The perspectives of eThekwini public service anaesthetic doctors on the informed consent process for anaesthesia

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Abstract

Objectives: This study aimed to ascertain the perspectives of anaesthetists with regard to their current practice of obtaining informed consent. The outcome of this study will eventually assist in creating a standardised system for informed consent which will be pivotal to the safe, ethical, medical and legally sound practice of anaesthesia.

Design: This was an observational descriptive study that assessed the perspectives of anaesthetists in public service using manually and electronically distributed questionnaires that consisted of open- and closed-ended questions.

Setting and subjects: The study canvassed the views of full-time anaesthetic doctors employed by state hospitals in the eThekwini municipality.

Outcome measures: The practice, general impression and overall skills in respect of informed consent obtained by anaesthetists were measured in four main areas: the preanaesthetic interview, optimisation of the process, influence of litigation on the process, and expertise in determining patients' competence for consent in 12 clinical scenarios.

Results: The current system of informal verbal consent was found to be unsatisfactory by 78.3% of the doctors. Most doctors (83.8%) advocated the recording of written consent on a specific anaesthetic consent form. While 93.8% of doctors were aware of the legal implications of not obtaining written consent, 61.8% of them admitted to not documenting important anaesthetic information. A doctor's ability to determine his or her patient's capacity to provide informed consent was determined by using a range of carefully constructed clinical scenarios. This assessment revealed that there were several areas of deficiency in respondents' knowledge.

Conclusion: The current process of obtaining informed consent for anaesthesia has been deemed by doctors in eThekwini to be substandard and legally indefensible. The process should be improved and standardised by creating a specific anaesthetic consent form on which written consent can be documented.

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Introduction

Informed consent is one of the defining elements of contemporary bioethics and has been in existence since 1957.[1] The right of patients to make decisions about their health care has been enshrined in legal and ethical statements throughout the world. The World Medical Association declaration on the rights of patients empowers them to take control of their health and make decisions regarding their care, provided that they are given all the relevant information to do so by the relevant healthcare professional. The South African Medical Association credo contains a similar statement: "I will strive to respect the rights of my patients to full information about their condition in order to make informed decisions regarding acceptance or refusal of proposed treatment".

However, no international consensus applies specifically to the informed consent process in anaesthesia. Obtaining consent for an anaesthetic procedure involves a set of issues and dilemmas that are unique to the anaesthetist. It is difficult to simply employ consent processes that are

used in other areas of health care. Although guidelines exist, for example, those given by the Anaesthetists Association of Great Britain and Ireland,[2] the General Medical Council[3] and the Health Professions Council of South Africa,[4] no set "rules" have to be followed.

The National Health Act of South Africa (Act No 61 of 2003) stipulates that "a health service may not be provided to a user without the user's informed consent". The Act further provides a broad framework for the implementation of the informed consent process.[5] However, the Act is understandably deficient in that it makes no provision for the unique set of circumstances which pertain to informed consent in anaesthesia.

The 2006 practice guidelines of the South African Society of Anaesthesiologists reinforces the need for informed consent to be obtained. They focus on "anaesthetic technique" and an explanation of "the more common and relevant risks of the anaesthetic procedure". A recommendation is also made that a patient information document should be provided. The ultimate goal is for "the patient's fears … to be allayed and reassurance given".[6]

Therefore, the individual anaesthetist is furnished with freedom regarding how, when and where informed consent is obtained. However, he or she remains medically and legally liable for consequences that may arise from the informed consent process.

The current practice by which the state hospitals in the eThekwini municipality obtain consent in anaesthesia is through an informal interaction between the patient and doctor. Usually, the task of conducting the preoperative interview is the responsibility of the junior doctors who have limited knowledge and skills.

This study focused on the process of obtaining informed consent for adult patients undergoing anaesthesia. An attempt was made to ascertain the knowledge of anaesthetists in terms of the elements that constitute valid informed consent and the perspectives of anaesthetists on the medico-legal aspects of the consent process. The attitudes of anaesthetists were also assessed with regard to the current informed consent process and their views obtained on how the current process could be modified.

Method

A survey was conducted among full-time anaesthetic doctors employed by the KwaZulu-Natal Department of Health and working within the eThekwini municipality. Private anaesthetists who were employed by the state and interns rotating through anaesthesia were excluded from the study. Questionnaires were manually and electronically distributed to anaesthetists. An attached letter requested the voluntary completion and timeous return of questionnaires. Doctors were allotted a period of two months in which to return the questionnaires. Completed questionnaires were kept confidential and anonymous.

Questionnaires canvassed the opinions, attitudes and skills of doctors with regard to the current process of obtaining informed consent from adult patients.

Closed-ended questions pertaining to the following were evaluated in the survey:

- Demographic data and rank or position held.
- The preanaesthetic interview, including logistical data, encountered problems, imparted information (to patients), the manner in which consent was obtained and opinions on the current system of obtaining consent.
- Doctors' views on optimising the process of obtaining informed consent.
- The influence of potential litigation on the practice of obtaining informed consent.
- Doctors' expertise in determining a patient's competence to give consent. Twelve clinical scenarios were presented and respondents were asked to determine the patient's ability to give consent in all of them.

All completed and received questionnaires were analysed. The SPSS® package was used to analyse the data. Descriptive and inferential statistical analyses were performed using analysis of variance, post hoc tests and Fisher's exact test. A p-value < 0.01 was deemed to be of statistical significance. The study was approved by the Biomedical Research Ethics Committee at the Nelson R Mandela School of Medicine.

Results

Seventy-two per cent (129/180) of the distributed questionnaires were completed and analysed. Seventy-one per cent of respondents were aged 31-50 years, 26% did not reveal their age, and the rest were equal numbers of doctors aged < 30 and > 50. There was an overall male preponderance (57%).

Table I highlights the surveyed aspects of the preoperative interview for each of the different ranks of respondents. Respondents were allowed to choose more than one alternative per question.

The preanaesthetic interview was conducted by 22.5% of anaesthetists in the operating theatre. Fourteen per cent of doctors performed their assessments in < 5 minutes (87.5% of these doctors were specialists). Most respondents (70.5%) documented the type of proposed anaesthetic. Of those who did not, there were almost equal numbers of registrars (26.2%) and specialists (28.6%). Respondents admitted to not documenting important information such as invasive techniques (60%), postoperative care (55.8%) and the use of blood and blood products (65.8%).

Table I: Summary of responses of the different ranks of anaesthetists pertaining to various aspects of the preoperative interview

Preanaesthetic interview	Number of respondents				
	Medical officer (n = 4)	Registrar (n = 61)	Specialist (n = 42)	Rank not disclosed (n = 22)	Total (n = 129)
Timing					
Day before surgery	4	59	28	16	107 (82.9%)
Morning of surgery	0	3	21	5	29 (22.5%)
Not seen	0	4	2	1	7 (5.4%)
Location					
Ward	4	59	27	15	105 (81.4%)
Clinic	0	3	3	0	6 (4.7%)
Theatre	0	4	20	5	29 (22.5%)
Duration					
0-5 minutes	0	2	14	2	18 (13.9%)
5-10 minutes	2	22	16	9	49 (38%)
10-15 minutes	2	24	9	6	41 (31.8%)
> 15 minutes	0	13	3	4	20 (15.5%)
Documented information					
Type of anaesthetic	4	45	30	12	91 (70.5%)
Risks and complications	3	15	22	10	50 (38.8%)
Invasive techniques	2	23	19	6	50 (38.8%)
Postoperative care	2	21	22	10	55 (42.6%)
Administration of blood and blood products	2	19	11	10	42 (32.6%)
Where documented?					
Anaesthetic evaluation form	4	48	31	17	100 (77.5%)
Surgical consent form	0	3	6	2	11 (8.5%)
Clinical notes	0	7	3	1	11 (8.5%)
Encountered problems					
Time constraints	1	36	22	7	66 (51.2%)
Language	3	55	35	15	108 (83.7%)
Establishing rapport	1	19	12	11	43 (33.3%)
Insufficient clinical information	4	46	34	17	101 (78.3%)
None	0	0	0	1	1 (0.8%)

In determining a doctor's ability to assess a patient's competence to provide informed consent, respondents were presented with a wide range of clinical scenarios. Responses were scored. An appropriate response scored one point and an inappropriate response, zero. These scores were then analysed per scenario according to the different ranks of doctors. The results are shown in Table II. No statistical difference in the number of appropriate responses as per the different ranks of doctors was observed using Fisher's exact test, with the exception of scenario five where registrars performed significantly worse (p-value = 0.01).

Figure 1 reflects the overall competency scores, out of a total of 12 points, that were obtained from the different ranks of doctors. These scores were determined by calculating the total number of obtained appropriate responses from each respondent according to the different clinical scenarios. The average obtained score for all ranked respondents was 8.79 ± 2.40; for medical officers 9.74 ± 1.71; registrars 8.43 ± 2.40 and specialists 9.21 ± 2.4. No significant difference in the overall obtained scores for the different ranks of doctors (p-value = 0.196) was found.

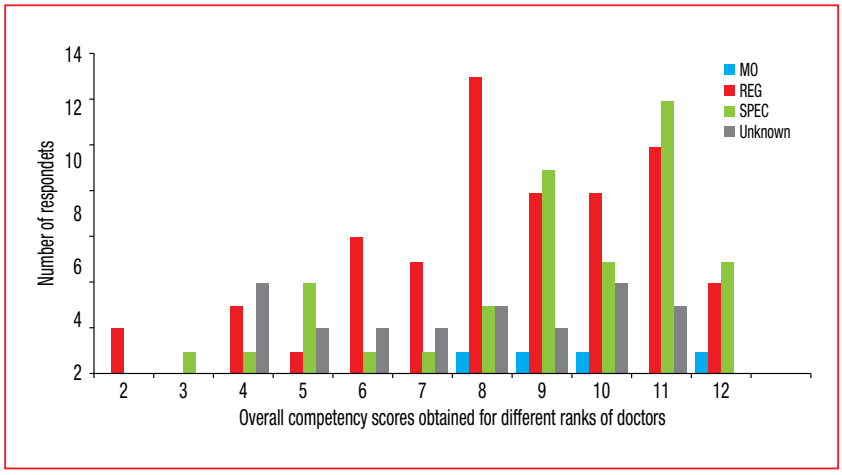
The current process of obtaining verbal consent was deemed to be unsatisfactory by 78.3% of respondents. Most doctors (79.8%) agreed that patients were not supplied with sufficient clinical information and were inadequately prepared for all possible anaesthetic sequelae. Sixty-eight per cent of doctors indicated that the threat of litigation would change the way in which their preanaesthetic practice was conducted. Seventy-nine per cent of doctors agreed that exclusive verbal consent was not legally defensible. Most respondents felt that documentation of the consent process, in the clinical notes (69.8%), on the anaesthetic form (69%) or on the surgical consent form (66.7%), was legally binding.

Most anaesthetists (93.8%) agreed that a specific anaesthetic form for informed consent was legally binding. Generally, doctors (96.9%) agreed that verbal consent alone was inadequate, with 83.8% indicating that a written consent form should replace the current system. Fifty-four per cent thought that both verbal and written consent should replace the current system. Respondents supported the introduction of consent guidelines for doctors (91.5%) and information pamphlets for patients (98.4%).

Table II: Summary of appropriate responses to different scenarios as per rank of doctor

Scenarios used to assess competence to give informed consent		Appropriate responses	Medical officer (n = 4)	Registrar* (n = 60)	Specialist (n = 42)	Rank not known (n = 22)	Total* (n = 128)
1	Jehovah's Witness patient, haemoglobin = 7 g/dl, requiring major surgery, but refusing a blood transfusion	Yes	3	42	36	13	94 (73.4%)
2	60-year-old patient, hypertensive, diabetic with severe asthma, for emergency below-knee amputation who refuses your choice of a regional technique	Yes	4	36	32	12	84 (65.6%)
3	75-year-old patient who is very anxious about his pending surgery	Yes	3	34	33	10	80 (62.5%)
4	18-year-old patient with low intelligence quotient and impaired intelligence	No	4	55	31	17	107 (83.6%)
5	12-year-old patient for elective surgery, who fully understands the benefits and possible complications of the proposed intervention	Yes	3	18	27	7	55(43%)
6	Patient who has had a benzodiazepine pre-medication 20 minutes prior	No	4	52	39	18	113 (88.3%)
7	Patient who has had an opioid 6 hours prior	Yes	3	34	25	11	73 (57%)
8	A patient who is in labour and is experiencing strong contractions, who is required to consent to a procedure (for example, epidural analgesia or delivery via Caesarean section)	Yes	1	26	25	12	64 (50%)
9	Patient with known major depression on chronic treatment, presenting for surgery	Yes	2	34	30	8	74 (57.8%)
10	Patient with Alzheimer's disease	No	4	54	37	16	111 (86.7%)
11	Patient who is HIV-positive, CD4 < 150 cells/ul, on antiretroviral drugs	Yes	4	52	36	15	107 (83.6%)
12	Patient who is HIV-positive, glucose = 2 mmol/l, and restless	No	4	58	40	19	121 (94.5%)

*: One registrar did not answer these questions
CD4: cluster of differentiation 4, HIV: human immunodeficiency virus



MO: medical officer, REG: registrar, SPEC: specialist, Unknown: rank not disclosed

Figure 1: Bar graph that reflects the distribution of competency scores according to the different ranks of doctors

More than half of the respondents (53.5%) supported the notion that consent for surgery did not imply consent for anaesthesia. Twenty-seven respondents thought that they were inadequately skilled to participate in the informed consent process. Of these, 15 were registrars and six were consultants. All the medical officers who were surveyed indicated that they were sufficiently skilled. Fifty-six per cent of the doctors who thought that they were not sufficiently skilled admitted that they sought assistance from a colleague, 77% indicated that they proceeded to the best of their ability, while 44% consulted a reference book to assist them.

Discussion

Obtaining informed consent is a complex process that depends on a relationship of mutual trust and understanding between the doctor and the patient. For informed consent to be valid, the principles of autonomy, beneficence, nonmaleficence and justice must be respected.

Questionnaires were distributed to the three ranks of doctors: medical officers, registrars and specialists. Registrars and specialists were adequately represented

in the sample population of respondents. However, there was a disproportionately low response rate from medical officers (only 3%). It is likely that medical officers comprised a large percentage of the 22 doctors who did not indicate their rank.

The preanaesthetic interview can, if correctly timed and situated, provide the perfect setting for the informed consent process. Available guidelines do not specify what the exact timing, location or duration of the preanaesthetic interview should be.[2-4] However, the recommendation is that the preanaesthetic interview should take place early enough so that important clinical problems can be identified and addressed before surgery. Furthermore, early consultation allows patients time to consider the information that has been imparted to them so that an informed decision can be made. Obtaining consent the day before elective surgery in the ward or on the day of surgery in theatre is not ideal. Patients are often emotionally and psychologically stressed and are not always completely rational. They may irrationally refuse to grant consent for a procedure that they do not completely understand. Most of our respondents indicated that they obtained consent the day before surgery (82.9%). Usually, consent is obtained in the ward (81.4%). Studies have shown that patients find it preferable to be seen by the anaesthetist no later than the day before surgery.[7,8]

The preanaesthetic clinic, cited as the place where informed consent was obtained by 4.7% of respondents, has been found to be a useful environment in which to conduct a preoperative interview.[9-11] The preanaesthetic clinic provides a stress-free, spacious, relaxed and private environment for the patient.[12] Of the state hospitals in eThekwini, only one facility has a preanaesthetic clinic. Lack of human resources, financial constraints and suboptimal infrastructure at the various hospitals makes the widespread operation of such a facility prohibitive.

The optimal duration of the preanaesthetic interview remains uncertain. The majority of our respondents (69.8%) indicated that they take 5-15 minutes to conduct the interview. Our results suggest that more highly qualified anaesthetists take a shorter time to interview their patients than the junior doctors (Table I). A study that was carried out by Marko et al showed that 77.7% of doctors (ranks not indicated) took 10-15 minutes to conduct the interview.[13]

Problems that were encountered by eThekwini doctors during the preanaesthetic interview were similar to those identified by doctors in a study that was conducted in Boston, USA, namely language barriers and time limitations.[14] The inability of doctors to speak indigenous languages is reflective of a medical education system that does not focus on the communicative abilities of its graduates. This is particularly relevant in South Africa, with its 11 official languages. The preoperative interview is usually undertaken by the anaesthetist at the end of the day, once the theatre slates are complete, hence time constraints are always a contentious issue.[15]

It was found that more than half of the respondents (61.8%) do not record important aspects of the anaesthetic process. It is not clear as to whether or not these aspects were discussed and merely not recorded, or not discussed and therefore not recorded. This practice continues despite the fact that most doctors (79.1%) knew that exclusive verbal consent might not always be legally defensible should a dispute arise. Perhaps the low level of litigation against anaesthetists who work in the public sector in South Africa has created a false sense of security. While it does not offer absolute protection, documenting the informed consent provides verification and evidence that the patient was informed of the risks and benefits of the procedure being contemplated, which is clearly strategically advantageous for the anaesthetist in terms of risk management.[16] The Australian Incident Monitoring Study demonstrated that almost one in four patients were asked for their consent by doctors who were different to those who performed the anaesthesia.[17] Therefore, documentation promulgates continuity of care, especially if the preanaesthetic assessment and intraoperative anaesthetic are conducted by different doctors.

Sixty-eight per cent of doctors admitted that the threat of litigation would change the way they conducted their preanaesthetic practice. However, it was unclear as to exactly what aspects of their practice they would change. Follow-up questions in the original survey would have addressed this, but only a single, closed-ended question on litigation was posed. This deficiency in the study could perhaps be a point of focus for future research.

Traditionally, the capacity to provide informed consent is only considered from a patient's perspective. However, it is also imperative to ensure that the anaesthetist is able to objectively assess the capacity of his or her patient to give informed consent. With the exception of a single scenario that assessed the competence of doctors in taking consent, comparative results for the various ranks of doctors showed no statistically significant differences. This is possibly because of the large discrepancy in the number of doctors within each rank, i.e. four medical officers compared to 61 registrars and 42 specialists. However, even though not statistically significant, in the opinion of the authors, the responses to several scenarios are a source of concern.

Interventions, such as open-forum discussions, seminars and workshops, should be offered to address these shortcomings. To the best of our knowledge, no objective yardstick exists in the literature by which a doctor's ability to obtain informed consent can be assessed. Therefore, comparisons cannot be made from the obtained results.

Forty-seven per cent of doctors felt that consent for surgery implied consent for anaesthesia. This is problematic, as it assumes that the surgeon is able to impart essential and relevant aspects of the anaesthesia to the patient. However, a lack of knowledge and experience in anaesthesia renders most surgeons unsuitable in fulfilling this role. Anaesthesia for surgery and the surgical procedure itself are separate treatment modalities, with differing risks and benefits. Although surgery and anaesthesia are functionally linked processes, separate consent processes are mandatory.[18] Several case studies published by Marcucci et al illustrate that a patient's capacity to consent to surgery may not always constitute an ability to consent to anaesthesia. They propose that in lieu of anaesthetic practice involving more abstract concepts, a higher state of cognitive capacity for an understanding of anaesthetic concepts is required.[18] Therefore, the capacity to provide surgical consent does not necessarily equate to the capacity to give anaesthetic consent.

There were several limitations to our study. Doctors may not have been completely truthful about their preoperative interview practices, especially if they feared that their practices would be subject to scrutiny and criticism. The use of closed-ended, rather than open-ended, questions, introduces bias. Most of the questions in the survey were based on ones that were used in previous studies, with modifications to fit the current context. Other questions, for example, the assessment of competence, were developed by the investigators and have not yet been tested in other studies.

Conclusion

Most doctors agreed that the current system of obtaining exclusive verbal consent for anaesthesia is inadequate, that the process of obtaining informed consent in the public sector should be formalised, and that guiding principles for doctors, and information pamphlets for patients, should be introduced.

Doctors recognised the need to legitimise the current process with the introduction of written consent on an anaesthetic-specific consent form. The authors advocate on-going medical education among peers which focuses on ethical dilemmas that surround the process of obtaining informed consent. This should create an environment in which consensus decision-making is promoted when informed consent is being obtained.

The opinions and recommendations of patients in eThekwini on the current process of obtaining informed consent are being determined in a follow-up study. The consultative process with all role players should culminate in the generation of a standardised process and a formalised anaesthetic consent form. Such a process to obtain informed consent, while offering doctors defence against litigation, should also afford patients more ethical, humane and considerate care.

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