Documenting informed consent in elective hip replacement surgery: a simple change in practice

Adequate documentation of informed consent is an important aspect of many doctors' work and failings in this area may result in patient dissatisfaction or litigation. In 2009 the documentation of risks and complications on the consent forms of patients undergoing primary hip replacement was audited at a specialist centre. Following this audit procedure-specific complication stickers were introduced in an attempt to improve the documentation of the consent process. This article discusses the results of a re-audit and aims to determine if this change in practice had resulted in any significant improvement in documentation.

The consent forms of 100 consecutive patients undergoing primary total hip replacement were re-audited using a standardized data collection sheet in order to close the audit loop. The re-audit found that 86 consent forms used the procedure-specific complication sticker to list the potential complications associated with a total hip replacement. Statistically significant improvements in the documentation of fracture, neurovascular damage, leg length discrepancy, failure, premature loosening, death, medical complications, ongoing pain, stiffness, wound healing problems and other were all seen in the 2012 re-audit in comparison to the 2009 audit ($P<0.0001$).

The cheap and simple introduction of procedure-specific complication stickers in order to help surgeons document the process of informed consent has resulted in significant improvements in practice. In the context of patient-focused care and satisfaction in the NHS, it is vital that simple measures such as the introduction of procedure-specific complication stickers are embraced.

Consent plays a large role in the everyday life of a doctor. Guidelines in the UK regarding informed consent mean that doctors should tell patients about any frequent or serious complications that could result from an operative procedure (Wheat, 2005; Cole, 2008; General Medical Council, 2008). The General Medical Council stipulates that 'in order to have an effective discussion with patients about risk, you must identify the adverse outcomes that may result from the proposed options' and 'you must tell patients if an investigation or treatment might result in serious adverse outcomes, even if the likelihood is small'. It is therefore good medical practice to address these points when obtaining informed consent from a patient.

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Consent is only considered legally binding if it is 'informed' and courts now expect that the 'reasonable' doctor would notify the patient of the frequent and serious risks associated with the relevant surgical procedure; if a patient can argue in a court of law that he/she would not have undergone a particular elective surgical procedure had he/she known about a specific complication that he/she has subsequently encountered, then it is arguable that the patient has a good chance of a successful legal claim (Dyer, 2004). Studies have shown that patient recall of the information at the consent interview is generally poor (Ashraff et al, 2006); even if a risk is discussed, if it was not documented then it might as well have not been discussed.

Total hip replacements are the most common orthopaedic surgical procedure in the UK, and one of the most successful and cost-effective (Learmonth et al, 2007). Data show 76759 hip replacements were performed in the UK in 2010; 68907 of these were primary and 7852 revisions. This is a 6% increase from the previous year (National Joint Registry, 2011), showing an increasing demand. The British Orthopaedic Association's online form (www.orthoconsent.com/documents/THR(4)(2).doc) for total hip replacement consent includes common risks (2–5%), less common risks (1–2%) and rare risks (<1%). The national total hip replacement outcome study reported the incidence of these risks as shown in *Table 1* (Royal College of Surgeons of England and British Orthopaedic Association, 2000).

In 2009 an audit at the Nuffield Orthopaedic Centre examined the extent to which fully informed consent was documented for patients undergoing primary total hip replacement (Dean et al, 2009). Fully informed consent was taken to include discussion of all the risks or complications noted on the British Orthopaedic Association online total hip replacement consent form, and evidenced by documentation on the consent form.

This audit found that the documentation of risks of surgery was extremely variable. Documentation of the risks of

Table 1. The incidence of complications within 12 months of primary total hip replacement

Risk of surgery	Incidence (%)
Sciatic palsy	0.1
Leg length discrepancy	12.2
Dislocation	2.7
Failure, loosening or revision	2.7/0.4/0.6
Wound problems	0.9
Deep infection	1
Deep vein thrombosis	2.9
Pulmonary embolus	0.8
Medical (myocardial infarction, cerebrovascular accident or lower respiratory tract infection)	1.5
Death at 3 months	<1
Limp	26.3
Ongoing pain	11

From Royal College of Surgeons of England and British Orthopaedic Association (2000)

deep vein thrombosis (97%), pulmonary embolus (92%), infection (98%) and dislocation (97%) approached 100% of the consent forms audited. However, the documentation of other risks of surgery such as fracture (35%), leg length discrepancy (75%), nerve injury (71%), vascular injury (70%) and loosening or need for revision (62%) was not as comprehensive. Complications that were not as comprehensively documented included risk of fracture and leg length discrepancy, which is considered by the British Orthopaedic Association to be a more common risk, and one of the highest reported complications of 2009–10.

Interestingly some of the complications listed by surgeons on the consent form were not included in the British Orthopaedic Association guide consent form. These included complications such as limp, stiffness and anaesthetic complications.

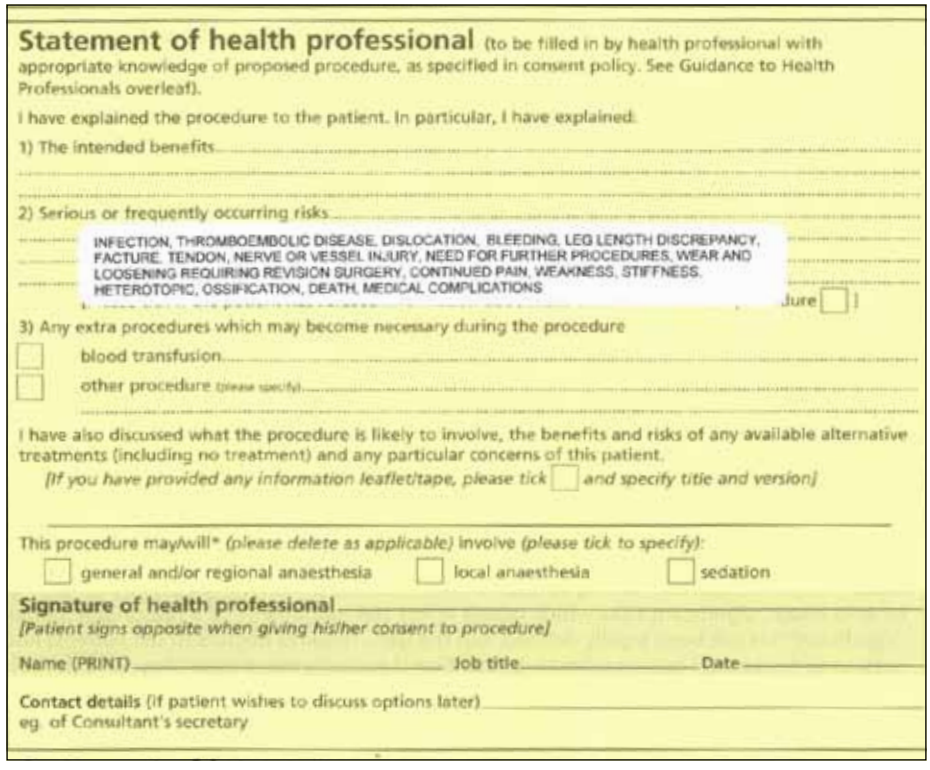
The audit resulted in the introduction of procedure-specific complication stickers listing all the surgical complications for surgeons to place on the consent forms and improve the documentation of the consent process. The procedure-specific complication sticker included all the common, less common and rare complications listed by the British Orthopaedic Association and deemed important by orthopaedic surgical specialists (*Figure 1*).

The introduction of procedure-specific complication stickers was included in the induction procedure for new doctors in the authors' NHS Trust to ensure the change in practice, and improved documentation of consent, would be sustained with the rotation of surgical trainees.

This study re-audited the adequacy of the documentation of the consent process following this change in departmental protocol introducing procedure-specific complication stickers, 3 years previously, and therefore closed the audit loop.

Materials and methods

A prospective audit of consent forms of 100 consecutive primary total hip replacements was performed over a 2-month period from April to May 2012. The same standardized data collection sheet as the original audit was used. The institution is a tertiary referral centre and teaching hospital where over 600 primary total hip replacements are performed every year.


Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy. See Guidance to Health Professionals overleaf).

I have explained the procedure to the patient. In particular, I have explained:

1) The intended benefits

2) Serious or frequently occurring risks

INFECTION, THROMBOEMBOLIC DISEASE, DISLOCATION, BLEEDING, LEG LENGTH DISCREPANCY, FACTURE, TENDON, NERVE OR VESSEL INJURY, NEED FOR FURTHER PROCEDURES, WEAR AND LOOSENING REQUIRING REVISION SURGERY, CONTINUED PAIN, WEAKNESS, STIFFNESS, HETEROTOPIC, OSSIFICATION, DEATH, MEDICAL COMPLICATIONS

3) Any extra procedures which may become necessary during the procedure

blood transfusion

other procedure (please specify)

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

[If you have provided any information leaflet/tape, please tick and specify title and version]

This procedure may/will* *(please delete as applicable)* involve *(please tick to specify)*:

general and/or regional anaesthesia local anaesthesia sedation

Signature of health professional

[Patient signs opposite when giving his/her consent to procedure]

Name (PRINT) Job title Date

Contact details (if patient wishes to discuss options later) eg. of Consultant's secretary

Figure 1. The procedure-specific complication sticker introduced to improve consent documentation.

There is a dedicated preoperative admission clinic which all patients attend before their admission; the consent forms are completed here as well as any necessary preoperative medical tests and documentation. The consenting surgeons are all fully trained to undertake a primary total hip replacement unsupervised. The preoperative admission clinic involves the whole multidisciplinary team including surgeons, junior medical staff, nursing staff, physiotherapists and occupational therapists.

The audit included only patients undergoing primary total hip replacement. All patients were adults. The patient details, the grade of consenting doctor, the aim of surgery, and the serious and frequent risks of surgery that were documented on the consent form were recorded. The patients and surgeons involved were not aware that the documentation of the consent process was being re-audited. The authors hypothesized that the introduction of the standardized stickers would have had no significant effect upon the adequacy of the documentation of consent.

Results

Table 2 shows the results of the re-audit in 2012 alongside the results from the initial audit in 2009. The results for each specific risk of surgery were tabulated on 2 by 2 contingency tables and *P* values were calculated by two-tailed χ^2 tests.

The re-audit found that 86 consent forms used the procedure-specific complication sticker to list the potential complications associated with a total hip replacement. In cases in which a sticker was used 100% of the risks were documented. Of the 14 cases in which a sticker was not used the complications were not fully documented; complications such as wound healing problems (86%), stiffness (86%), ongoing pain (86%), death (86%) and other (limp, amputation or Girdlestone) (86%) were completely omitted in all 14 cases. Documentation of leg length discrepancy (100%), infection (98%), dislocation (98%), fracture (96%) and deep vein thrombosis or pulmonary embolus (96%) were more adequately documented.

Statistically significant improvements in the documentation of fracture, neurovascular damage, leg length discrepancy, failure or premature loosening, death, medical complications, ongoing pain, stiffness, wound healing problems and other were all seen in the 2012 re-audit in comparison to the 2009 audit ($P<0.0001$).

Table 2. Documentation of the risks of total hip replacement from 100 consecutive patients in 2009 and 2012

Risk of surgery	% Cases with specific risk documented on consent form		Included in BOA guidelines (BOA risk category)	*P* value (* shows significant values)
	2009	2012		
Fracture	35	96	Yes (<1%)	<0.0001*
Neurovascular damage	71	94	Yes (<1%)	<0.0001*
Leg length discrepancy	75	100	Yes (2–5%)	<0.0001*
Deep vein thrombosis or pulmonary embolus	95	96	Yes (<5%)	0.733
Infection	98	98	Yes (1–2%)	1.00
Dislocation	97	98	Yes (2–5%)	0.6506
Failure, loosening, revision	62	90	Yes (2–5%)	<0.0001*
Death	7	86	Yes (<1%)	<0.0001*
Anaesthetic or medical complications	31	90	No	<0.0001*
Ongoing pain	34	86	Yes (2–5%)	<0.0001*
Stiffness	27	86	No	<0.0001*
Wound healing problems	2	86	Yes (<1%)	<0.0001*
Other (limp, amputation or Girdlestone)	11	86	No	<0.0001*

BOA = British Orthopaedic Association

Discussion

These results show that the introduction of procedure-specific complication stickers has led to significant improvements in the adequacy of the documentation of consent in total hip replacement surgery following the closure of the audit loop. The results show that with use of a procedure-specific complication sticker all the serious complications of surgery are fully documented. It also supports the findings of the original audit that without the sticker it is rare for all the serious complications to be documented.

There is still room for improvement at the authors' institution and further work is necessary in order to increase the use of procedure-specific complication stickers to nearer 100%; the continued education and training of staff about the benefits of procedure-specific complication stickers will be a key part of further action in this area. A key benefit of procedure-specific complication stickers is the ease and cheapness with which they can be created for use relating to consent for other surgical procedures; procedure-specific complication stickers are already used for other procedures including total knee replacement at the authors' institution.

During the re-audit 14% of consent forms did not use the procedure-specific complication sticker. On these consent forms documentation of risks did not reach 100%. The complications most commonly missed included ongoing pain, wound healing problems, stiffness and pain. According to the British Orthopaedic Association all these complications, except ongoing pain, have an incidence of 1% or less in the 12 months following surgery. This demonstrates that the majority of the most frequently occurring complications were usually documented even in the absence of the procedure-specific complication sticker. However, ongoing pain was omitted on all consents that did not use the procedure-specific complication sticker, and other important complications such as infection, fracture or failure were also omitted, demonstrating poorer documentation of these consent processes.

This study only analyses what has been documented on consent forms. It does not guarantee that the complication has been discussed, and it does not analyse what has been documented elsewhere in the notes. This study also does not look at what the patient recalls from various discussions with the surgical team. Other studies have shown that patient recall of the information at the consent interview is generally poor (Langdon et al, 2002). Current practice could be improved by providing an information booklet which gives details of the complications listed. This would act as an aide memoire for patients, aid the consent discussion between the doctor and patient, and guarantee that information about all the complications listed had been provided.

Poor communication is often an important factor in the origins of complaints and litigation (Kinnersley and Edwards, 2008). A study by the American Association of Hip and Knee Surgeons showed that improving patient education and counselling during the process of obtaining consent could decrease the incidence of malpractice claims (Upadhyay et al, 2007). This also supports the use of an information booklet to improve communication (Bhattacharyya et al, 2005). Booklets could be offered to the patient in clinic at the time of booking the operation, allowing the patient to prepare any questions, and again on the day of surgery to reinforce the discussion of informed consent.

The use of procedure-specific complication stickers has been maintained for 3 years since they were introduced. This demonstrates sustainability. However, compliance was not 100% at re-audit. The use of procedure-specific complication stickers is included in the induction procedure for new doctors in the Trust to attempt to maintain compliance. It has

been suggested that instead of procedure-specific complication stickers the generic total hip replacement consent forms available on the British Orthopaedic Association website be used. The use of a generic consent form is limited in that it has no space for additional complications, which may be specific for individual cases, to be added or to mention the design of implant to be used. This may be relevant if an experimental implant or an implant with no 10-year survivorship data is used.

This cheap and simple change in practice, having closed the audit loop, has the potential to improve patient understanding, and therefore lower anxiety and improve satisfaction. The failure to mention the complications of surgery when obtaining informed consent not only results in patient dissatisfaction when complications occur, but may also result in the surgeon being held liable for a negligent failure to inform (Cleeve and Curry, 2006; Cole, 2008; Hassan, 2008).

The patient simply stating that he/she would have thought about the risk and postponed or cancelled the surgery can establish causation. In the case of the Chester ruling, if a patient experiences an adverse outcome, he/she need only demonstrate that he/she would not have gone ahead with a procedure if he/she had been informed of the risks at the time (Wheeler, 2006). In Chester, it was suggested that the patient would have sought a second opinion. It is therefore obligatory that doctors record in the notes exactly what complications have been discussed with the patient, as this is the crucial evidence to assist in defending a breach of duty allegation (Hassan, 2008).

Skene and Smallwood (2002) compared events in Australia to those in the UK, remarking on the trend of judges to apply a tougher standard to the information that doctors should give their patients. In the NHS both the number of claims in elective orthopaedic surgery and the associated legal costs are increasing year on year (Khan et al, 2012). In this context improving the documentation of the process of consent is in the interests of the providers of health care, as well as both doctors and patients.

The use of procedure-specific complication stickers in the consent process could be further improved by introducing patient information leaflets. As mentioned these are useful tools for the surgeon to improve the recall of the information given to the patient (Ashraff et al, 2006). The leaflets could also provide more detail about each individual complication, such as the probability of a complication, hence its risk. It is important to document when these leaflets are given to patients. The procedure-specific complication stickers could be adapted to include a tick box when a leaflet is given. However, the information leaflets should not be a substitute for the rigorous documentation of the risks associated with surgery.

Improvements could also be made to ensure 100% compliance with the procedure-specific complication stickers on consent forms, and ensure the change of practice is sustained in future years. The use of procedure-specific complication stickers is already included in the doctor's induction but it could also be introduced into the induction procedure for nursing staff. This would improve both the sustainability and compliance as the nursing staff, in the authors' trust, produce the admission packs for each patient the day before admission. These admission packs include the consent forms, along with anaesthetic charts, nursing admission documents and medical clerking forms.

Conclusions

Improving the documentation of the process of consent is in the interests of healthcare providers, doctors and patients. The use of a procedure-specific complication sticker will ensure more thorough documentation and act as an aide memoire for doctors guiding the consenting conversation, and a prompt for patients to ask questions before signing. Together this will improve the patient's understanding, satisfaction and expectations. BJHM

Conflict of interest: none.

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LEARNING POINTS

- The use of procedure-related complication stickers improves the documentation on consent forms for total hip replacements.
- Procedure-related complication stickers can act as an aide memoire facilitating the consenting conversation between doctors and patients.
- Thorough consent improves patient understanding, manages the patient's expectations and can result in the patient's experience being overall more satisfying.