Assessing the adequacy of procedure-specific consent forms in orthopaedic surgery against current methods of operative consent

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ABSTRACT

INTRODUCTION This is an audit of patient understanding following their consent for orthopaedic procedures and uses information on new Orthoconsent forms endorsed by the British Orthopaedic Association as the set standard. The objectives were to: (i) assess whether patients' understanding of knee arthroscopy (KA) and total knee replacement (TKR) at the point of confirming their consent reaches the set standard; and (ii) to ascertain whether issuing procedure-specific Orthoconsent forms to patients can improve this understanding.

SUBJECTS AND METHODS This was a prospective audit using questionnaires consisting of 26 (for KA) or 35 (for TKR) questions based on the appropriate Orthoconsent form in a department of orthopaedic surgery within a UK hospital. Participants were 100 patients undergoing KA and 60 patients undergoing TKR between February and July 2008. Participants were identified from sequential operating lists and all had capacity to give consent. During the first audit cycle, consent was discussed with the patient and documented on standard yellow NHS Trust approved generic consent forms. During the second audit cycle, patients were additionally supplied with the appropriate procedure-specific consent form downloaded from <www.orthoconsent.com> which they were required to read at home and sign on the morning of surgery.

RESULTS Knee arthroscopy patients consented with only the standard yellow forms scored an average of 56.7%, rising to 80.5% with use of Orthoconsent forms. Similarly, total knee replacement patients' averages rose from 57.6% to 81.6%.

CONCLUSIONS Providing patients with an Orthoconsent form significantly improves knowledge of their planned procedure as well as constituting a more robust means of information provision and consent documentation.

KEYWORDS

Informed consent – Consent documentation – Orthopaedic surgery – Audit – <www.orthoconsent.com>

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Consent forms currently used in many UK National Health Service Trusts for surgical procedures are typically generic documents which leave blank spaces for pertinent information to be added by hand but are devoid of any explanation relating to the specific procedure being performed. Despite a comprehensive verbal explanation by the surgeon, the reality of time constraints within out-patient clinics often limits the extent to which these forms are completed and, unfortunately, increasing numbers of hospital trusts and individual surgeons are threatened with litigation following a poor documentation of consent.³

Although, at present, verbal consent is the minimum legal requirement before most invasive procedures, written consent is preferred where significant risk is involved.^{1,2} The UK Department of Health (DH) guidelines¹ and the 2008 General Medical Council guidance on consent² state that valid consent revolves around sharing and discussing

information, rather than simply obtaining a written signature from a patient.¹ They also emphasise that side-effects, complications and other risks should be discussed and that a record of such dialogue should be made.^{1,2}

A recent article has described new procedure-specific consent forms for orthopaedic procedures,⁴ which are available online free-of-charge at <www.orthoconsent.com>. These Orthoconsent forms adhere to the parameters of consent recommended by the DH¹ and are intended to constitute a more efficient mode of information provision, with up-to-date descriptions of each procedure including its benefits, risks, and alternatives in simple layman's terms.⁴ The forms are also a means to reduce variability of hand-written, and often incomplete, consent forms with respect to any legal disputes. Orthoconsent has been endorsed by the British Orthopaedic Association (BOA) and the standard of information has been passed by their professional practices and medicolegal and patient liaison groups. It

is intended (for elective procedures at least) that patients read their form at home between their initial appointment with the surgeon and the pre-operation assessment clinics, and again between then and the morning of surgery, thus consolidating much of the information which is discussed in person with the patient. Hence, Orthoconsent forms are not intended to replace these discussions but to compliment them. As their signature on the day of surgery constitutes the patient's written consent, it denotes that they have indeed read the form and give their consent in the knowledge of the information.

In this audit, we assessed how closely our department was achieving the standard of complete patient understanding prior to either a knee arthroscopy (KA) or total knee replacement (TKR) procedure. During the first audit cycle, consent was discussed and then documented on traditional yellow forms supplied by the NHS Trust, in accordance with practice at the time, and patients were assessed using questionnaires on the morning of surgery. During the second audit cycle, Orthoconsent forms were supplied to patients in addition to the usual discussion. Patients were told that they must read the Orthoconsent form and would be required to sign it in order to confirm consent. Information recall was tested with the same questionnaires as used in the first cycle.

Subjects and Methods

Audit approval

Prior to the acquisition of patient data, the audit design was formally registered with, and approved by, the Maidstone and Tunbridge Wells Audit Department. No specific ethical approval was obtained for this audit.

Patients

A total of 160 patients who were fluent in spoken and written English and undergoing either knee arthroscopy (KA; $n = 100$) or total knee replacement (TKR; $n = 60$) at the Kent and Sussex Hospital from February to July 2008 were studied in this audit. All were deemed competent to give consent and none was known to suffer with any form of dementia or learning difficulties.

Consent

Consent was taken by senior members of the surgical team at specialist registrar level and above. All patients were consented initially at the out-patient clinic, involving explanation and discussion with the surgeon, and a traditional yellow consent form completed by hand (as was the authorised practice within the Trust). However, the information discussed and entered onto the generic yellow forms was entirely at the discretion of the consenting surgeon and no set list of complications or *aide-memoir* was provided in advance.

Patients had the opportunity to ask questions in the out-patient clinic, in the pre-operative assessment clinic and on the morning of surgery. A separate Arthritis Research Concern

(ARC) leaflet was provided to everybody at out-patient clinic and again at the pre-operative assessment clinic with the advice to read it thoroughly.

During the first audit cycle, 50 KA and 30 TKR patients gave their written consent on the traditional yellow consent form alone at the out-patient clinic and confirmed consent on the morning of surgery. During the second audit cycle, 50 KA and 30 TKR patients were consented with the yellow form but were also provided with the appropriate Orthoconsent form at the out-patient clinic and at the pre-operative assessment clinic. These patients were instructed, on both occasions, to read the document thoroughly and, on the morning of surgery, they confirmed consent for their procedure by signing the Orthoconsent forms as well as the traditional yellow consent form.

Questionnaires

Patients' knowledge of the KA and TKR procedures was assessed by means of a questionnaire developed by the authors and consisting of 26 questions for KA patients and 35 questions for TKR patients (see Appendices 1 and 2, published online only). Piloting of these questions on a few patients early on highlighted that some needed a subtle re-wording, such that specific answers rather than just a suggestible 'yes' or 'no' were required. The questions encompassed the majority of information on the equivalent Orthoconsent form and were kept constant between cycles.

The questionnaire was administered on the day of surgery. The purpose of the audit was explained to all participants and verbal consent was obtained before questioning. Questions were read aloud to the patients by one of the authors. Any issues raised by the questionnaires were discussed at the end of questioning. No patient withdrew their consent as a result of our questions and all were satisfied with their consent process overall.

As part of the questionnaires, patients were asked to list, in their own time, as many of the potential risks or complications of which they were aware to be associated with their planned procedure (see Tables 1 and 2). The risks or complications which a patient did not recall (but are written on the equivalent Orthoconsent forms) were then read to them and they were asked whether or not they were aware of the associated risk. If patients answered 'yes', they scored an extra mark. Every patient thus scored two totals: one before and another after prompting.

Standards

The set standard is information contained within the online procedure-specific consent forms endorsed by the BOA. These encompass the generic principles outlined in the UK DH¹ and General Medical Council² published documents on informed consent and include information on who can be expected to treat the patient, the type of anaesthesia, risks/complications, benefits of the procedure, alternatives to surgery and postoperative limitations.

Statistical analysis

The data were tabulated within a Microsoft Excel (2003) spreadsheet such that the overall percentage of accuracy, as well as the score for individual questions, could be calculated. Further statistical analysis was conducted within Microsoft Excel and began with the *f*-test to compare the variance of each group such that the appropriate unpaired

t-test function could be conducted. Data graphs were compiled in SigmaPlot. All data were collected confidentially in accordance with Data Protection Laws and Caldicott Principles.

Results

Knee arthroscopy patients

KA patients consented with only the yellow forms had a mean score of 11.3 for 26 questions (43.5%) before prompting for risk factors and 14.7 (56.7%) after prompting. The range of scores was 19.2–57.7% and 23.1–73.1%, respectively. Unpaired *t*-test analysis demonstrated a significant difference between these data sets ($P < 0.01$; Fig. 1).

After introduction of consent with both the traditional yellow form and Orthoconsent form, patients had a mean score of 16.2 for 26 questions (62.2%) before prompting for risk factors which unpaired *t*-test analysis demonstrated to be a significant increase from prompted patients consented without Orthoconsent forms ($P = 0.023$; Fig. 1). The mean score rose significantly ($P < 0.01$; Fig. 1) to 20.9 (80.5%) when Orthoconsent patients were prompted for risk factors. The range of scores was 38.5–88.5% and 65.4–100%, respectively. Mean percentages scored for each parameter of the questionnaire are shown in Appendix 1 (published online only).

Total knee replacement patients

TKR patients consented with only the yellow forms had a mean score of 13.4 for 35 questions (38.4%) before prompting and 20.2 (57.6%) after prompting. The range of scores was 14.3–65.7% and 28.6–82.9%, respectively. Unpaired *t*-test analysis demonstrated a very significant difference between these data sets ($P < 0.01$; Fig. 2).

In the second audit cycle, patients consented with both the traditional yellow form and Orthoconsent form had a mean score of 19.4 for 35 questions (55.5%) before prompting. This was significantly different from unprompted patients ($P < 0.01$; Fig. 2), consented with the yellow forms only. When Orthoconsent patients were prompted for risk factors, their mean scores rose to 28.6 (81.6%), significantly higher than other scores on unpaired *t*-test analysis ($P < 0.01$; Fig. 2). The range of scores was 37.1–71.4% and 65.7–94.3%, respectively. Mean percentages scored for each parameter of the questionnaire are shown in Appendix 2 (published online only).

Discussion

We have demonstrated that the level of patients' understanding of both KA and TKR procedures at the time of confirming consent was significantly improved by use of the procedure-specific consent forms available from <www.orthoconsent.com>.

Figure 1 Questionnaire scores for knee arthroscopy patients. Baseline scores for patients consented with the traditional yellow form (Yellow) were significantly better (*) when prompted for risk factors (Yellow+Pr). Following the addition of Orthoconsent forms to the consent procedure, patients' baseline scores (Ortho) rose significantly before (**), and again after prompting (Ortho+Pr) for risk factors (***).

Figure 2 Questionnaire scores for total knee replacement patients. Baseline scores for patients consented with the traditional yellow form (Yellow) were significantly better (*) when prompted for risk factors (Yellow+Pr). Baseline scores for Orthoconsent patients (Ortho) were also significantly greater than Yellow baseline (*) but no different to Yellow+Pr scores. However, prompting Orthoconsent patients for risk factors (Ortho+Pr) significantly increased their baseline scores (***).

In practice, achieving a standard of fully-informed consent is not straightforward. Patients vary considerably with respect to how much they want to know about their operation, the extent to which they are able to acquire extra information about it (such as books or internet resources) and how much they will actually remember factually at the point of confirming consent. The wide range of scores collected in all patient groups during this study indeed reflects these, perhaps inevitable, variables. Equally, doctors taking consent will not always give exactly the same information or be able to discuss some of the much rarer complications. A balance must be struck in which the procedure is explained along with its common and serious side-effects in a digestible format to the patient who must then decide whether to proceed in spite of the risks. These discussions should ideally be spread over several sessions,⁵ enable the patient to express any concerns they may have,⁶ and be documented thoroughly in their case notes. This is especially important for those patients who are keen to 'do what the doctor thinks best'. Although consent to surgery does ultimately rely on patients trusting in the expertise of their surgeons, consent is still only valid if the necessary information is disclosed. Medicolegal challenges arise when a patient experiences an adverse outcome and there is no documentary evidence to refute the claim that they were unaware of it as a risk. About 4% of surgical negligence claims settled by the Medical Defence Union between 1990 and 2000 were the result of inadequate consent.⁵

Orthoconsent forms available online at <www.orthoconsent.com> comprise a suitable level of information for patients, which is endorsed by the BOA. However, they are not intended to replace careful discussion between the surgeon and patient in out-patient clinics, pre-operative assessment clinics and on the morning of surgery, but to be used as an adjunct. They should be issued as soon as surgical management is indicated to enable patients to assimilate the relevant facts in between appointments. The forms have a reading age of 14 years and itemise the common, less common and rare side-effects.⁴ This is in line not only with advice from the General Medical Council,⁷ but also with what patients actually wish to know about their procedure.⁸ El-Wakeel and colleagues⁸ showed that amongst patients' most important considerations were major risks, alternative options, rank of surgeon performing the procedure, type of anaesthetic used and technical details of the operation. We have shown that Orthoconsent forms can increase patient understanding of all of these parameters and, in particular, awareness of all the risk factors mentioned. Our questionnaires were not intended to test recall of long lists of complications from memory and, as such, we felt it necessary to introduce the prompting score so that a fairer assessment of patients' actual knowledge could be realised. The questions also had to be worded carefully and required a specific response in order to avoid 'giving the answer away' or eliciting a string of unreliable 'yes/no' responses. Patients were approached within minutes of confirming consent and their overall scores thus reflect their knowledge at this crucial time.

Statistical tests were used on these scores to demonstrate just how effective the use of Orthoconsent forms was at meeting the audit standard, although we acknowledge that the analysis is subject to some bias. Audit cycles were, by definition, run in series rather than in parallel and patients would have been subject to their individual variations as discussed above. Patients consented at other NHS Trusts may also score differently on our questionnaires owing to alternative consent practices and modes of information provision. Despite the wide variation in scores, however, we have shown a clear improvement in patients' knowledge of the relevant procedure after the introduction of Orthoconsent forms at our Trust. This audit was not powered to provide data on cases which might lead to litigation but, to the authors' knowledge, none of the patients involved in this audit have since filed complaints.

Conclusions

By reinforcing relevant surgical information in simple terms, improving the formal record of consent, and constituting the document which must be signed as understood, Orthoconsent forms will enable patients to make more informed decisions and might reduce the number of successful medicolegal claims against orthopaedic surgeons. It will be interesting to establish in future studies whether different designs of Orthoconsent form, perhaps incorporating diagrams and symbols, can further improve their ability to improve the standard of patient understanding of surgical procedures.

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