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Informed consent: using a structured interview changes patients' attitudes towards informed consent

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Abstract

Patients want to know more about their condition and its proposed treatment. Gaining patients' confidence before treatment reduces the chances of their seeking legal redress for an unexpected outcome. As part of a prospective study of informed consent for surgery we have assessed the attitudes of patients towards informed consent when different types of consent interview are used.

We found that most patients are happy to do as their doctor advises but think the informal consent interview is important because it gives them information; they also want to know about most, but not all, complications of the procedure. One quarter worried about the anaesthetic, about one eighth worried about 'not waking up' and similar proportions worried about complications and other things such as pain and nausea. Most patients think that the consent form is a legal document.

In addition patients who had an informal interview felt obliged to sign the consent form and thought it had medicolegal implications. In contrast those who had a structured interview felt less obliged to sign the consent form and more involved in the decision to operate.

Key words: Informed consent

Introduction

Informed consent has become an important area of medical practice. Patients now want to be told more about their condition and its treatment. They have high expectations of a successful outcome and are more inclined to seek legal redress for an unsatisfactory outcome. If one gains patients' confidence before treatment starts they will be more inclined to accept problems arising during, or after, treatment (Morrison, 1990).

The procedure for obtaining 'informed consent' is often poorly appreciated by patients. They recall little of the interview and think the prime aim is to provide legal protection for the doctor (Robinson and Merav, 1976; Muss *et al.*, 1979; Byrne *et al.*, 1988).

Information sheets have been shown to improve patients' understanding of treatment (Askew *et al.*, 1990; Gibbs *et al.*, 1990). We have shown that presenting information in a structured fashion helps patients remember more potential complications of their surgery without increasing their anxiety (Dawes *et al.*, 1992). This study examined the attitudes of patients towards informed consent when three techniques were used to obtain informed consent.

Method

This study had local ethics committee approval. All patients were admitted to the ENT ward of Southmead Hospital, Bristol. Verbal consent was sought from all patients before they entered the study.

The study ran concurrently with a study examining anxiety changes and information recall on the day informed consent was given for an operation. To avoid biasing information for this study, patients were recruited to Group A prior to Groups B and C (*vide infra*). Patients were subsequently randomly allocated to Groups B and C.

Patients

Patients over 16-years-old were eligible provided they were admitted the day before their operation which was to be performed under general anaesthesia. Patients who did not understand the study or understood English poorly were excluded from the study. We studied the following operations: tonsillectomy; intranasal polypectomy; submucosal resection of the nasal septum; septoplasty and intranasal antrostomy.

One hundred and fifty patients entered the study. Initially major ear surgery was included in the study, but as only nine patients had this surgery we excluded their results because the nature of the information given was substantially different to that for nose and throat operations.

Study groups

Group A. Patients had an informal interview prior to giving their consent. This interview reflected current practice, patients were told the name of the operation, briefly what would be done and some of the possible complica-

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tions. Care was taken to maintain the usual pre-operative interview technique used by the senior author.

Group B. An information sheet was used to guide the interview with patients before they signed the hospital consent form. It explained why the operation was being done, what it involved, listed and explained complications, explained how the patient would feel after the operation, the chance of success and any alternative treatment. The information sheet was not read by the patient and not given to the patient.

Group C. The information sheet, described above, was read with the patient before they signed the hospital consent form. It was then given to the patient so they could read it that afternoon. It was returned that evening before the first assessment.

Study design

On entering the study data was collected about the patient's age, sex and educational level. A record was made of previous general anaesthesia. Patients then entered one of the above groups and consent for surgery was obtained. Four to five hours later patients completed the first of two questionnaires assessing their attitudes towards informed consent. The second questionnaire was completed the morning after their operation. The questions used are shown in the Questionnaire (Parts 1 and 2). Additional questions were asked about whether patients were satisfied with the operation explanation given to them and what information they would like before an operation. These have been excluded because the very high positive response rate by all groups may have reflected bias. The patients answering positively either to please the doctor questioning them or because they thought their responses might influence their treatment while in hospital.

QUESTIONNAIRES

Pre-operative attitudes questionnaire (Part 1)

1. Having arrived in hospital do you feel you must sign the Consent Form?
   Yes
   No
2. If there was a chance an operation would threaten your life or permanently handicap you would you still have it?
   Yes
   Depends upon nature of problem and degree of risk
   No
3. The consent procedure is:
   Important
   (i) because it provides me with information
   (ii) because it helps me make my mind up
   (iii) because it provides medicolegal protection for the doctors
   Not important
   (iv) because I'll do as the doctor says
   (v) because I've already decided to have the operation
4. Do you think you can change your mind once you have signed the Consent Form?

Post-operative attitudes questionnaire (Part 2)

5. Do you think you should be involved in the decision to operate?
   (i) I expect to make the final choice
   (ii) I find the discussion of the pros and cons of treatment helps me agree with the advice given
   (iii) I want to know about the operation and its effects, but would have it anyway
   (iv) I will do as the doctor says – he knows best
6. Which complications do you want to know about?
   (i) All of them
   (ii) None of them
   (iii) The important ones
   (iv) Not the rare but serious ones
7. Was there anything you were worried about before your operation?
   (i) The anaesthetic
   (ii) The complications
   (iii) The operation being successful
   (iv) Not waking up
   (v) Others
8. Did you feel you had to sign the consent form?
   Yes (If yes, why was that)
   No
9. Is the consent form a legal document?
   Yes
   No
   Don't know

Statistics

The chi-squared test was used to assess any differences between the groups for different questions asked. A five per cent significance level was set.

Results

One hundred and forty-one patients entered the study but only 135 completed it. Six patients left hospital before completing the second assessment and have been excluded from the analysis. There were 45 patients in Group A, 48 in Group B and 42 in Group C. All groups had a similar distribution for age, sex, educational status and previous anaesthesia (Table I). The results for the different questions are shown in Tables II and III.

Questions 1 and 8: Did you feel you had to sign the consent form?

Questions one and also question eight asked the same question and achieved similar results. The majority of patients in Group A felt obliged to sign the consent form compared with less than half of those in the other groups. The main reasons for feeling obliged to sign the consent form were either to allow the operation to go ahead or because not signing the form would be 'messing the doc-

TABLE I
DEMOGRAPHIC DATA

Group	A	B	C
Mean age (years)	37.8	38.3	35.4
95% confidence interval	32.4 to 43.2	36.0 to 40.6	33.1 to 37.7
Sex			
M:F	28:17	23:25	23:19
Education			
Nil	15	21	11
CSE	8	9	10
O	17	10	13
A	1	6	6
Higher	4	1	2
Previous surgery			
None	13	12	12
Yes	20	21	19
Yes – ENT	12	15	11

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TABLE II

RESULTS FOR QUESTIONS 1 TO 4 (FIGURES IN PARENTHESES ARE PERCENTAGES)

	Question 1			Question 2			Question 3					Question 4			
	Yes	No	Don't know	Yes	%	No	Important (i)	Important (ii)	Important (iii)	Not important (i)	Not important (ii)	Yes	No	Don't know	No response
A	36	8	1	2	35	8	20	3	32	8	18	25	17	2	1
$n = 45$	(80)	(18)	(2)	(4)	(78)	(18)	(44)	(7)	(71)	(18)	(40)	(56)	(38)	(4)	(2)
B	21	27	–	9	19	20	25	14	15	1	1	31	14	0	3
$n = 48$	(44)	(56)		(19)	(40)	(41)	(52)	(29)	(31)	(2)	(2)	(65)	(29)		(6)
C	18	24	–	6	22	14	15	11	14	0	3	27	15	0	–
$n = 42$	(43)	(57)		(14)	(52)	(33)	(36)	(26)	(33)		(7)	(64)	(36)		

TABLE III

RESULTS FOR QUESTIONS 5 TO 9 (FIGURES IN PARENTHESES ARE PERCENTAGES)

	Question 5					Question 6					Question 7					Question 8		Question 9			
	(i)	(ii)	(iii)	(iv)	No record	All	None	Important	Not rare but serious	No record	Anaesthetic	Complication	Success	Death	Other	Yes	No	Yes	No	Don't know	Not asked
A	4	13	13	15	–	9	3	26	7	–	11	4	4	6	5	33	12	19	4	5	17
$n = 45$	(9)	(29)	(29)	(33)	–	(20)	(7)	(58)	(15)		(24)	(9)	(9)	(13)	(12)	(73)	(27)	(68)	(14)	(18)	–
B	7	9	9	21	3	22	2	17	7	–	12	12	14	16	9	10	38	36	7	3	2
$n = 48$	(15)	(19)	(19)	(44)	(6)	(46)	(4)	(35)	(15)		(25)	(25)	(30)	(33)	(19)	(21)	(79)	(78)	(15)	(7)	–
C	11	11	3	17	–	19	3	11	8	1	12	5	6	7	6	14	28	28	4	1	9
$n = 42$	(26)	(26)	(8)	(40)	–	(45)	(8)	(26)	(19)	(2)	(29)	(12)	(14)	(17)	(14)	(33)	(67)	(85)	(12)	(3)	–

tors about'. This difference is significant (chi-squared test: $P<0.001$; 2 degrees of freedom).

Question 2: If there was a chance an operation would threaten your life or permanently handicap you, would you still have it?

Patients in Group A were much more likely to consider the relative risks of such an operation before deciding. In Groups B and C consideration of the risks was still important but an increased proportion would also refuse the operation. These differences are significant (chi-squared test: $P<0.01$; 4 degrees of freedom). Closer analysis shows that the difference is due to that between Groups A and B with Group C having attitudes that lay between Groups A and B but which are not significantly different from either group.

Question 3: The consent procedure is important/not important?

There were five items to the question and patients could give a positive response to any of them.

(i) The consent procedure provides me with information: Between 36 and 52 per cent of patients agreed with this statement. There was no difference between groups.

(ii) The consent procedure helps me make my mind up: Significantly more patients in Groups B and C agreed with this compared with Group A (chi-squared test: $P<0.02$; 2 degrees of freedom). However, most patients did not agree with this.

(iii) The consent procedure provides medicolegal protection for doctors: Nearly three-quarters of Group A agreed compared to about one-third of Groups B and C (chi-squared test: $P<0.001$; 2 degrees of freedom).

(iv) The consent procedure is not important because I'll do as the doctor says: Few patients responded positively to this statement, most were in Group A (18 per cent) compared with Groups B (2 per cent) and C (none). The difference is significant (chi-squared test: $P<0.01$; 2 degrees of freedom).

(v) The consent procedure is not important because I've already decided to have the operation: Significantly more patients in Group A agreed with this compared with Groups B and C (chi-squared test: $P<0.001$; 2 degrees of freedom).

Question 4: Do you think you can change your mind once you have signed the consent form?

Between one-half and two-thirds of patients believe they can change their mind after having signed the consent form. There is no difference between the three groups.

Question 5: Do you think you should be involved in the direction to operate?

Patients were asked which of four statements best reflected their attitude. There was a broad spectrum of responses throughout the groups. Group C appear the most independent, 52 per cent responding to items (i) and (ii). However, no statistical difference is demonstrated (chi-squared test: 0.1; $P>0.05$; 6 degrees of freedom).

Question 6: Which complications do you want to know about?

Most patients wanted to know about either all the complications or the important ones. There was no difference between the groups.

Question 7: Was there anything you were worried about before your operation?

About a quarter of patients admitted worrying about the anaesthetic; fewer, with the exception of Group B, worried about 'not waking up'. Group B also showed more concern about complications. Overall most patients denied worrying about the topics listed and we did not demonstrate a significant difference between the groups.

Question 9: Is the consent form a legal document?

Most of the patients asked thought it was a legal document. The numbers are similar for all groups.

Discussion

The three groups have matching attitudes for many aspects of informed consent and these are not changed by the different interview techniques used. About half the patients considered the consent interview important because it provided them with information; they wanted to know about either all the complications or the important ones. When asked who should be involved in the decision to operate there was a broad range of responses with half to two-thirds happy to do as their doctor advised. About one-quarter admitted to being worried about the anaesthetic and half this number about 'not waking up'. Ten to fifteen per cent admitted worrying about the complications, the chance of success and other things such as pain and nausea. Two-thirds thought they could change their mind after signing the consent form, and three-quarters thought it was a legal document.

In addition to the above, patients who had the 'current consent' interview felt more obliged to sign the consent form, they viewed it as a medicolegal document which was otherwise unimportant because they had decided to have the operation.

In contrast, the structured interview techniques resulted in patients feeling less obliged to sign the consent form, more likely to think they had been involved in the decision to operate and less likely to consider the interview a formality. Interestingly, more of these patients think they would be less likely to have a health/life threatening operation compared with Group A although more than half would still have the operation or consider its risks. This finding may represent the greater feeling of autonomy Groups B and C have about the decision to operate, they are more confident to refuse treatment because they feel less dependent upon the doctor to make the final decision. The question asked was hypothetical and it may be that when necessarily faced with the arguments for and against such surgery these patients will also be confident to agree to the treatment. The contrary and more simplistic argu-

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ment is that because we are telling these patients more about their surgery we are frightening them and they therefore think they would refuse life threatening surgery. However, our parallel study of these patients, which simultaneously assessed anxiety, failed to show increased anxiety in Groups B and C which would be expected if fear was being generated (Dawes *et al.*, 1992).

Our findings are similar to those of the President's Commission for the study of ethical problems in medicine (1982) which found that 65 per cent of those questioned thought that written consent forms help doctor/patient communication. Seventy-five per cent thought the consent form was for medico-legal purposes. Denney *et al.* (1975) used information booklets when consenting patients for hysterectomy; 93 per cent of patients reacted favourably to the booklet. Although 28 per cent thought too much information was given, there was no increased anxiety amongst those given the booklet compared with patients not given the booklet and nobody refused their operation.

Our study assessed attitudes at the time of surgery and cannot predict patients' attitudes weeks or months later. However, if the first impressions of the consent interview are improved it is likely that this will affect later attitudes. This may enable patients to become more accepting of an unexpected outcome after treatment. Morrison (1990) stresses that the patients who sue tend to be those who thought inadequate time had been spent explaining either their treatment or the reasons for its real or perceived failure.

Our findings in association with having demonstrated that using information sheets improves recall of potential complications without increasing anxiety (Dawes *et al.*, 1992) supports their use as an aid to structuring the discussion when recommending surgical treatment.

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