Informed consent documentation for total hip and knee replacement using generic forms with blank spaces

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ABSTRACT

Purpose. To analyse informed consent documentation of 100 patients undergoing elective primary total hip replacement (THR) or total knee replacement (TKR) using generic forms with blank spaces.

Methods. Informed consent documentation of 57 men and 43 women (mean age, 54 years) undergoing elective primary THR (n=50) or TKR (n=50) using generic forms with blank spaces were analysed. The consent forms were explained to the patients mostly on the morning of surgery by a consultant surgeon (n=21), specialist registrar (n=23), or senior house officer (n=56). Data on patient demographics, planned procedure, benefits and risks of surgery, and the grade of the surgeon were collected.

Results. In the consent forms for THR, the most frequently documented complications included infection (98%), bleeding (96%), deep vein thrombosis (94%), nerve damage (94%), and pain (90%). Common complications (2–5% of occurrence) that were less frequently documented included prosthesis wear or loosening (76%), dislocation (68%), and leg length discrepancy (62%). In the consent forms for TKR, the most frequently documented complications included infection (96%), bleeding (92%), deep vein thrombosis (90%), nerve damage (90%), and blood vessel damage (90%). Common risks (2–5% of occurrence) that were less frequently documented included pain (84%), prosthesis wear or loosening (54%), and knee stiffness (40%).

Conclusion. Documentation of all clinically significant complications was insufficient when generic informed consent forms with blank spaces were used. The use of standardised procedure-specific consent forms is recommended.

Key words: arthroplasty, replacement, hip; arthroplasty, replacement, knee; complications; informed consent

INTRODUCTION

Consent is required before any investigation or treatment.¹ According to the United Kingdom
Department of Health guidelines\(^2\) and General Medical Council guidance,\(^3\) valid consent is a process of sharing and discussing information with patients so that they can make an informed decision about their treatment. Legally, informed consent must contain a discussion of the diagnosis and the proposed procedure, the alternative therapy, the risks and benefits of surgical intervention, and the prognosis if no intervention is pursued.\(^4,5\) Verbal consent is the minimum legal requirement; written consent is preferred.\(^2,3\)

In most trusts, consent forms are usually generic documents with blank spaces. There is no further information related to the specific procedure or treatment proposed.\(^6\) Although comprehensive verbal explanation is usually given in out-patient clinics by the surgeon, the consent forms are usually completed in the morning of the planned procedure by less experienced junior doctors.\(^6,7\) This is due to the increasing work load and time constraints in out-patient clinics. Poor documentation of consents and failure to inform patients about serious risks of surgery may result in litigations against hospital trusts and individual surgeons.\(^6,8\)

To improve patient understanding and comprehension, efforts have focused on intensive education, written handouts, or video presentations,\(^4,9-11\) as well as the use of standardised pre-written procedure-specific consent forms,\(^4\) such as those available in www.orthoconsent.com. Patient knowledge and understanding of the procedures improve significantly after using such standardised consent forms.\(^6,12\) This study analysed informed consent documentation of 100 patients undergoing elective primary total hip replacement (THR) or total knee replacement (TKR) using generic forms with blank spaces.

**MATERIALS AND METHODS**

Between February and May 2011, informed consent documentation of 57 men and 43 women (mean age, 54 years) undergoing elective primary THR (n=50) or TKR (n=50) using generic forms with blank spaces were analysed. The consent forms were explained to the patients mostly on the morning of surgery by a consultant surgeon (n=21), specialist registrar (n=23) or senior house officer (n=56).

Data on patient demographics, planned procedure, benefits and risks of surgery, and the grade of the surgeon were collected. Documentation of all clinically significant complications listed in the British Orthopaedic Association\(^12\) was evaluated.

**RESULTS**

Data on patient demographics and the planned procedures were documented in 100% of the consent forms, whereas information about benefits and risks of surgery and types of anaesthesia was documented in 89% and 92% of the consent forms, respectively. Only 6% of patients received their copy of the consent form. Documentation of all clinically significant complications listed in the British Orthopaedic Association was insufficient (Table).

In the consent forms for THR, the most frequently

<table>
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<tr>
<td><strong>Documentation of complications of total hip/knee replacement in 100 patients</strong></td>
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<tr>
<td><strong>Complications (rate)</strong>*</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Infection (1–2%)</td>
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<tr>
<td>Bleeding (2–5%)</td>
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<tr>
<td>Deep vein thrombosis (2–5%)</td>
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<tr>
<td>Nerve damage (&lt;1%)</td>
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<td>Blood vessel damage (&lt;1%)</td>
</tr>
<tr>
<td>Pain (2–5%)</td>
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<tr>
<td>Pulmonary embolism (&lt;1%)</td>
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<td>Altered wound healing (&lt;1%)</td>
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<tr>
<td>Prosthesis wear/loosening (2–5%)</td>
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<tr>
<td>Dislocation (2–5% for THR, &lt;1% for TKR)</td>
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<tr>
<td>Altered leg length (2–5% for THR, &lt;1% for TKR)</td>
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<tr>
<td>Bone fractures (&lt;1%)</td>
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<tr>
<td>Death (&lt;1%)</td>
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<tr>
<td>Knee stiffness (2–5%)</td>
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* 2–5% indicates common, 1–2% less common, and <1% rare
documented complications included infection (98%), bleeding (96%), deep vein thrombosis (94%), nerve damage (94%), blood vessel damage (94%), and pain (90%). Common complications (2–5% of occurrence) that were less frequently documented included prosthesis wear or loosening (76%), dislocation (68%), and leg length discrepancy (62%).

In the consent forms for TKR, the most frequently documented complications included infection (96%), bleeding (92%), deep vein thrombosis (90%), nerve damage (90%), and blood vessel damage (90%). Common risks (2–5% of occurrence) that were less frequently documented included pain (84%), prosthesis wear or loosening (54%), and knee stiffness (40%).

Complications that were not listed in the British Orthopaedic Association but were nonetheless documented in the consent forms included the need for revision surgery (n=21), strokes (n=7), myocardial infarction (n=12), anaesthetic complications (n=58), and pneumonia (n=13).

In 17 of the consent forms, one or more abbreviations such as ‘CVA’ instead of cerebrovascular accident, ‘MI’ instead of ‘myocardial infarction’, and ‘DVT/PE’ instead of ‘deep vein thrombosis’ and ‘pulmonary embolism’ were used.

DISCUSSION

Legal proceedings involving medical negligence claims for alleged failure to provide adequate information about the risks of surgery are primarily governed by the Bolam principle: medical practitioners are not guilty of negligence if they have acted in accordance with accepted best practice of a body of responsible and skilled medical opinion. The essential principles of informed consent are that patients are competent and have received sufficient information to make their decision about the proposed treatment without duress or external influence. In most malpractice lawsuits against orthopaedic surgeons, patients argue that they suffered from a complication about which they had not been informed prior to the surgery. This may have been forgotten owing to the lengthy waiting lists for arthroplasty surgeries. Documentation of these complications during the consent process provides evidence to defend the breach of duty allegation. However, there is large variability in the documentation of complications of surgery.

In our study, not all the common complications were documented in all consent forms. Senior house officers completed 56% of the consent forms, but they have limited experience in orthopaedics and may not be able to explain all complications adequately. Although pre-assessment clinics routinely provide supplementary literature, this cannot act as a proof of informed consent.

In 17 of the consent forms, one or more abbreviations were used, and patients might not understand them although explanations may have been given. Similar findings regarding the use of abbreviations have also been reported in a study for distal radial fractures. Standardised procedure-specific consent forms may reduce variability of hand-written, often incomplete, consent forms. One website (www.orthoconsent.com) provides such consent forms and is endorsed by the British Orthopaedic Association.

CONCLUSION

Documentation of all clinically significant complications was insufficient when generic informed consent forms with blank spaces are used. The use of standardised procedure-specific consent forms is recommended.

DISCLOSURE

No conflicts of interest were declared by the authors.

REFERENCES