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Research

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Patients' perceptions of written consent: questionnaire study

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Abstract

Objective To examine patients' understanding of the status, function, and remit of written consent to surgery.
Design Prospective questionnaire study. Questionnaires were sent to patients within one month of surgery. Responses were analysed with frequencies and single variable analyses.
Setting Large teaching hospital.
Participants 732 patients who had undergone surgery in obstetrics and gynaecology over a six month period.
Main outcome measures Patients' awareness of the legal implications of written consent and their views on the function and remit of the consent form.
Results Patients had limited understanding of the legal standing of written consent. Nearly half (46%, 95% confidence interval 43% to 50%) of patients believed the primary function of consent forms was to protect hospitals and 68% (65% to 71%) thought consent forms allowed doctors to assume control. Only 41% (37% to 44%) of patients believed consent forms made their wishes known.
Conclusions Many patients seem to have limited awareness of the legal implications of signing or not signing consent forms, and they do not recognise written consent as primarily serving their interests. Current consent procedures seem inadequate as a means for the expression of autonomous choice, and their ethical standing and credibility can be called into question.

Introduction

The role of consent to treatment, in ethical terms, is to safeguard patients' autonomy.[1] Formal guidance on obtaining consent to treatment in England has been disseminated by the Department of Health.[2] As a consequence, a standardised consent form for competent adults, introduced in an attempt to make the consent process more structured and focused on the patient, is now used in all English hospitals.[3] Although there has been some research on patients' retention of information after the consultation when consent is obtained,[4 5] we do not know much about patients' knowledge and understanding of the consent process and the role of the consent form. Our previous work suggests that many patients tend to view written consent as a ritualistic and bureaucratic hurdle, may feel frightened and pressured by having to give written consent, and report that they do not read or understand the consent form.[6 7] We used a questionnaire to study patients' perceptions of the status, function, and remit of written consent.

Methods

The study was conducted in the department of obstetrics and gynaecology of a large teaching hospital.

Participants—Within one month after their operation we sent letters to 1040 consecutive women who had undergone elective or emergency surgery in obstetrics and gynaecology over a six month period, inviting them to participate in a questionnaire survey. The questionnaire was sent to women who chose not to opt out. Detailed information on the recruitment process and data collection including demographic descriptors has been published previously.[7]

Study questionnaire—The development of the questionnaire was informed by qualitative research[6] and a panel of eight patients. The questionnaire was piloted with 17 patients and modified when appropriate.[7]

Data analysis—We analysed responses to questions relating to patients' awareness of the legal status of the consent form, understanding of its remit, and views on the value and function of written consent. We used the χ^2 test and Mann-Whitney U test to compare categorical and ordinal variables, respectively, and have presented results with 95% confidence intervals.

Results

Of the 1040 patients approached, 34 opted out, and we sent out questionnaires to 1006 patients. The response rate was 71%; 732 usable questionnaires were returned. Non-responders were significantly younger than responders (39.8 *v* 36.9 years; $P<0.001$), less likely to be white (25% *v* 13%; $P<0.001$), and more likely to be living in an area of material deprivation (43% *v* 27%; $P<0.001$).

Of those who responded, 499 (68%) women had elective and 233 (32%) had emergency surgery; 242 women (33%) underwent obstetric procedures and 490 (67%) underwent gynaecological procedures. Overall, 302 (41%) women had more than 24 hours between giving written consent and undergoing surgery.

Legal status of consent

Although verbal informed consent to treatment after a documented consultation satisfies legal requirements, most participants (646, 88%) believed it was a legal requisite to sign a consent form before surgery (table 1). A fifth (20%) did not know whether they could change their mind after they had signed the form, and 118 (16%) incorrectly thought that signing a consent form removed their right to compensation.

More than a third (34%) of responders were unsure whether the operation could be performed if they refused to sign the consent form, and 122 (17%) incorrectly believed it could. Nearly a quarter (169, 23%) did not know whether the operation could be performed if they were unable to sign the consent form, even if non-intervention could result in their death, and 55 (8%) mistakenly assumed it could not. Many patients (517, 71%) were

Table 1 Patients' understanding of the legal implications of signing or not signing the consent form. Figures are numbers of women with percentages and 95% confidence intervals

Statement	True	False	Don't know	Not answered
Signing the consent form is a legal requirement	646 (88, 86 to 90)	23* (3, 2 to 5)	56 (8, 6 to 10)	7 (1, 0 to 2)
Signing the consent form removes your right to compensation	118 (16, 14 to 19)	358* (49, 45 to 53)	238 (33, 29 to 36)	18 (2, 1 to 4)
You have the right to change your mind after signing the consent form	553* (76, 72 to 79)	22 (3, 2 to 5)	144 (20, 17 to 23)	13 (2, 1 to 3)
If you are not able to sign the consent form, the operation cannot take place, even if this means you could die	55 (8, 6 to 10)	492* (67, 64 to 71)	169 (23, 20 to 26)	16 (2, 1 to 4)
If you refuse to sign the consent form, the operation cannot take place, even if this means you could die	345* (47, 43 to 51)	122 (17, 14 to 20)	249 (34, 31 to 38)	16 (2, 1 to 4)
If you can't sign the consent form, your next of kin can sign on your behalf	517 (71, 67 to 74)	62* (8, 7 to 11)	138 (19, 16 to 22)	15 (2, 1 to 3)

*Factually correct responses.

unaware that their next of kin could not sign on their behalf if they were unable to sign for themselves.

Scope of consent

One in 10 patients reported that they did not know what they agreed to when they signed the consent form (table 2). Over half (56%) believed that the doctor could in fact perform a different procedure from that specified on the form if it was life saving, or (50% of patients) if he or she thought it was best for the patient. Only 41% of patients thought the consent form made their wishes known (table 3). Most patients (86%) thought their signature confirmed that they understood what was going to happen to them, and that there are risks involved in having surgery (82%) (table 2).

Value and function of the consent form

Two thirds of patients (70%) reported that signing the consent form was important to them; one in eight (12%) saw the consent form as just another piece of paper they had to deal with; and 292 (40%) reported that they had signed it just so that they could have their operation (table 3). Almost half of all participants (46%) believed that the main function of signing the consent form was to protect the hospital from litigation, and two thirds (68%) thought it gave doctors control over what happened.

Many patients (71%) agreed that the consent form made clear what was going to happen to them, and 564 (77%) reported that it made them aware of the risks of the operation they were to undergo. Over a third (36%) saw it as a safeguard against mix-ups in the operating theatre.

Table 2 Patients' views on the scope of the consent form. Figures are numbers of women with percentages and 95% confidence intervals

By signing the consent form I thought I agreed. . .	Yes	No	Not answered
to exactly what was on the form	549 (75, 72 to 78)	104 (14, 12 to 17)	79 (11, 9 to 13)
that the doctor may do something different from what was on the form if he/she thinks it is best for me	363 (50, 46 to 53)	293 (40, 36 to 44)	76 (10, 8 to 13)
that the doctor cannot do anything different from what was on the form unless it is life saving	408 (56, 52 to 59)	235 (32, 29 to 36)	89 (12, 10 to 15)
that I understood what was going to happen	626 (86, 83 to 88)	36 (5, 3 to 7)	70 (10, 8 to 12)
that I understood that there are risks involved in having the operation	602 (82, 79 to 85)	67 (9, 7 to 11)	63 (9, 7 to 11)
not really sure what I was agreeing to	74 (10, 8 to 13)	545 (74, 71 to 78)	113 (15, 13 to 18)

Table 3 Patients' agreement with statements on the value and function of the consent form. Figures are numbers of women with percentages and 95% confidence intervals

Statement	Strongly agree/agree	Neither agree nor disagree	Disagree/ strongly disagree	Missing
The consent form was important to me	510 (70, 66 to 73)	169 (23, 20 to 26)	37 (5, 4 to 7)	16 (2, 1 to 4)
The consent form made it clear what was going to happen	523 (71, 68 to 75)	104 (14, 12 to 17)	92 (13, 10 to 15)	13 (2, 1 to 3)
The consent form made me aware of the risks of the operation	564 (77, 74 to 80)	88 (12, 10 to 15)	69 (9, 7 to 12)	11 (2, 1 to 3)
The consent form made my wishes known	298 (41, 37 to 44)	219 (30, 27 to 33)	203 (28, 25 to 31)	12 (2, 1 to 3)
The consent form prevents mix-ups during the operation	264 (36, 33 to 40)	231 (32, 28 to 35)	224 (31, 27 to 34)	13 (2, 1 to 3)
The consent form was just another piece of paper	90 (12, 10 to 15)	110 (15, 13 to 18)	519 (71, 67 to 74)	13 (2, 1 to 3)
I just signed the consent form so I could have the operation	292 (40, 36 to 44)	120 (16, 14 to 19)	309 (42, 39 to 46)	11 (2, 1 to 3)
Signing the consent form was mainly to protect the hospital	339 (46, 43 to 50)	214 (29, 26 to 33)	166 (23, 20 to 26)	13 (2, 1 to 3)
The consent form gave the doctors control over what happened	498 (68, 65 to 71)	156 (21, 18 to 24)	52 (7, 5 to 9)	26 (4, 2 to 5)
Signing the consent form was a waste of time	46 (6, 5 to 8)	132 (18, 15 to 21)	540 (74, 70 to 77)	14 (2, 1 to 3)

Discussion

Although patients want to know their legal rights in hospital,[8] their awareness of legal and ethical issues related to the consent process is often limited. Our findings add to evidence showing that even when the consent process satisfies administrative and legal requirements, patients' needs may not be met, and some patients may even consent to surgery they do not want.[6]

Though patients did identify several important advantages of the consent process, there was substantial uncertainty about the implications of signing or not signing the consent form, including uncertainty about whether surgery can proceed in the absence of written consent, rights to compensation, and the legality of proxy consent. Many patients did not see written consent as functioning primarily in their interests nor as a way of making their wishes known. As suggested in previous work,[9] many thought the primary function of the form was to protect the hospital. Although there is no straightforward relation between knowledge of rights and ability to exercise those rights,[10] a lack of awareness of the limits and scope of consent is clearly undesirable, potentially causing patients to feel disempowered and lacking in control.

Our data are limited to women in the obstetrics and gynaecology setting, and we identified important differences between responders and non-responders. Some impact of recall bias also needs to be considered. Similar studies in other settings, and with different populations, would be useful. There is a need

to investigate other vulnerable groups, perhaps including people with poor literacy and people who do not speak or read English.

Notwithstanding these limitations, we consider that there is substantial disparity between the ideals of the consent process as depicted in the bioethical model and how it is perceived and experienced by patients. These findings are disconcerting for healthcare professionals and patients alike and raise questions about how far current consent processes genuinely fulfil their aim of safeguarding autonomy and protecting patients' rights.

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What is already known on this topic

In ethical terms, the role of the consent process is to safeguard patients' autonomy

A standardised consent form for competent adults, introduced by the Department of Health in an attempt to make the consent process more structured and focused on the patient, is now used in all English hospitals

What this study adds

Many patients have limited knowledge of the legal implications of signing or not signing consent forms and do not recognise written consent as primarily serving their interests

A substantial disparity remains between the essence of consent as depicted in the bioethical model and its role as perceived by patients

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