



Patients' perception of the adequacy of informed consent: a pilot study of elective general surgical patients in Auckland

Mikayla McKeague and John Windsor

Abstract

Aim This study was designed to determine the adequacy of the informed consent process from the patient's perspective and in the light of published standards.

Methods A pre-operative survey questionnaire was filled in during an interview with 77 patients before an elective general surgery operation. Forty two (58%) of the patients also completed a post-operative postal questionnaire.

Results The results show that there is a need for more specific information (including the nature of the planned operation, the alternatives and complications) to be given by the senior doctor undertaking the procedure and before the patient is admitted to hospital.

This study has highlighted the importance of confirming that the patient considers that they understand and are fully satisfied with the information provided, and that they have been able to ask questions without any sense of pressure.

Conclusions In giving voice to our patients' views on the adequacy of the informed consent process, this study has identified where improvements could be made in this important aspect of patient care.

Informed consent has been defined as "the process whereby someone who has the capacity/competence to consent, having been given sufficient information, arrives at a reasoned and unpressured decision as to whether or not to agree to a proposed therapy or procedure".¹ There have been several published statements in New Zealand on information disclosure and consent.¹⁻³ These statements embody the four imperatives of the informed consent process, namely: 1) the nature of, risks associated with, and alternatives to treatment must be disclosed; 2) the consent giver considers that they understand this information; 3) consent must be given freely by the consent giver; and 4) the consent giver must be competent to give consent.

There have been no New Zealand studies to determine whether informed consent is obtained in a way that meets these imperatives. Further, there have been no studies to determine whether the process of obtaining informed consent meets patient expectation. The aim of this study was to evaluate the adequacy of informed consent in a cohort of elective general surgical patients.

Methods

Permission for this study was obtained from each of the twelve surgeons from the four surgical teams within the Department of General Surgery at Auckland Hospital. Ethical approval was obtained from the North Health Ethics Committee (No. 1004).

Consecutive patients listed for elective general surgery in Auckland Hospital during a six-week period were approached to participate in this study. Verbal consent was obtained after the patient had been given an information sheet and any questions answered. The patients were interviewed before surgery

using a structured survey questionnaire and a similar questionnaire was posted to each patient after discharge from hospital.

Pre-operative survey Patients were interviewed after they were fully admitted to the ward, had been consented for surgery and before they were given any pre-operative medication. The interviews were conducted at the bedside by one interviewer. The interview questions were structured and designed to determine the perceived adequacy of informed consent in three areas: 1) disclosure of information – was there sufficient information given about the proposed operation, its risks and any alternatives to surgery; 2) understanding – did the patient feel they understood the information given; and 3) freedom of choice – did the patient feel free to give or refuse consent. Twenty questions required either a yes or no answer or a short answer, the latter of which were transcribed. Six further questions required the use of a 10-point linear analogue scale to record the answer. It was considered that a cut-off value of 8 or less was significant.

Post-operative questionnaire All patients were sent a similarly structured questionnaire within a week of their discharge, accompanied by a stamped self-addressed envelope. This allowed certain questions to be raised that might have created difficulty if asked by a third party immediately prior to the operation, such as “Did you realize that you could have refused treatment?” The post-operative questionnaire also allowed some questions to be asked that couldn’t have been answered before the operation, such as ‘Having been through the operation, is there further information that you would have liked?’

Results

Of the 84 patients approached, 79 agreed to participate in this study. Five patients were not interviewed because: they refused to participate in the study (n = 1); they were unable to be interviewed because an interpreter could not be found before surgery (n = 2); or the consent form was only signed once the patient arrived in the operating theatre complex and there was no time for the interview (n = 2). In addition, two patients were excluded from the study because the operation was cancelled after the interview took place. This meant that data from 77 patients (female 51, male 26; median age 52 years, range 19–89 years; European 49, Pacific Island 10, Maori 1, other 17) were available for analysis. There were 42 (58%) patients who responded to the post-operative questionnaire at an average of 10 days (range 1–30) following surgery. The categories of general surgical operations for which consent was obtained are listed in Table 1.

Table 1. The categories of general surgical operations for which informed consent was obtained

Category	Number of patients
Head and neck	14
Breast	12
Upper gastrointestinal	22
Colorectal	25
Other	4

There were 23 (30%) patients who were admitted directly to hospital with an acute problem, did not attend an outpatients clinic, and had their operation on an elective list. Less than half (23/54, 43%) of the remaining patients gave their informed consent prior to admission to hospital, in the outpatients or pre-admission clinic.

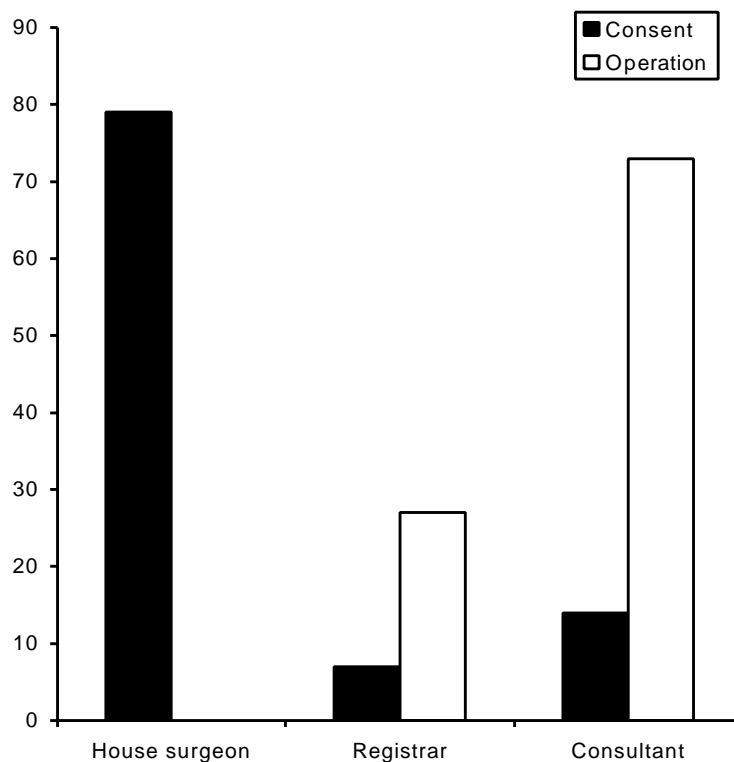
The median interval between the time that written informed consent was obtained and the time of the operation was 6 days with a wide range (1.5 hours to 63 days). Forty

eight (62%) patients gave written consent within 24 hours of surgery. Sixteen (21%) patients gave consent more than one week before the time of surgery, of whom six patients gave consent at more than one month.

The disclosure of information Almost half of the patients (38/77, 49%) received information about their operation in verbal form only, while 37 (48%) patients were given verbal and written information. A further two (3%) patients were shown a video in addition to the verbal and written information.

Information was obtained from multiple sources. The consent form requires the naming of the person who has taken responsibility to ensure that informed consent is obtained, and this was the same person who signed the consent form in almost every case. Overall, the house officer obtained written consent from 79% (61/77) of the patients, the registrar 6% (5/77), and the consultant 14% (11/77). A house surgeon obtained consent from all patients in one team compared with 41% of the patients in another. Figure 1 shows the number of patients consented and the number of operations performed by the house officers, registrars and consultants.

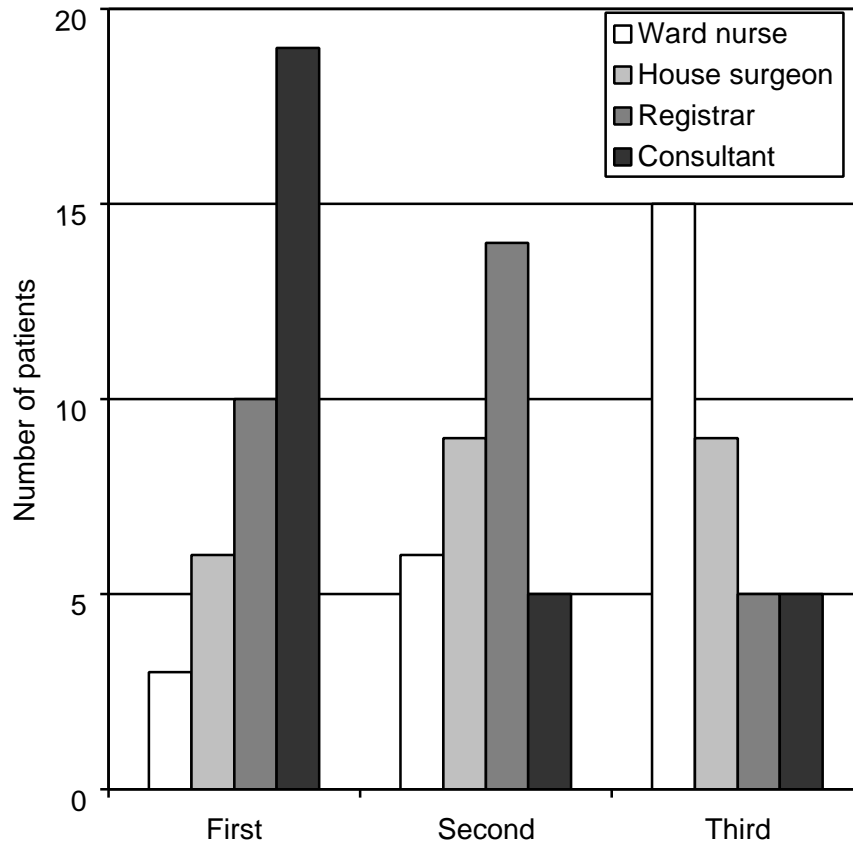
Figure 1. Number of patients consented and operations performed by house surgeons, registrars and consultants



It was of interest that only 34 (44%) patients could name the person who was going to perform their operation and 33 (43%) knew their seniority. The usefulness of the information, as perceived by the patient, was related to the seniority of the person

giving the information (Figure 2). House surgeons were perceived to provide less useful information than the registrars or consultants.

Figure 2. The usefulness of information from four sources, ranked by the patients



Thirty nine (51%) patients were less than “totally satisfied” with the amount of information given before the operation. Only 36 (47%) patients considered that they had received enough information about the risks and complications of the proposed operation. Eighteen (23%) patients did not recall being “told about the risks or dangers of the operation”. Thirty seven (48%) patients could not list a single risk of the operation, although 68 (88%) could identify the consequences of not having the operation. Sixty one (79%) patients stated that alternative approaches to treatment had not been discussed.

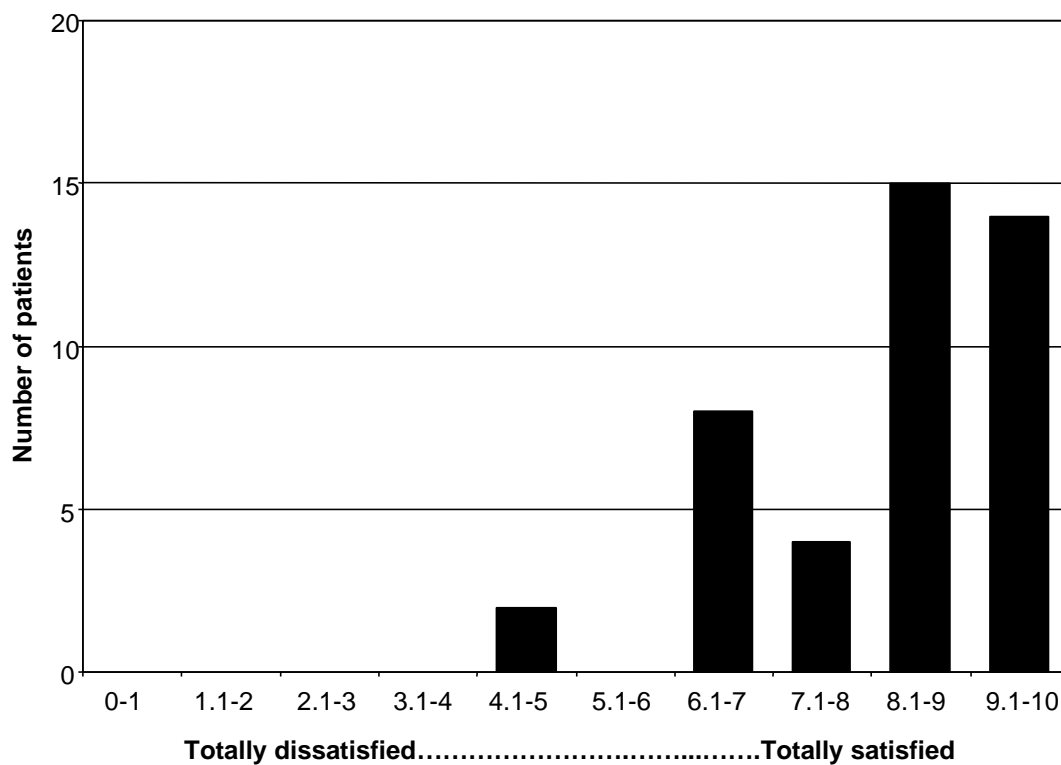
The post-operative survey found that 45% (19/42) of patients were less than totally satisfied with the information that they had been given about the operation, 50% (21/42) with the amount of time spent discussing the operation, and 48% (20/42) with the amount of information received about the operation. The information that patients would have liked before their operation is summarised in Table 2.

Table 2. Specific information patients would have liked to receive before their operation

Information	Number of patients
Complications and risks of operation	13
Recovery time after operation	9
How they would feel after the operation	8
Alternative treatments to operation	8
Likelihood of success of operation	7
Risks of the anaesthetic	6
Nature of the disease	5

The results from the post-operative rating of overall satisfaction with the informed consent process are shown in Figure 3. It can be seen that 69% (29/42) patients were less than totally satisfied.

Figure 3. Overall satisfaction with the informed consent process at the time of the post-operative survey



Understanding the information The language that was used to obtain informed consent was readily understood by all but one of the patients, although the preferred language was English in 63 (81%) patients. Of the remaining 14 patients, 5 were not offered a professional interpreter and 9 had someone available to interpret for them (5 were accompanied by a family member, 3 had a professional interpreter and on 1 occasion a medical student was able to interpret).

Twenty six (34%) patients said they did not understand what the operation itself consisted of. Over one third of the patients (40%) could not name a single complication of the proposed operation. The proportion of patients who considered that they “fully understood” the information provided was 45% (35/77) before the operation, and 43% (18/42) after the operation. In the post-operative survey, 31% (13/42) of patients stated that they would have liked more information about the operation after they had been admitted to hospital.

Giving consent freely The majority of patients felt free to ask questions about the proposed treatment (61/77, 79%) and had enough time to think about having the operation and to discuss it with friends and family (72/77, 94%). The post-operative survey found that 86% (36/42) of patients had enough time to read the consent form before signing it. Some degree of pressure to sign the consent form was experienced by 38 % (16/42) of patients. One third of the patients (14/42, 33%) did not realise that they could change their mind after they had signed the consent form.

The patients before and after surgery rated their overall satisfaction with the process of gaining informed consent. Less than total satisfaction was scored by 38/77 (49%) patients before surgery and 14/42 (33%) patients after surgery.

Discussion

This study has examined patient satisfaction with the way that informed consent is obtained from elective general surgical patients at Auckland Hospital. Three of the four key components of the informed consent process¹⁻³ have been examined and there is room for improvement in each of them. These are: 1) the actual disclosure of information about the nature of, risks associated with, and alternatives to treatment; 2) whether the consent giver feels they understood the information; and 3) whether consent was given freely. The fourth component regarding the competency of the consent giver was not evaluated in this study. In 1994, the Health and Disability Act established the patient’s legal right to informed consent by stating that “no health care procedure shall be carried out without informed consent”.⁴ Subsequently, a Code of Consumer Rights developed by the Health and Disability Commissioner was given the status of law under the authority of the Act.⁴ Of particular relevance to this study are Right 5 (the right to effective communication), Right 6 (the right to be fully informed), and Right 7 (the right to make an informed choice and give informed consent).

In law, there are three different recognised standards for determining the adequacy of information disclosure. The first is the ‘professional standard’ (also known as the Bolam’s test), which is determined by the practice of the majority of the profession. The second is the ‘reasonable person’ standard (also known as the ‘objective standard’), which is determined by what a reasonable or prudent person would require. The third is the ‘subjective standard’, which is determined by what an individual patient seeks.

In United Kingdom case law, the professional standard is applied most frequently. In North America and Australia, there appears to be a balance between the objective and subjective standards. In New Zealand, the law is less clear.⁵ The New Zealand Medical Council considers that the focus of the standard of disclosure should be on

what a reasonable patient would expect rather than on what a reasonable doctor considers appropriate.³ The guideline states “that information must be conveyed to the patient in such detail and in such a manner, using appropriate language, as to ensure that an informed decision can be made by that particular patient. The necessary standard for the requirement (that is the extent, specificity and mode of offering information) should be what reflects the existing knowledge of the actual patient and practitioner. More generally, it should also reflect what a prudent patient in similar circumstances might expect.” The Health and Disability Act (1994) states that “the information needed must be determined both objectively (the information needed by a reasonable consumer) and subjectively (the information needed in that consumer’s circumstance).” The present study has evaluated both the objective and subjective standards. It has determined whether individual patients consider that informed consent has been obtained in a manner that meets their standards and it also provides some information about what the profession is currently doing in regards to informed consent.

One of the limitations of this study is that no distinction was made between the person(s) who provided the information during the informed consent process and the person who was the signatory to it. It was clear from this study that the majority of signatories were also the main source of information, and it shown that this is usually the least experienced member of the medical staff, the house officer. The patient considers that the house surgeon provides the least useful information regarding the nature, risks, benefits, and alternatives to treatment. This is in accord with a Scottish study, which showed that the junior doctors gave patients most of the information they had acquired during their stay in hospital.⁶ The company policy for the Auckland District Health Board states that the primary responsibility for ensuring that information is imparted lies with the person who is responsible for the procedure.¹ The policy also states that when responsibility for obtaining informed consent is delegated, the patient should be told the reason why the person carrying out the procedure could not personally obtain consent.¹ It was our observation that this was rarely done. Furthermore, the majority of patients did not know the name (56%) or the seniority (57%) of the person who was to perform the operation.

In New Zealand, the failure to provide adequate information or to ensure the patient’s understanding of the information are grounds for ‘medical misadventure’ as a result of Accident Compensation Corporation legislation. Legal action would likely involve more than just the health professional who failed to adequately disclose information, but would also include the person to whom the health professional was responsible or by whom they were supervised.

It was Cartwright’s view that the onus is on the health provider “to ensure that information, particularly regarding alternatives and diagnosis, is given to the client in an appropriate situation and with sufficient time and in a manner which the client can understand”.⁵ It was asserted that any difficulty in achieving this was “more likely to be due to the health provider’s (doctor’s) inability to communicate, than genuine problems with the client’s ability to understand”.⁵ The possibility of alternative treatments was not discussed with over three quarters of the patients in this study and about one quarter of the patients did not consider that they were informed of the specific risks associated with the operation.

It has been previously demonstrated that a higher patient satisfaction rating was obtained when information was given in written form⁷ and prior to admission to hospital.⁶ In this study, written information was given to fewer than half of the patients. A recent study has shown that patients prefer to receive information verbally, rather than in a written or video format.⁸ It has been shown that additional written or verbal information, to reinforce what has already been provided, does not necessarily improve a patient's understanding of the risks and complications of a procedure.⁹ The same study demonstrated that the complete disclosure of risks and complications associated with a procedure did not appear to have any benefit over a more simple explanation. It was therefore considered that complete disclosure was not a moral or legal necessity.⁹ In this and another study the provision of more information did not appear to increase patient anxiety.^{9,10}

This study has demonstrated a significant knowledge deficit on the part of some patients. Half of the patients were not totally satisfied with the level of information provided and one third of the patients did not know of what the operation consisted or of a single complication relating to it. About one third of the patients expressed ongoing concerns about details of the operation, even after informed consent had been obtained. Ensuring that patients have sufficient time to express all of their concerns and ask all their questions will go some way towards addressing this issue.

It appears that the majority of patients in this study gave informed consent in less than ideal circumstances, as they had already been through the admission process and were within 24 hours of surgery. The patients were usually changed out of their own clothing, in bed and in a room with other patients and staff. In these circumstances, it is difficult to conceive how the patients could feel free to refuse surgical treatment, especially if they had been on a waiting list for a long time. Fewer than half of the patients who could have given informed consent in an outpatient setting did so. Patients need to feel completely free to give informed refusal or consent and should not feel dependent, vulnerable or uncomfortable about asking questions or suggesting alternative points of view. One third of the patients in this study did not realise that they could change their mind after they had signed the consent form.

The process of informed consent is complex and continues to evolve. The codification of patient rights and a better understanding of health provider obligations have been important steps forward. These now need to be matched by the development of patient obligations and health provider rights.⁵ This would help to bring a balance to this process, moving away from an overemphasis on patient autonomy¹¹ and towards a partnership between patient and health provider. It is helpful to consider informed consent as a process of shared decision making¹² and to determine the readiness and willingness of a patient to participate in that process. There are still many patients who willingly adopt a passive approach to informed consent, while others seek active participation in all phases of the process.

In conclusion, this study examines the patient's perception of the adequacy of the informed consent process. It has highlighted a number of areas in which improvements could be made. There is the need for more specific information to be given by more senior doctors before admission to hospital. It is important to confirm that the patient understands and is fully satisfied with the information provided and that there has been ample opportunity to ask questions without any sense of pressure.

Author information: Mikayla McKeague, Medical Student; John A Windsor, Associate Professor in Surgery, Faculty of Medicine and Health Science, University of Auckland

Acknowledgements: This research was supported by the Maurice & Phyllis Paykel Trust who funded the summer studentship for Mikayla McKeague.

Correspondence: John A Windsor, Faculty of Medicine and Health Science, University of Auckland, Private Bag, Auckland. Fax: (09) 377 9656; email: j.windsor@auckland.ac.nz

References:

1. Auckland Healthcare Ltd. Quality of service: informed consent. Auckland: Auckland Healthcare Ltd, 1997. Report No.: 0300/530/DO56.
2. New Zealand Medical Association. Code of Ethics. Wellington: NZMA, 1989.
3. New Zealand Medical Council. A statement for the medical profession on information and consent. Wellington: New Zealand Medical Council, 1990.
4. Commissioner for the Health and Disability Commission. Code of Rights for Consumers of Health and Disability Services. Wellington: Health and Disability Commission, 1995.
5. Townshend PL, Sellman JD, Haines R. The Cartwright Report ten years on: the obligations and rights of health consumers and providers. *NZ Med J* 1998;111:390-3.
6. Lavelle-Jones C, Byrne DJ, Rice P, Cuschieri A. Factors affecting quality of informed consent. *BMJ* 1993;306:885-90.
7. Edwards MH. Satisfying patient's needs for surgical information. *Br J Surg* 1990;77:463-5.
8. Newton-Howes PA, Bedford ND, Dobbs BR, Frizelle FA. Informed consent: what do patients want to know? *NZ Med J* 1998;111:340-2.
9. Stanley BM, Walters DJ, Maddern GJ. Informed consent; how much information is enough? *Aust N Z J Surg* 1998;68:788-91.
10. Kerrigan DD, Thevasagayam RS, Woods TO, et al. Who's afraid of informed consent? *BMJ* 1993;306:298-300.
11. Seedhouse D. Ethics: the Heart of Health Care. Great Britain: John Wiley & Sons; 1988.
12. Meisel A, Kuczewski M. Legal and ethical myths about informed consent. *Arch Intern Med* 1996;156:2521-6.