TEACHING AND LEARNING ETHICS

What do patients really want to know in an informed consent procedure? A questionnaire-based survey of patients in the Bath area, UK

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Background: Medical decision making is based on patient autonomy and informed consent, which is an integral part of medical ethics, risk management and clinical governance. Consent to treatment has been extensively discussed, but the viewpoint of patients is not well represented. A new consent form was introduced by the Department of Health in 2001.

Aims: To determine the information most important to patients, to facilitate evidence-based guidelines and to provide a valid and reliable consent-procedure-satisfaction questionnaire.

Methods: An anonymous quantitative survey was carried out, asking 100 patients 15 questions regarding procedures they may need to undergo, using a Visual Analogue Scale to test the importance of each question.

Results and discussion: In total there were 77 respondents and the mean age was 48.8 (SD 17.63, range 20-82) years. There were 52% women and 48% men. Major complications, such as not undergoing the procedure, future management and long-term effect on work, all scored a median of 95%. Least concerns were related to technical details of the procedure and minor complications (median 64% and 63%, respectively). All other questions were still considered important (median 79-93%). No significant differences were observed between sex, age and professional groups, but a significant difference was observed between the education groups. Qualifications of the doctor did not correlate to any other question.

Conclusions: This questionnaire is proposed as a basis for informed consent guidelines to health workers and for measures of satisfaction with the consent procedure.

Medical decision-making is based on the doctrine of patient autonomy and informed consent. This is one of the four principles of medical ethics, the others being beneficence, non-maleficence and social justice.¹⁻² In ancient Greece and later on in Byzantine times, not only was the consent of the patient necessary but also doctors were asking for more safeguards before undertaking a difficult operation, either because of respect for the patient's autonomy or from fear of the consequences of their failure.³ Informed consent has developed further in a complex way over the past century.⁴⁻⁶ Full disclosure and shared decision making may not have come naturally to clinicians.⁵⁻⁷⁻¹¹ However, there is a clearer understanding of informed consent as being an integral part of risk management and clinical governance.¹²⁻¹³ Current debate exists on whether there should be one internationally recognised standard of informed consent.¹⁴⁻¹⁹

A truly informed consent requires full disclosure of all relevant information by the doctor, competence of the patient to appreciate what the information signifies, understanding of the facts and issues by the patient and a voluntary non-coerced choice by the patient leading to an autonomous authorisation for treatment. Each of these conditions is hard to fulfil, making a fully informed consent seldom, if ever, possible.²⁰⁻³³ This may have led some researchers to introduce the concept of a "valid" consent as a more manageable criterion.³⁴ The legal requirement is vague and provides little help in predicting when consent is satisfactory.²¹⁻³¹⁻³³⁻³⁵⁻³⁹ In the UK, the process of informed consent is underpinned by the Bolam principle, according to which an individual doctor's standards are set by peer standards of professional conduct.³¹⁻³³⁻⁴⁰⁻⁴²

Consent to treatment has been discussed extensively from the viewpoint of law, ethics and policy experts; the viewpoint

of patients is less well represented. Evidence suggests that patients generally understand the nature and aim of operations and their specific risks, but are more concerned about the outcome.⁴³⁻⁴⁸ In one study,⁴⁹ most patients had correctly understood the information, but 69% of the patients stated that they had been unable to ask all the questions they wished and 62% required additional information. Patients often indicate that they should be informed of all possible complications associated with a procedure, regardless of severity or risk, albeit practically impossible to achieve.⁵⁰⁻⁵³

AIM

With the introduction of the new consent forms and guidelines by the Department of Health (DH) in 2001,³¹⁻³³ we were interested in determining what information was essential and most important from the patients' point of view. This would facilitate producing evidence-based guidelines regarding the information required by the patients as well as attempting to formulate a valid and reliable consent-procedure-satisfaction questionnaire.

Literature search

We carried out an internet search for English publications with an abstract, published between 1993 and 2003, using Cinhal, Embase and Medline. We used the keywords: informed consent with: ethics, history, legislation-and-jurisprudence, patient-autonomy-and-physician-beneficence-within-clinical-medicine, standards, statistics-and-numerical-data, and brief, producing 777 results. Another search, using the same limit, with keyword consent in the title produced a similar number of

Abbreviations: DH, Department of Health; GCSE, general certificate of secondary education; NVQ, national vocational qualification

articles. Further refinement excluded duplicate articles and articles referring to research, children and adolescents, and the mentally incapacitated.

We used the DH's website (<http://www.doh.gov.uk/consent>) to review the new consent guidelines.

METHODS

Study design

We decided that a quantitative survey to test patients' attitudes was appropriate in our study, as there was enough pre-existing knowledge, permitting the use of standardised data collection methods. We chose an anonymous, paper-based, structured and self-administered patient questionnaire for data collection, which is practical, economic, minimises social desirability and interview bias, and allows testing sensitive topics.^{54 55}

Questionnaire

We used information from guideline documents published on the DH's website,^{31–33} alongside data from a published study that showed the questions considered to be most important by the patient.⁵⁶

We asked the patients 15 questions (table 1) and requested them to indicate how important each question was with respect to investigations, procedures or operations they may need to undergo. We used the Visual Analogue Scale, as it is a valid and reliable measure, to test the importance of each question to the patients.^{54 55} We requested the patients to give a score between 0 (not important at all) and 100 (extremely important) for each question.

We collected demographic data on age, sex, profession (professional, managerial and technical, skilled non-manual, skilled manual, partly skilled, and unskilled or none) and highest education achieved (postgraduate degree/diploma, graduate degree, school A-level, general certificate of secondary education (GCSE)/national vocational qualifications (NVQ) and no qualifications) by questions positioned intentionally at the end of the questionnaire.⁵⁵

The questionnaire was reviewed within the research team. Samples were then informally discussed with nursing and auxiliary members of staff to validate the content and to gauge the language and expressions used before the questionnaire was introduced to patients.

Sample

After consultation with the statistics department, we empirically chose a sample size of 100 patients. We chose patients attending the gastrointestinal outpatient clinic and the gastrointestinal endoscopy unit that shared one reception (50 patients), and the day surgery unit (50 patients), at the Royal United Hospital, Bath, UK, as a convenient sample that would represent our hospital patient population. Patients ≥ 18 years of age (the consent age) were included. Patients < 18 years of age, those suffering from mental or learning disabilities and those not conversant with English as a written language were excluded.

Ethics and consent

We contacted the local ethics committee and they indicated that no formal ethics approval or consenting procedures were required for this survey. However, we developed the questionnaire in consultation with a member of the ethics committee, who was also one of the researchers responsible for the statistical analysis of the study.

Data collection

Anonymous questionnaires were handed to the patients in sealable envelopes, by the receptionist, as they arrived at the different departments, and they were asked to leave them with the receptionist when they were leaving. Data were collected over a period of 1 week in February 2002.

The data were retrieved by the main researcher and were counterchecked before and after entry into a computer Microsoft Excel-XP sheet. Data were transferred to SPSS for statistical analysis.

Statistical analysis

SPSS V.10 for Windows was used for data analysis. Descriptive statistics included means, medians, standard deviation (SD) and confidence intervals (CIs). CIs were calculated at 95%; $p < 0.05$ was considered significant and $p < 0.01$ highly significant (two-tailed significance). As data from the questions were non-parametric, non-parametric tests (Mann–Whitney U, Wilcoxon W and Kruskal–Wallis tests) were used to detect marked differences between groups. We used Spearman's rank correlation coefficient (two-tailed significance) test for bivariate correlation significance, which was considered to be significant when the

Table 1 Descriptive statistics of Visual Analogue Scale scores of importance of questions to patients

Questions	n	Median	Quartiles	Range	Mean (SD)	95% CI for mean
Major risks or complications of undergoing the procedure	75	95	82.0, 100.0	1–100	83.8 (27.31)	77.13 to 90.45
Minor risks or complications of undergoing the procedure	74	63	42.0, 95.0	0–100	63.1 (31.60)	55.35 to 70.77
Consequences of not undergoing the procedure	73	95	80.0, 99.5	5–100	86.4 (19.81)	81.54 to 91.21
Consequences of the procedure with regard to future management of your condition	75	95	79.0, 99.0	0–100	83.5 (24.83)	77.42 to 89.53
Alternative options	73	91	55.0, 99.0	0–100	75.5 (30.43)	68.05 to 82.90
General nature of the procedure	74	80	51.0, 98.3	1–100	74.0 (25.46)	67.79 to 80.21
Technical details of the procedure	73	64	42.5, 83.0	0–100	62.3 (27.85)	55.46 to 69.05
Anaesthesia, analgesia or sedation used	74	79	50.0, 98.0	0–100	70.1 (29.60)	62.84 to 77.28
Qualifications of the doctor undertaking the procedure	76	93	64.8, 100.0	0–100	80.2 (26.46)	73.72 to 86.63
Effects of the procedure on your quality of life in the short term (immediately and up to 1 month) after the procedure						
Work or house work	75	88	52.0, 98.0	12–100	77.0 (25.69)	70.70 to 83.24
Leisure activities and sports	74	75	45.0, 96.3	1–100	65.3 (31.66)	57.62 to 73.06
Personal and sexual relations	74	82	50.0, 97.0	2–100	71.5 (27.95)	64.72 to 78.36
Effects of the procedure on your quality of life in the long term (from 1 month onwards) after the procedure						
Work or house work	72	95	85.3, 98.8	18–100	88.1 (17.25)	83.88 to 92.30
Leisure activities and sports	73	89	55.0, 97.0	2–100	77.1 (27.72)	70.30 to 83.82
Personal and sexual relationships	72	93	77.0, 98.0	21–100	83.3 (21.22)	78.09 to 88.45

Table 2 Demographic data of the sample

Sex	n (%)
Men	39 (52)
Women	36 (48)
Age (years)	
Mean (SD)	48.8 (17.63)
Median	48.6
Range	20–82
Profession	n (%)
Unskilled or none	12 (17.39)
Partly skilled	2 (2.90)
Skilled manual	10 (14.49)
Skilled non-manual	5 (7.25)
Managerial and technical	19 (27.54)
Professional	21 (30.43)
Education	n (%)
No qualifications	11 (16.42)
School (GCSE/NVQ)	15 (22.39)
School A-level	15 (22.39)
Graduate degree	11 (16.42)
Postgraduate degree/diploma	15 (22.39)

GCSE, general certificate of secondary education; NVQ, national vocational qualifications.

coefficient value was >0.4 or <-0.4 and $p<0.05$ (highly significant when $p<0.01$). A cluster analysis was also undertaken using the between-groups linkage cluster method and Pearson's correlation interval.

RESULTS

Of the 100 questionnaires, 80 were returned. Three questionnaires were excluded (two were not filled in and one was ineligible), making the total number of valid returned questionnaires 77. This rate of response ($>75\%$) was considered to be good.⁵⁴

The mean age of patients was 48.8 (SD 17.63, range 20–82) years, of whom 52% were women and 48% men. Professionally, the participants in the sample comprised 17.39% who were unskilled or with no professional skills, 2.90% partly skilled, 14.49% skilled manual, 7.25% skilled non-manual, 27.54% managerial and technical, and 30.43% professional people. Educationally, the sample comprised 16.42% with no qualifications, 22.39% with school (GCSE/NVQ) education, 22.39% with school A-level, 16.42% with a graduate degree and 22.39% with a postgraduate degree or diploma (table 2).

Table 1 shows the median scores, quartiles and mean scores (SD) with the 95% CI for the 15 questions.

Non-parametric Mann–Whitney U and Wilcoxon W tests failed to show any significant differences between men and women in responding to the questions. The non-parametric Kruskal–Wallis test failed to show any significant differences between the age groups (≤ 34 , 35–51, 52–63 and >63 years) and between professional groups. However, the same test showed a significant difference between the education

groups in responding to not undergoing the procedure ($p=0.026$) and alternative options ($p=0.023$), with the lowest scores in the GCSE/NVQ group.

The relationships between the factors under investigation, using Spearman's rank correlation coefficient (two-tailed significance) showed the following: correlations among major and minor complications were highly significant. The factors major complications, not undergoing the procedure, future management of condition and alternative options were highly correlated with each other. The factors general nature of the procedure, technical details of the procedure, and anaesthesia, analgesia and sedation were highly significantly correlated with each other. Qualifications of the doctor was not found to be correlated to any other factor in question and all the quality of life variables correlated highly significantly with each other. The hierarchical cluster analysis produced similar results.

DISCUSSION

The results indicate that the top score goes equally to major complications, effect of not undergoing the procedure, effect on future management of the condition and long-term effect on work. Least concerns were related to technical details of the procedure and minor complications. All the other questions were still considered important.

These results are similar to those of a previous study,⁵⁶ which showed that patients considered major risks, quality of life, outcome, consequences of not undergoing the procedure and quantity of life as the five most important aspects of informed consent. It also generally agrees with other studies that rated the following as important from the patients' point of view: complications, details of the procedure and hospital stay, quality of life, positive outcome expectations, confidentiality, inappropriate therapeutic techniques, consequences of not undergoing the procedure and alternative treatments, and anaesthesia.^{48 52 57–59}

No difference was observed between sex groups, age groups and professional groups in responding to the questions. However, there was a significant difference between the educational groups in relation to alternative options and the effects of not undergoing the procedure, with the lowest scores in the GCSE/NVQ group (table 3).

The responses to all questions on quality of life were highly correlated with each other and correlated well with the general nature of the procedure and with not undergoing the procedure. Responses significantly correlated, considering alternative options to short-term effects on leisure and personal relationships and long-term effects on work. Major complications, such as not undergoing the procedure, future management and alternative options, significantly correlated with each other.

The responses did not significantly correlate the general nature of the procedure, the technical details of the

Table 3 Effect of education on patient responses for NUP and AO

	Education	Median	Range
NUP	No qualifications	94	76–100
	School (GCSE/NVQ)	84	5–99
	School (A-level)	99	64–100
	Graduate degree	99	70–100
	Postgraduate degree/diploma	95	50–100
AO	No qualifications	93	50–100
	School (GCSE/NVQ)	58	0–99
	School (A-level)	89	0–100
	Graduate degree	98	0–100
	Postgraduate degree/diploma	98	22–100

AO, alternative options; GCSE, general certificate of secondary education; NUP, not undergoing the procedure; NVQ, national vocational qualifications.

procedure, anaesthesia, analgesia and sedation, or the questions on quality-of-life to complications. They did not significantly correlate short-term effects on work and all long-term quality-of-life to the future management. Surprisingly, the responses did not remotely correlate the qualification of the doctor to any other question, although its score remained high and consistent. Other studies indicated that information about the personal characteristics and qualifications of the therapist were the least important,³⁷ and that patients depend on and trust their therapists.³⁸

Our results agree with many studies about aspects that need to be emphasised and improved in the consent procedure. These included explaining the general risk of surgery and alternative treatments, and discussing the future life expectancy and lifestyles.^{43–48}

Hierarchical cluster analysis showed that questions on short-term quality-of-life could not be substituted by one question. The same applied to questions on long-term quality-of-life. The results show them to provide the same information while remaining different.

There are two limitations to our study. The first was regarding questions about major and minor complications, as we did not indicate descriptively or quantitatively what they meant—for example, affecting the expectancy of life, affecting the outcome of their condition or occurring in more than 1 in 1000 people. However, previous studies indicated that patients considered major complications as those posing serious risks and those occurring in more than 1 in 1000 people.³⁶ The second limitation is due to omitting questions relating to diet in our questions on quality of life. However, the high correlation between all the questions on quality of life may have compensated for this limitation. Both limitations need to be remedied in future studies.

CONCLUSION

Patients in our study considered all the questions posed to be important. However, major complications, such as not undergoing the procedure, future management of their conditions and long-term effect on work, were equal and highest on the list. Least concerns were directed to technical details and minor complications. No significant differences by sex, age or profession were found between the groups. However, there was a significant difference between the education groups.

Questions on quality-of-life were considered to be equally important and related. They correlated with the effects of not undergoing the procedure in the short term and with the general nature of the procedure in the long term. Patients considered personal relationships and leisure activities in the short term to be highly related to the nature, details and alternatives of the procedure. Patients did not correlate doctors' qualifications with any of the other questions. Anaesthesia and analgesia correlated with details of the procedure.

The group of questions on short-term quality-of-life cannot be substituted by one question. The same applied to the group of questions on long-term quality-of-life. The results show that they provide the same information although they remain different.

We propose using our questionnaire as a basis for informed consent guidelines to health workers and as a basis for measures of satisfaction with the consent procedure.

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