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Effectiveness of Consenting in Otorhinolaryngology

Research Article

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Abstract: Informed consent in today's medical practice has become a cornerstone and a routine ethical component playing a major role in forming a therapeutic alliance with the patient. The present study sought to analyse the effectiveness of the consent forms and the consenting process in Otorhinolaryngology. This three month questionnaire-based study covered varying operations which ranged from tonsillectomies, grommet insertions to pharyngeal pouch stapling. Twenty-nine percent of consent forms were signed on the day of the operation. Of the patients who received leaflets (51%) during the process of informed consent, a majority (88%) found it useful. The respondents were satisfied with the explanation of the procedure, benefits and complications (70 – 74%). Majority kept their consent forms at home (60%) and did not bother engaging in further search with regards to the information in the consent form (81%). Majority of the patients agreed that they had enough time to make an informed consent. Patients were satisfied with the consent process but more can be done to improve the consenting process.

Keywords: *Ear • Nose and Throat (ENT) • Informed consent • Consenting • Surgery*

1. Introduction

Modern medical practice has the informed consent, not only as a cornerstone and routine ethical component [1] or to play a major role in forming a therapeutic alliance with the patient [2], but most importantly, as a legal requirement standard for all surgical procedures [3]. In the USA, Hopper and colleagues reported that informed consent forms are universally used by hospitals before surgery or invasive procedures [4].

It is worthy to note that there are vital guidelines prescribed by General Medical Council (GMC) of the United Kingdom (UK) concerning informed consent for medical practitioners. It reads: 'the patient must be given sufficient information, in a way that they can understand, in order to enable them to exercise their right to make informed decisions about their care'. It may be that the doctor has legal and ethical responsibility to the patient to provide sufficient information which would enhance patient-doctor relationship [5]. The use of the informed consent in varied areas of medical practice and research has been the practice [6-11].

In April 2002, a new consent form model was introduced by the Department of Health (UK) for use throughout the NHS following the Bristol Royal Infirmary Inquiry and has, since October 2002, been implemented throughout England [12].

Noteworthy is that the benefits / successes of operation, information source from doctors, post-operative recovery and the ability to list potential complications catered for by the new consent form has been reported although the 100% ideal standard was not attained [13]. Wiseman *et al.*, in an attempt to unravel patients' attitude to informed consent, pointed out that, the experience and identity of the surgeon should be made known to the patient to improve their attitude towards making informed decision on operative procedures [10]. Good-

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year and colleagues, in a nine month study, investigated the proportion of complications recorded during otolaryngology procedures in a modern Ear, Nose and Throat (ENT) department. Consent forms for these operations were examined and recorded prior to the surgery. It was reported that considerable proportion of either serious or frequent complications was not documented on the national consent forms prior to otolaryngological procedures and may likely not have been described. As a result, these workers opined that this may reflect a lack of openness during the consent process [14].

Literature is not yet clear about the degree of effectiveness of the present consent forms and therefore, further investigation in this regard necessitated the present study. It was the objective of the present study to determine the effectiveness of the present consent forms in ENT surgery.

2. Patients and methods

2.1 Sampling and Population

A questionnaire-based study was carried out over a three month period at a district general hospital which has a typical ENT unit. The general hospital is located within southern England with a catchment population of over 100,000 and serves the wider community within her vicinity. A pilot survey was done to ensure the reliability of results. This enabled an estimate of the response rate expected for the main study to be determined. It established the questionnaire used as adequate and understandable. Results obtained from the pilot survey determined the sample size of main study.

2.2 Questionnaire and Data Collection

The questionnaire was constructed to determine the overall effectiveness of the whole informed consent process. Validation of questionnaire was carried out collectively by the authors. Another colleague, with a keen interest in consenting, was employed for further validation to enhance patient's understanding of the questions. A total of fifteen (15) questions were presented (Table 1) with some of the questions having sub-sections. Parents of patients completed the questionnaires when the patients were less than 16 years of age. Questionnaires were administered post-operatively and voluntarily to patients by hand after different procedures, ranging from tonsillectomies to pharyngeal pouch stapling, etc. Standard ethical procedures were followed prior to the administration of questionnaires. Some patients declined participation in the study. All patients who participated had signed the consent form. Out of 130 patients who were presented with the questionnaires, 123 agreed to partake in the study giving a high response rate of approximate 95%. The outcome of study was based on the responses presented in the questionnaires

Table 1. Patient Questionnaire

1. When did you sign the consent form?
2. Where did you sign the consent form?
3. Which member of the surgical team countersigned the consent form with you?
4. Did you have the benefits, procedure and complications of the surgery explained to you?
5. How satisfied were you regards with their explanations?
6. Were you given a leaflet about the procedure?
7. Was the leaflet useful?
8. Were you given a copy of your signed consent form?
9. Was above (number eight) consent form helpful?
10. What did you do with the copy of the consent form?
11. Did you do a further search for information about the procedure?
12. Did you have enough time to make an informed consent?
13.Were there useful information in the consent form copy?
14. Did the leaflet help you understand the procedure?
15. Do you have suggestions for improvement of the consent form?

2.3 Statistical Analysis

Microsoft Office Excel 2007 (Microsoft Corporation, USA) was used to run the statistical analysis of the data. Data collated from the questionnaire were inputted into spreadsheets and were analysed either in percentages, or in accordance to equal weighting to each question.

2.4 Limitations

A limitation of the study was our inability to ascertain the reasons for those patients who came for the surgery more than 6 months after signing the consent form.

3. Results

Age range of patients was between 4 and 89 years but with mean and median of 39 years. There were more males (n=70) in participation relative to females (n=50) although three patients did not indicate their gender. The surgeries obtained were as follows: tonsillectomy, septoplasty, nasal polypectomy, mastoid surgery grommets, neck dissection, pharyngeal pouch stapling, parotidectomy, adenoidectomy and pinnaplasty.

Out of all the questionnaires, 17 were filled in by the parents of the patients.

Time at which the consent forms were signed is shown in Table 2. More patients signed the consent on the day of surgery (29%). Consent forms were signed in the respective locations: On the day of surgery (n= 33[27%]); Pre-assessment clinic (n=44 [36%]); and outpatient department (n=46 [37%]). According to the patients' knowledge, countersigning of the consent forms was carried out by the following medical personnel:

Table 2. Timing of signing of consent forms.

Timing	Percentage
Operative stage	29
Less than one month	15
1 – 3 months before operation	17
3 – 6 months before operation	20
6 months to 1 year before operation	15
1 – 2 years before operation	2
Greater than 2 years	2

Consultant (n=67 [54%]); Registrar/Middle grade (n=10 [8%]); and Senior House Officer (n=9 [7%]). However, the remaining respondents did not indicate who countersigned their consent forms.

The benefits of the surgery explained to the patient remained high in the data collected (n=104 [85%]), although those who could not recall (n=6 [5%]) outnumbered those who were not informed of the benefits (n=4 [3%]). The surgical procedure was explained to most of the patients (n=112 [91%]) compared to those who claimed not to have received any explanation (n=5 [4%]). Most of the patients were educated about the complications which could arise from the surgery (n=104 [85%]). However, some patients could not recall receiving education about surgical complications (n=14 [11%]). Some others (n=5 [4%]) claimed not to have been informed about surgical complications. The degree of satisfaction about explanation of what the surgeries entailed are outlined below in Table 3.

Table 3. Degree of satisfaction with explanation of surgery.

	Satisfied	Not satisfied
Benefits of surgery	86 (70%)	7 (6%)
Surgical procedure	96 (74%)	8 (7%)
Complications of surgery	86 (70%)	5 (4%)

Patients who received leaflets about the procedure (n=63 [51%]) outnumbered those who did not (n=45 [37%]). However, the remaining could not recall (n=15 [12%]). Interestingly, the number of patients who attested to the usefulness of the information carried on the leaflet (n=54 [44%]) remained higher than those who did not find it useful (n=8 [7%]). However, the remaining respondents did not comment on the usefulness (n=61 [49%]).

Majority of patients confirmed that they received copies of the signed consent form (n=88 [72%]). Also, a majority of respondents indicated that the copy of consent form was helpful (n=66 [54%]). Only 4 patients indicated that the copy of consent form was not helpful. The rest were either equivocal or did not comment. A majority of respondents kept the copy of consent forms at home (n=74 [60%]). Also, a majority did not bother engaging in further search about the surgical procedure (n=100 [81%]). Of the respondents who engaged in a further search, very few consulted the internet (n=12 [10%]) or much less when it was internet plus medical books (n=3 [2%]). However, only one patient consulted another medical practitioner for more information. Majority of the patients agreed that they had enough time to make an informed consent (n=111 [90%]). 58 respondents [47%] indicated the leaflets helped them understand the surgical procedure against only one respondent who disagreed.

A number of patients (10%) reported that the clinic staffs were good in administering the consent forms to them. Other comments by patients were that the wards were too hot, notification on changes in appointment dates need be improved as well as information not really needed due to fear of risks should not be included. Suggestions were also given on what could be done to improve the consent process. They include: 1) More information should be given; 2) Leaflets should be replaced with video or DVD where possible; and 3) Repetition is important in the consent process.

4. Discussion

Some workers have reported about the quality of informed consent [13]. Falagas et al reported five elements which underscore the process of any informed consent which include voluntarism, capacity, disclosure, understanding, and decision. It was viewed that when appropriate information becomes relayed, it promotes understanding and as such, enhances sensible decision making without compulsion [15]. How the medical information is communicated to patient can really pose difficulties since there is need to put in plain words the scientific language which may be involved. As a result, medical officers need to communicate the details of medical information in a gentle and empathetic way [15].

The aim of this study was to investigate the effectiveness of consenting in a typical ENT Unit. The fact that majority of the patients presented in our study indicated that the consent forms were useful shows that the recall of information given to patients signals an improvement in the consenting process. This can be partly attributed to the key sources of information made available by the doctors and nurses when engaged in the pre-assessment clinic [13]. The ability of individuals to understand the process, purpose, risks as well as the benefits of consenting go hand in hand with their ability to decide upon whether to participate voluntarily [16]. In our opinion, a copy of consent form is expected to remind the patient about the procedure that was explained, risks, benefits as well as complications that could arise from the surgery. More so, when patients are given written

information, they can show a better recall and therefore, a better chance to make informed decisions [17].

Consequently, the fact that 70 – 74 % of patients in our study were satisfied with the explanation of the procedure, benefits and complications provides good evidence that patients have good understanding of the consenting process. In general terms, the use of good written information therefore enables surgeons, not only to serve their patients better, but also, to simplify their practices for all common operations [17].

Twenty-nine percent of the forms were signed on the day. This is comparable with the study done by Berry et al in which they got almost 15% of their candidates signing the consent form on the same day. In that study, they reduced this to 2% by introducing a simple policy in their department which prevented patients from progressing from the pre-operative assessment clinic if the consent form had not been filled [18]. A small percentage of patients (4%) signed the forms a year or more before surgery. This is not acceptable and is probably due to long waiting times for the surgery and patient cancellation.

In the study, it was found that a reasonable number of patients did not comment on the usefulness of the leaflets administered to educate them about the surgery. It is most likely that the majority of the respondents, who did not comment, probably did not receive the leaflets. As a result, more effort is needed to ensure that every patient receives a leaflet to inform them about the surgical procedures in order to facilitate informed consent and not just for medico-legal purposes. Efforts should also be made to ensure that a leaflet is produced for every procedure.

Although only 58 respondents indicated the leaflets helped them understand the surgical procedure against only one respondent who disagreed, it should be noted that a number of patients did not receive the leaflets and this may account for the number of respondents who appreciated the leaflets. Majority of the patients did not bother engaging in further search about the surgical procedure. A probable reason which may have led to this occurrence is patient satisfaction with the information provided. This may explain why very few consulted the internet (10%) or much less when it was internet plus medical books (2%) while a greater number had no information (84%).

5. Conclusion

The present study investigated the effectiveness of consenting obtained in a typical ENT surgery unit. There is much evidence to show that patients were reasonably satisfied with the consent process. Patients who received written information (leaflets) found the provision of written information beneficial and useful. The effectiveness of informed consent can be improved by ensuring that patients adequately receive written information, addition of videos to the consent process and the repetition of information to ensure adequate comprehension of the surgical procedure.

References

[1] Hoehner PJ. Ethical aspects of informed consent in obstetric anesthesia – new challenges and solutions. Journal of Clinical Anesthesia 2003;15 (8): 587-600

[2] Jones JW, McCullough LW, Richman BW. Informed Consent: Its Not Just Signing a Form. Thoracic Surgery Clinics 2005;15(4): 451-460

[3] General Medical Council (1998). Seeking Patients' Consent: The Ethical Considerations. London: GMC

[4] Hopper KD, TenHave TR, Tully DA, Hall TE. The readability of currently used surgical / procedure consent forms in the United States. Surgery.1998 May; 123(5):496-503

[5] Langdon IJ, Hardin R, Learmonth ID. Informed consent for total hip arthroplasty: does a written information sheet improve recall by patients? Ann R Coll Surg Engl 2002; 84: 404-408

[6] Adachi H. Informed consent in cardiovascular surgery. Kyobu Geka 2008 Mar; 61(3): 231-237

[7] Glock RS, Goldim JR. Informed consent in gerontology. Eubios J Asian Int Bioeth. 2003 Jan;13(1):6-8

[8] Nichols CM, Pendlebury LC, Jennell J. Chart documentation of informed consent for operative vaginal delivery: Is it adequate? South Med J. 2006; 99(12):1337-9

[9] Chappell D, Taylor C. A survey of the consent practices of specialist orthodontics practitioners in the North-West of England. J Orthod. 2007 Mar; 34(1): 36-45

[10] Wiseman OJ, Wijewardena M, Calleary J, Masood J, Hill JT. 'Will you be doing my operation doctor?' Patient attitudes to informed consent. Ann R Coll Surg Engl 2004; 86: 462-464

[11] Philipson SJ, Doyle MA, Gabram SG, Nightingale C, Philipson EH. Informed consent for research: a study to evaluate readability and processability to effect change. J Investig Med. 1995 Oct;43(5):459-67
[12] Mallardi V. The origin of informed consent. Acta Otorhinolaryngol Ital. 2005 Oct;25(5):312-27
[13] Ibrahim T, Ong SM, Taylor GJS-C. The new consent form: is it any better. Ann R Coll Surg Engl 2004; 86:206-209
[14] Goodyear PW, Anderson AR, Kelly G. How informed is consent in a modern ENT department. Eur Arch Otorhinolaryngol. 2008 Aug; 265(8):957-61
[15] Falagas ME, Korbila IP, Giannopoulou KP, Kondilis BK, Peppas G. Informed consent: how much and what do patients understand? The American Journal of Surgery. 2009; 198 (3): 420-435
[16] Jefford M, Moore R. Improvement of informed consent and the quality of consent documents. Lancet Oncol. 2009 May; 9(5):485-93
[17] Campbell B. New consent forms issued by the Department of Health. Ann R Coll Surg Engl. 2004 Nov; 86(6): 457-8
[18] Berry NH, Phillips JS, Salam MA. Written Consent – A Prospective Audit of Practices for ENT Patients. Ann R Coll Surg Engl. 2008 March; 90(2): 150-152