

Informed consent: a patients' perspective

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Abstract

The medico-legal issues surrounding informed consent are highly topical and contentious. Current attitudes to consent emphasize the high level of 'good medical practice' expected by a 'reasonable patient/parent'. The authors' objectives were to assess the levels of knowledge and information expected by patients and parents, prior to signing consent forms for a surgical procedure. Each patient or parent was asked a series of questions prior to signing a consent form. Answers were recorded on a standard questionnaire. More than 80 per cent of respondents were happy with the information provided in out-patients, however, over half of these could not list even one complication of their operation. Two-thirds of those surveyed sought information elsewhere, while over half expected to be informed of all known complications, even if the rate of complications was less than one per cent. In conclusion, the information provided by surgeons might not meet the expectations of today's informed patients.

Key words: Informed Consent; Legislation and Jurisprudence

Introduction

The cornerstone of informed consent is that the proposed procedure and its risks, benefits, and alternative treatments, be explained fully to the patient so that they may decide to proceed with treatment. It also requires that the consent be of the patient's own free will, without coercion.¹

The amount of detail that is to be included in the informed consent process is inexact.² Some have adopted the 'prudent patient standard', in which the surgeons must disclose all risks that a reasonably prudent patient would consider material to the informed consent process. Others support the view that it is necessary to inform the patient of risks that a reasonably prudent 'surgeon' would disclose to his or her patient.³ Defining which risks are significant is arguably the most crucial aspect of informed consent law.⁴

The purposes of the present study were to assess the level of information patients possess and, more significantly, expect prior to the consent process, and whether this correlates with current practice.

Materials and methods

A prospective study of all patients who were undergoing elective surgery at the Royal Victoria Eye and Ear Hospital, Dublin, from July to November 2003, was undertaken. The criterion for

inclusion in the study was any elective procedure requiring general anaesthesia. A list of all procedures carried out is shown in Table I. The mean waiting time from out-patient booking to date of operation was recorded. In the out-patients clinic, the proposed operation and its potential complications were discussed in detail, and a recording of this discussion was made in the case notes.

Prior to surgery, each patient or parent was asked a series of questions by a specialist registrar, different from the one initially assessing the patient in the out-patient clinic. Answers were recorded on a standard questionnaire. The scope of the questionnaire included information provided in out-patients, sources of additional information, and what complication rate patients or parents expected to be informed about (Appendix 1). A record was kept of which parent was signing their child's consent form. After this discussion, patients and parents were taken through the consenting process and standard consent forms were signed.

Results

A total of 100 questionnaires were collected. Fifty-three per cent of these were from adults and the remaining 47 per cent were from parents signing their child's consent form. A child's mother signed their consent form in 35 cases and their father in just 12 cases. Fifty-six per cent of patients were male and

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TABLE I

LIST OF PROCEDURES PERFORMED

Procedure	Number	Total
Adenotonsillectomy/tonsillectomy	37	28.5%
Grommet insertion	25	21.5%
EUA ears and microsuction	18	14%
Functional endoscopic sinus surgery	8	6%
Septoplasty	7	5.4%
EUA ears and post nasal space biopsy	7	5.4%
Panendoscopy and biopsy	4	3%
Thyroid lobectomy	3	2%
Mastoid exploration	3	2%
Microlaryngoscopy and vocal fold biopsy	3	2%
Septorhinoplasty	3	2%
Tracheostomy	2	1.5%
Tympanoplasty	2	1.5%
Neck dissection	2	1.5%
EUA nose	1	0.8%
Submandibular gland excision	1	0.8%

44 per cent female. The mean waiting time between out-patient booking to date of surgery was 6.2 weeks for children and 7.8 weeks for adults.

The majority of patients questioned (90 per cent) were satisfied with the explanation given to them in out-patients prior to surgery and considered themselves fully informed. Complications listed prior to consenting, i.e. complications recalled by the patient or parent, that had been discussed in out-patients, are shown in Table II. However, over half of patients questioned could not list even one complication of their procedure.

Two-thirds of those questioned sought information elsewhere prior to consenting. Sources ranged from family and friends, information leaflets, to family practitioners and the Internet. More than 75 per cent of those questioned claimed to understand the term 'Informed Consent' while almost 98 per cent claimed to understand the function of a consent form.

Significantly, 73 per cent of patients questioned expected to be informed of all known complications, even if the incidence was less than one per cent.

Discussion

Patients receive information about their treatment from the time of initial consultation to just before signing their consent form. Even after a relatively short time patients can have poor recall of information they have been given, and in elective surgery there can be a considerable time gap between listing and admission.⁵ Perhaps this explains why 90 per cent of our subjects claimed to be happy with the information they received in out-patients, while over half of these could not list even one complication prior to signing their consent form. Given that patients' memories fade with time, and that there is often a limited record of the consent interview, an information sheet documents what was discussed as well as acting as an 'aide-mémoire'.⁶ Pre-operative information

TABLE II

COMPLICATIONS LISTED PRIOR TO CONSENTING

Complication	Adult	Parent	Total
No complication listed	31	25	56%
Bleeding	17	12	29%
Infection	4	4	8%
Anaesthetic complication	3	1	4%
Damage to teeth and gums	2	1	3%
Swelling	2	0	2%
Pain	2	2	4%
CSF leak	3	(0)	3%
Nerve damage	3	0	3%
Anaphylaxis	1	0	1%
Tracheostomy	1	(0)	1%

(number) = Not applicable to operations carried out on children.

sheets will improve patients' understanding of their condition and treatment as well as compliance.⁷ In this regard, obviously it is important to ensure easy readability of both consent forms and information sheets because an underpinning element of informed consent is that the patient understands what they are told in order for consent to be valid.⁸

- **In this paper 100 patients undergoing surgery were surveyed prospectively to ascertain their understanding of the informed consent process**
- **More than 80 per cent of all respondents were happy with information provided in out-patients and two-thirds had asked relatives, friends or had perused the Internet about their procedure. In spite of this most were unable to recall even one potential complication of the proposed operation**
- **Over half of those surveyed expected to be told of all known complications and the authors conclude that the information provided by surgeons is not likely to meet these expectations and that patients' expectations may not be reasonable**

Interestingly, two-thirds of patients in this study sought information elsewhere prior to signing their consent form. To the authors' knowledge, this is the first time such an observation has been noted. This may reflect an increased awareness and interest in the patients' own treatment and a desire to become more involved in the decision-making process. Houghton *et al.* emphasized this point while also showing that patients' expectations had increased in recent times.⁹

Of importance, 73 per cent of those questioned in this study expected to be informed of all known complications, even if the incidence was less than one per cent. Dawes *et al.* show an increase in complication disclosure among British otolaryngologists, reflecting the increase in both doctor and patient awareness.⁹ Perhaps the reasonable practitioner is giving more

Appendix 1
SURVEY ON INFORMED CONSENT

1. Date: _____
- 2: Patient Details/Hospital Label: _____
- 3: Patient _____ or Parent _____
Relationship to Patient _____
4. Operation/Procedure _____
5. Date Listed for surgery in out-patients _____ Waiting time _____
6. Were you satisfied with the information regarding your surgical procedure/your child's surgical procedure, provided by your doctor in out-patients?
- | | | |
|-----|----|---------------|
| Yes | No | Comment _____ |
|-----|----|---------------|
7. Have you looked for further information regarding your procedure?
- | | | |
|-----|----|--------------|
| Yes | No | Source _____ |
|-----|----|--------------|
8. Do you understand what surgical consent form is?
- | | | |
|-----|----|---------------|
| Yes | No | Details _____ |
|-----|----|---------------|
9. Do you understand the term 'Informed Consent'?
- | | | |
|-----|----|---------------|
| Yes | No | Details _____ |
|-----|----|---------------|
10. Can you list any of the possible complications of your/ your child's procedure?
- | | | |
|-----|----|------------|
| Yes | No | List _____ |
|-----|----|------------|
11. Where did you learn about these complications: _____ Details: _____
12. What frequency of occurrence of a complication would you expect to be informed about?
- <1%
 - 1-5%
 - 5%
 - 10%
 - 20%
 - 50%
 - All known complications

THANK YOU FOR TAKING THE TIME TO FILL OUT THIS QUESTIONNAIRE.

information as the patient's desire to be informed becomes more clearly voiced, or because of increased concern of being sued.

Conclusion

Information provided by surgeons may not meet the expectations of today's informed patient. To avoid the ominous rise in confrontation between the medical profession and the public, these expectations must be taken into consideration, even if they are seen to be unreasonable. Pre-operative information sheets, informing patients about potential complications, may help.

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