Audit

The new consent form: is it any better?

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Background: The UK Department of Health (DoH) introduced a new consent form into the National Health Service (NHS) in April 2002 following the Bristol Royal Infirmary Inquiry.

Aim: To compare the efficacy of the new consent form with the old on the quality of consent.

Methods: A questionnaire consisting of 11 questions was distributed to two groups of 100 patients before and after the introduction of the new consent form in the pre-assessment clinic at Glenfield Hospital, Leicester.

Results: Of the 11 questions, there were four significant differences that favoured the new consent form. These were: (i) success and benefits of the operation (old, 81%; new, 97%, $P < 0.001$; 95% CI, 7.3–24.4%); (ii) information that patients received about the operation from the doctor (old, 34%; new, 93%; $P < 0.001$; 95% CI, 46.7%–68.9%) and nurse (old, 21%; new, 67%; $P < 0.001$; 95% CI, 33.3–58.3%) in the pre-assessment clinic; (iii) postoperative recovery (old, 56%; new, 96%; $P < 0.001$; 95% CI, 30.0%–51.2%); and (iv) ability to list potential complications that could arise from the operation (old, 61%; new, 97%; $P < 0.001$; 95% CI, 26.4–52.6%). Despite the above differences, an overall assessment involving all questions failed to show a significant improvement with the new consent form (old, 57%; new, 67%; $P = 0.264$; 95% CI, –35.6% to 12.6%).

Discussion and Conclusions: The new consent form resulted in improvement in some, but not all, aspects of consent and no question reached the ideal standard of 100%. We suggest a formatted consent form for procedures in conjunction with additional information.

Key words: Informed consent – Questionnaire – Elective surgery – Great Britain

Doctors have an ethical and legal responsibility to provide patients with adequate information when obtaining informed consent. Failure to do so may leave a doctor liable to criminal offences such as battery and action by their professional body. In 1995, a consultant anaesthetist was charged with failure to obtain informed consent and assault by the General Medical Council after the insertion of a suppository without specific pre-operative warning.¹ In the UK, there are no statutes outlying the general principles of obtaining informed consent. However, validity of consent

requires a mentally competent patient, the delivery of adequate information, and a voluntary decision on behalf of the patient. Besides the legal aspects of informed consent, ethical issues such as the moral obligation and duty of care to the patient are of importance and failing to give adequate information may breach these responsibilities.

The importance of patient-focused consent emerged following the Bristol Royal Infirmary Inquiry. In 1998, the British Medical Association (BMA) undertook an investigation into the practice of seeking patients' consent. Since

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Table 1 Patient questionnaire

1.	Have you been told the name of the medical problem you are having treated today?
2.	Do you know the likelihood of success and benefits of the operation?
3.	What is the purpose of the operation?
4.	What information did you receive about the operation?
5.	Have you been told what will happen after the operation?
6.	Were other treatments discussed with you?
7.	Were you given information about complications or problems that could happen from the operation?
8.	Do you know the name of the consultant orthopaedic surgeon who is in overall charge of your care?
9.	Were you told that trainee surgeons might be performing your operation under consultant supervision?
10.	Did you know you are allowed to change your mind about whether to have the operation right up to the last minute?
11.	Did you know you have the right to get a second opinion about your treatment?

then, the BMA has been urging a reform in the whole process of obtaining consent because of its inadequacy. The Department of Health in conjunction with several organisations issued guidelines on consent and introduced a new consent form in April 2002. This new consent form has been implemented throughout England since October 2002.

This prospective study was undertaken to quantify the quality of patient consent and compare the efficacy of the new consent form after its introduction with the old consent form.

Patients and Methods

This study was undertaken in the orthopaedic pre-assessment clinic at Glenfield Hospital, Leicester, UK. Patients are seen in the pre-assessment clinic 2 weeks prior to their surgical procedure by junior surgical staff. Two groups of 100 patients were recruited before and after the introduction of the new consent form. After signing the consent form, patients were asked to complete a questionnaire based on the General Medical Council guidelines. The questionnaires were given to patients sequentially. Doctors obtaining consent in the pre-assessment clinic were not informed of the study. There were 11 questions (Table 1) that asked about the surgical

Table 2 Questions that favoured the new consent form

	Consent form		P	95% CI
	New (%)	Old (%)		
Success rate	97	81	< 0.001	7.2–24.4
Postoperative course	97	56	< 0.001	30.0–51.2
Name any complication	67	28	< 0.001	26.4–52.6
Information source				
Doctor	93	34	< 0.001	46.7–68.9
Nurse	67	21	< 0.001	33.3–58.3

procedure, surgical team, and alternatives such as the discussion of other treatments and seeking a second opinion.

The analysis involved expressing each question as a percentage of positive responses and an overall assessment giving each question an equal weighting.

Results were analysed using the chi-square and Mann-Whitney tests.

Results

The response rate for any one question in our study ranged from 91% to 99%. Four of the 11 questions favoured the new consent form (Table 2). When asked about the likelihood of success and benefits of the surgical procedure, 81% of patients within the old consent form group were aware compared to 97% of patients within the new consent form group (χ^2 , 12.56; P < 0.001; 95% CI, 7.2–24.4%). Of patients within the old consent form group, 56% were aware about the postoperative course compared to 97% of patients within the new consent form group (χ^2 , 45.13; P < 0.001; 95% CI, 30.0–51.2%).

The ability to name complications that had been discussed with patients varied considerably. Of patients in the old consent form group, 28% were able to name one or more complication compared to 67% of patients in the new consent form group (χ^2 , 47.13, P < 0.001; 95% CI, 46.7–68.9%). The four most frequently remembered complications in the new consent form group were infection (69%), thromboembolism (48%), bleeding (18.5%), and death (5%). The source of information about the procedures for the patients had changed with the new consent form. The key sources were the doctor and nurse in the pre-assessment clinic, whereas, previously the doctor in the out-patient was the key source. Amongst the two groups, 34% and 21% of patients in the old consent group received information from the doctor and nurse in the pre-assessment clinic, respectively, compared to 93% and 67% of patients in the new consent group (χ^2 , 53.50; P < 0.001; 95% CI, 46.7–68.9% and 33.3–58.3%). Electronic sources played a very little part for the vast majority of

Table 3 Questions that scored poorly in both consent forms

	Consent form		P	95% CI
	New (%)	Old (%)		
Trainee operating	15	12	0.520	−6.7 to 12.5
Other treatments	25	24	0.934	−9.8 to 15.2

patients regardless of the new consent form. Of patients in the old consent form group, 3% used the internet as a source of information compared to 5% of patients in the new consent form group.

Some aspects of consenting scored poorly before and after the introduction of the new consent form (Table 3). These included questions about a trainee performing the surgical procedure under consultant supervision and the discussion of other treatment modalities. Patients' awareness of a trainee performing the procedure was 12% in the old consent form group compared to 15% in the new consent form group (χ^2 , 0.415; $P = 0.520$; 95% CI, −6.7% to 12.5%). The discussion of other treatment options was 24% in the old consent form group compared to 25% in the new consent form group (χ^2 , 0.007; $P = 0.934$; 95% CI, −9.8% to 15.2%).

The overall assessment involving all 11 questions showed that the new consent form improved consent by 10% from 57% to 67% ($P = 0.264$; 95% CI, −35.6% to 12.6%).

Discussion

Informed consent prior to surgical procedures has become an issue of great debate. Methods of obtaining valid informed consent have been investigated in several previous studies. The introduction of the new consent form by the Department of Health has improved matters by 10%, although this was not statistically significant in our 200 patient study. No question in our study achieved the ideal standard of 100%. Any improvement in consenting is important and we need to continue to investigate avenues that may improve the process of consenting and patient understanding. Patient understanding and improved consenting does, however, come at a price. In our study, we noted the time taken to consent a patient with the new consent form was greater than the old consent form. Although we did not specifically measure the time taken, we estimate the new consent form took at least twice the time. We would recommend that any future assessment of consenting include measurement of the time taken.

The recollection of information given by doctors to patients at the time of consenting is usually poor and can be improved. A survey conducted by Byrne *et al.*² showed that signing a consent form does not guarantee that a patient is fully aware of the exact nature of the treatment.

Methods of educating patients have been investigated. A small study by Askew *et al.*³ showed that patients given an information sheet before an operation had a better recall of their operations compared to controls. However, Hutson and Blaha⁴ showed that after an operation, a patient's recollections are not reliable about the risks and benefits, despite pre-operative instruction and tutoring. Despite these results, they believe that a tutoring session may only increase recall at the time of signing the consent form. Educational techniques such as teaching patients to recite risks and providing written information sheets have also been studied. White *et al.*⁵ showed that patients' recall was better by teaching patients to recite the procedure risks to the doctor as part of obtaining informed consent. Conversely, Langdon *et al.*⁶ showed that patients' recall improved with providing written information sheets as part of the informed consent process.

Other important aspects of informed consent that need to be considered include the information provided to patients and their understanding of medical terms. A prospective study conducted by McCormack *et al.*⁷ showed that many patients willingly consent to procedures that they do not fully understand. The assumption that patients understand simple medical terms is incorrect and this adds to the process of poor informed consent. The information given to patients is also variable and differs within and between doctor grades. A study performed by McManus and Wheatley⁸ showed a lack of consensus from surgeons to which risks are significant to discuss with patients in a particular procedure. Soin *et al.*,⁹ in a pilot study, also demonstrated the inconsistency of knowledge amongst junior surgical staff.

The General Medical Council has provided the medical profession with guidelines on providing good consent with the use of written material and aids such as visual and others. These aids provide the patient with information that can be kept and referred to at a later date and improves the understanding of the procedure to be undertaken. However, doctors, in obtaining consent from patients, may forget certain aspects of a procedure or complications and not discuss this in the consenting process.

Conclusions

We believe that a formatted consent form for procedures in conjunction with written, audio, or video information will ensure no omissions of aspects of consent and provide the patient with details of a procedure that can be kept for future reference.

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