fully informed of the scope and extent of procedures (including lines, tubes and catheters). Significant sequelae (“potential but rare” consequences) should be discussed [23]. Courts may disagree with the professional or

Table 2

Predicted incidence of anesthetic associated morbidity (from Jenkins and Barker [22], modified)

Event	Incidence
Peri-operative cardiac arrest	0.5–1:10000
Anaphylaxis	1:10000
Deafness, idiopathic	1:10000
Aspiration	1:3000
Awareness with pain	1:3000
Failure to intubate	1:500
Awareness without pain	1:300
Total dental damage	1:100
Headache	1:5
Sore throat, after LMA	1:5
PONV	1:4
Pain	1:3
Sore throat, after intubation	1:2

subjective standards of disclosure practiced, when in their opinion, particular risk information is “so obviously necessary that it would be negligent not to provide it” [24]. The legal, contractual and moral requirement to *adequately inform* with up-to-date information exists irrespective of whether the anesthesiologist considers the notion of informed consent inapplicable to anesthesia, and prefers to conceptualise of information and consent separately.

How much of the risk involved in a procedure should be divulged? Jenkins and Barker recently published a comprehensive review of the literature on anesthetic mortality and morbidity [22]. The expected incidence of anesthetic associated mortality is in the vicinity of 1:100,000 (in ASA1-11 patients; 1:50,000 overall). An illustrative list of anesthetic-associated morbidity is summarized in Table 2.

Our purpose – to convey a realistic sense of risk – is not served by reciting to our patients confusing statistical lists of alarming complications. Yet, it is impossible to conceptualise risks without some comprehensible reference to expected or probable incidences. We should have some basis to give a reasonably accurate assessment, such as personal or institutional complication figures, provided our database is adequate for statistical purposes.

As an alternative to statistical data that are difficult to conceptualise, Jenkins and Barker suggest the use of a scale that provides a practical sense of risk classification. Calman’s verbal scale describes risk based on probability as *very high, high, moderate, very low, minimal* and *negligible*. These descriptives can be related to commonly encountered community groupings (Table 3), or similar comparisons relating to daily life, to provide alternative understandable measures of risk classification.

Where applicable the patient should be informed of clearly identifiable boundary risks (e.g. related to success and morbidity rates in particular institutions, and of particular operators), provided the intention is not to influence unduly (coerce or manipulate) but to inform. However, for self-evident reasons, this should be done with great circumspection.



Table 3  
Alternative risk classification (data from Jenkins and Barker) [22]

Morbidity	Predicted incidence	Calman scale	Community grouping
PONV, sore throat	>1:10	Very high	Siblings
Death in emergency surgery	1:10–1:99	High	Street
Awareness without pain	1:100–1:9999	Moderate	School
Anaphylaxis	1:10000–1:99999	Very low	Small town
Post-epidural haematoma	1:100000–1:999999	Minimal	Town
Spontaneous epidural haematoma	<1:1000000	Negligible	City

### 2.7. The use of aids in informed consent

Written material, visual and other aids may be useful additional information, and in explaining complex issues [25–27]. It does not replace the informed consent interview, but broadens the basis for discussion. Another useful possibility is web-based information tools.

### 2.8. What is done in practice?

In a postal survey amongst tutors of the Royal College of Anaesthetists, only 4.5% of respondents used separate anesthetic consent forms; 72% thought them unnecessary. Oral consent is usually documented [28]. A particular concern is that the majority (70%) do not obtain consent to use patients in student training; 92% regard this superfluous.

## 3. Consent for anesthesia in ambulatory patients

The foregoing discussion applies equally to ambulatory practice. Two particular difficulties undermine proper informed consent: time and timing of consent.

1. *Timing*: It is suboptimal to have the first pre-anesthetic interview and a discussion of anesthetic morbidity immediately preceding a procedure. Appropriate informed consent is unlikely, and paternalism, coercion and inadequate information are potential risks. The informed consent interview should ideally take place a few days prior to surgery to facilitate a frank discussion, an unhurried, uncoerced decision, time to obtain more information if required, and to reflect on and review decisions taken. Although there may be less need for the latter than, for instance, in surgical informed consent, the need for an early interview was, for example, recognised and specifically legislated for anesthesiology (in all but emergencies) in France in 1994, with a predominantly positive result (and is practised in other countries in formal and less formal ways) [29]. The need for a clinical evaluation in good time to optimise host morbidity supports this practice.

2. *Time*: Managed care and time-management aim to limit doctor–patient contact to limit costs. Procedures are increasingly performed on ambulatory basis, and patients admitted even for major procedures, on the day of surgery [30]. A possible risk is that anesthesiologists may be pressured to expedite pre-op checks and tempted to downplay possible risks for the sake of expediency. With such constraints, “real” informed consent has been described as “difficult” in the NHS; “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 further questions” [7]. From a management perspective, increased doctor–patient exposure equates to increased workload or staff increases. Managers and funders do not always appreciate the importance and time-consuming nature of obtaining informed consent in anesthesia [7], which may tempt anesthesiologists to resign themselves to suboptimal practices perceived to be inevitable, instead of questioning their moral and legal soundness and justifiability. “Morality only really begins where one breaches customary behaviour, or works to change it” [31].

Other difficulties may include denying admission in favour of ambulatory procedures when the former is more appropriate, and limiting choice in anesthetic techniques and drugs. Most patients accept a limitation of free choice when joining a particular insurance or health care scheme, and similar limitations exist in the public sectors of almost all countries. No person is guaranteed access to the type and quantum of services that she might require, or want. However, as advocates of our patients, we should object when such limitations are to the detriment of patients. Our primary responsibility is to our patient, whose interests are our first concern.

Given these difficulties, we have three options:

1. *Regard these difficulties as insurmountable*: Informed consent for anesthesiology, particularly in ambulatory surgery, is bound to be insufficient and subservient to other needs and demands. This attitude is neither acceptable nor required. Firstly, informed consent is not an option but an imperative, and secondly, we have the power to alter the presently accepted paradigm. Furthermore, our unique knowledge and experience imply a *professional and moral duty* to correct this attitude where and when appropriate.
2. *Increase the amount of anesthesiologist–patient contact time*: For example, make funders and managers aware of the moral and legal requirements for informed choice in anesthesiology, including ambulatory surgery, which can only be satisfied by an increase in contact time. Additionally, this sound investment may provide worthwhile returns: improved patient-satisfaction [13,14,16,18] and consequently, less likelihood of litigation. We should explain that informed consent is only realistic if patients are empowered to make rational choices,

which presupposes adequately informed patients, and that informing patients is time consuming. Anesthesiology is unique; patients temporarily lose consciousness, increasing their vulnerability since they cannot fend for themselves; vulnerability defines a moral relation [32]. The moral response to vulnerability is *responsibility*. Explain that our responsibilities include empowering the patient with a full knowledge and understanding of treatment. We are guilty of misconduct if we neglect this, and have broken the implied tenets of our contract even without actual, direct acts of negligence.

3. *Improved time-management*: Promote aids like specific pre-printed information sheets in ambulatory surgery, and make these available as early as possible (e.g. as soon as an operation is scheduled), not to replace but enhance the pre-operative interview. Telephonic pre-admission interviews are useful, with the advantage that nursing staff can initially be employed, though the anesthesiologist remains finally responsible. Worthwhile, too, is the extension of pre-operative clinics to include ambulatory patients who are entitled to the same respect as complicated cases.

#### 4. Take-home message

An ethically defensible and legally sound informed consent practice in anesthesiology should be based on the following principles: Separate anesthetic informed consent is mandatory. Although only some countries require written, patient co-signed consent, the process should nevertheless always be documented in some way or another. The crux of informed consent is the supply of information, and the dilemma is often how much; when in doubt, it is better to supply more, rather than less information, not to impress or dominate, but to inform. Use understandable and down-to-earth language, adjusted to the level of the patient, to discuss all invasive procedures and realistically expected extensions, all common and serious complications, and all options and alternatives.

Since both knowledge and the ability to reason are requirements, ill-informed patients cannot provide informed consent. Informed consent may be time consuming since more knowledge often leads to more questions and further discussion. Make a sincere attempt to come as close to the ideal given the limitations of time, language and cultural difficulties. Note that particular consent should be obtained when patients are to be used in teaching students, and that the requirements set out above are inadequate for informed consent in any form of research. Particular difficulties exist in ambulatory patients and those admitted on the day of surgery, since they, too, are entitled to proper informed consent.

Anesthesiology is a science, but its practice an art; obtaining adequate informed consent within the constraints of the ambulatory setting lies at the heart of this art.

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