Customizable pre-printed consent forms: a solution in light of the Montgomery ruling

ABSTRACT

Introduction: This article presents an audit cycle supported quality improvement project addressing best practice in the consent process for lower limb arthroplasty which takes into account the new standard in surgical consent and the importance of material risks.

Methods: 50 consecutive total hip and total knee replacement consent forms over a 3-month period were reviewed for legibility and completeness. Following the introduction of a new, pre-printed but customizable consent form the review process was repeated.

Results: The introduction of a customizable, pre-printed consent form that can be adjusted to reflect the individualized material risks of each patient increased legibility, reduced inappropriate human error variation and abolished the use of abbreviations and medical jargon.

Conclusions: When used as part of an extended consent process, the authors feel that the use of pre-printed but customizable consent forms improves legibility, completeness and consistency and also provides the ability to highlight those complications that are of particular importance for that patient to satisfy the new accepted standard in surgical consent.

The judgement from the Montgomery case in 2015 has encouraged further debate on what is considered best practice in consenting patients. To obtain informed consent from the legal perspective, the doctor has a duty to take reasonable care to ensure the patient is aware of any material risks in the recommended treatment (Montgomery v Lanarkshire Health Board, 2015). Material risks are those that 'a reasonable person in the patient's position' would attach significance to or those that the doctor is aware or should have known were pertinent to that particular patient. Before this judgement, the Bolam test was the benchmark. This was based on acting in accordance with a practice accepted as proper by a responsible body of similar professionals (Bolam v Friern Hospital Management Committee, 1957). The Montgomery case has resulted in a shift from expert medical opinion to the court of law determining what discussions are required for consent to be adequate.

Although consenting a patient is a process and the consent form itself is only a part of this process, it is used to record key elements of the discussion including the risks involved (Royal College of Surgeons of England, 2016). This can form an important part of the defence in medical negligence claims. This article presents a quality improvement process following an audit which demonstrated areas for improvement in the authors' unit's use of consent forms for hip and knee arthroplasty. Issues with illegibility and omitted risks led to the introduction of standardized consent forms that were deliberately designed to also allow tailoring of individual risks to account for the Montgomery ruling.

Method

A retrospective review of 50 consecutive consent forms used for total hip replacements and total knee replacements was performed between May and July 2015 (cycle 1). Standards based on guidance taken from the General Medical Council, Royal College of Surgeons of England, and the British Orthopaedic Association-endorsed website Orthoconsent.com were used to assess the adequacy of the consent forms. The three categories of standards assessed included:

1. Form information
2. Risks documented
3. Legibility (*Table 1*).

Legibility was assessed using the Legibility Index (Hongyi and Green, 2013) and Legibility score of the Adjusted Note Keeping and Legibility (ANKLe) scoring system (Dexter et al, 2008). Analysis was performed independently by two assessors and in cases of disagreement, a third assessor was brought in.

The findings from the audit were presented at the departmental audit meeting. The senior author (DK) designed a pre-printed standardized consent form and after further discussions with the hip and knee arthroplasty surgeons in the unit, a template for the department was agreed (*Figure 1*). The templates that were agreed upon did not include all the risks listed in the consent forms from Orthoconsent – for example, the authors did not feel that 'altered leg length' or 'joint dislocation' were risks that needed to be mentioned routinely for total knee arthroplasty (*Table 1*). In addition, 'need for further surgery' was included as a risk for both total hip replacement and total knee replacement. The wording of risks were agreed upon – for example, instead of 'nerve damage', the authors felt it was better to specify 'injury to nerves with foot drop'. There is additional space available on the consent forms for hand-writing should the surgeon feel the need to add further risks.

The consent form was designed such that risks could be tailored to the individual – a box was placed next to each risk to be ticked if the surgeon felt that the patient was at higher risk of developing that particular complication or if the patient placed particular importance to that particular risk

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Table 1. Core standards used for auditing

Element	Standard	Description
Form information	Patient demographics	'Ensure that all medical records… have the patient's identification details on them.' (Royal College of Surgeons of England, 2014) 'The record must include the name, date of birth and the address of the patient. The hospital number should be clear…' (British Orthopaedic Association, 2012)
	Consultant name	'…and the hospital and surgeon with responsibility for care of the patient should be named' (British Orthopaedic Association, 2012)
	Side of operation in full	'Ensure that the written consent… include the side to be operated on using the words 'left' or 'right' in full.' (Royal College of Surgeons of England, 2014)
	No abbreviations	'Documents you make to formally record your work must be clear, accurate and legible.' (Royal College of Surgeons of England, 2014) 'Ensure that all medical records are accurate, clear, legible, comprehensive and contemporaneous' (Royal College of Surgeons of England, 2014)
	No medical terminology	As for No abbreviations above
	Copy accepted by patient	'Sign the consent form at the end of the consent discussion, allowing the patient to take a copy for reference and reflection.' (Royal College of Surgeons of England, 2014)
	Information leaflet offered	'You must use… a consent form to record the key elements of your discussion with the patient. This should include… any written, visual or audio information given to the patient.' (General Medical Council, 2008) 'Where possible, you should provide written information to patients to enable them to reflect on and confirm their decision… This can include information such as patient leaflets…' (Royal College of Surgeons of England, 2014)
Risks documented		Risks listed in consent form of total hip replacement (www.orthoconsent.com/body2.asp?BodyPartID=4) and total knee replacement from 'OrthoConsent' (www.orthoconsent.com/body2.asp?BodyPartID=7)
Legibility		'Documents you make (including clinical records) to formally record your work must be clear, accurate and legible.' (General Medical Council, 2013)

(material risk). There is a note on the form to clarify that all risks are applicable but that the ticked boxes indicate particular importance of that risk. The template was incorporated into the hospital consent form packs at the printers and rolled out for use. A re-audit was performed between December 2016 and February 2017 (cycle 2).

Figure 1. New consent form template for (a) total hip replacement and (b) total knee replacement.

Results

The introduction of standardized consent forms led to the abolishment of use of abbreviations and medical terminology and improvement in completeness of patient demographics as well as documentation that patients were provided with leaflets or guides for their upcoming procedure (*Table 2*). There was no significant change in the provision of a copy of the consent form to the patient or in documentation of the consultant whose care the patient was under. Neither of these factors were incorporated into the pre-printed portions of the new consent forms and remain dependent upon case by case input.

When comparing the risks documented in the consent form during cycle 1, there was variation in practice for both total hip replacement and total knee replacement (*Tables 3* and *4*). In cycle 2, all risks were consistently documented.

The legibility in cycle 1 was variable – overall, 78% of consent forms were deemed legible but a large proportion were deemed illegible or legible with difficulty. All consent forms in cycle 2 were deemed legible (*Table 5*).

Table 2. Quality of form information between cycle 1 and 2

Form information	Cycle 1 (*n*=50)	Cycle 2 (*n*=62)
Patient demographics	44 (88%)	62 (100%)
Consultant name	13 (26%)	10 (16%)
Side of operation in full	50 (100%)	62 (100%)
Abbreviations	21 (42%)	0 (0%)
Medical terminology	27 (54%)	0 (0%)
Copy accepted by patient	9 (18%)	17 (27%)
Documented that information leaflet given to patient	12 (24%)	62 (100%)

Discussion

When using hand-written consent forms, legibility becomes an issue probably because the surgeon is pressed for time. In addition, risks can and have been completely omitted as a result of human error – for example, risks such as dislocation, infection and nerve damage were omitted on consent forms for a total hip replacement in cycle 1 of this audit. Pre-printed consent form stickers have previously been described in the literature (Isherwood et al, 2013). These stickers resulted in a similar improvement in capture of complications and completeness as found in this study. However, the use of a generic, catch-all device limits the ability to invidualize the consent process. The latest Royal College of Surgeons of England (2016) guidance states that 'use of preprinted proforma outlining risks of a specific procedure is not sufficient, as it is not tailored to the particular patient'. Although no specific mention is made about consent forms, it is probably safe to deduce that the same principles apply.

The pre-printed standardized consent forms the authors introduced address two issues:

1. The problems with illegibility and incompleteness associated with hand-written forms
2. The ability to tailor the risks to individuals in light of the Montgomery ruling.

The boxes next to each risk should also act as a reminder for the surgeon obtaining consent to discuss and individualize risks for each patient. In addition, without the need to hand-write, more time can be spent on the actual discussion with patients.

Table 3. Risks documented for total hip replacement in cycle 1 and cycle 2

Risks outlined in Orthoconsent for total hip replacement (wording used in the standardized consent forms, if different)	Cycle 1 (*n*=25)	Cycle 2 (*n*=32)
Blood clots (clots in blood vessels of legs and/or lungs)	24 (96%)	32 (100%)
Bleeding	22 (88%)	32 (100%)
Pain (pain, stiffness or swelling, persistent groin pain)	14 (56%)	32 (100%)
Prosthesis wear or loosening (failure to last)	15 (60%)	32 (100%)
Altered leg length (leg length discrepancy)	24 (96%)	32 (100%)
Joint dislocation (dislocation)	23 (92%)	32 (100%)
Infection	24 (96%)	32 (100%)
Altered wound healing (scarring)	15 (60%)	32 (100%)
Nerve damage (injury to nerves with foot drop)	22 (88%)	32 (100%)
Bone damage (fracture)	15 (60%)	32 (100%)
Blood vessel damage (injury to blood vessels)	19 (76%)	32 (100%)
Pulmonary embolism (clots in blood vessels of legs and/or lungs)	23 (92%)	32 (100%)
Death	13 (52%)	32 (100%)

Table 4. Risks documented for total knee replacement in cycle 1 and cycle 2

Risks outlined in Orthoconsent for total knee replacement (wording used in the standardized consent forms, if different)	Cycle 1 (*n*=25)	Cycle 2 (*n*=30)
Pain	17 (68%)	30 (100%)
Bleeding	9 (36%)	30 (100%)
Deep vein thrombosis (clots in blood vessels of legs and/or lungs)	25 (100%)	30 (100%)
Knee stiffness	13 (52%)	30 (100%)
Prosthesis wear (failure to last)	21 (84%)	30 (100%)
Infection	25 (100%)	30 (100%)
Pulmonary embolus (clots in blood vessels of legs and/or lungs)	21 (84%)	30 (100%)
Altered leg length*	1 (4%)	N/A
Altered wound healing (scar and skin numbness)	12 (48%)	30 (100%)
Joint dislocation*	3 (12%)	N/A
Nerve damage (injury to nerves with foot drop)	9 (36%)	30 (100%)
Bone damage (fracture)	19 (76%)	30 (100%)
Blood vessel damage (injury to blood vessels)	19 (76%)	30 (100%)
Death	11 (44%)	30 (100%)

** The risks 'Altered leg length' and 'Joint dislocation' were not included in the final template following discussion with the hip and knee arthroplasty surgeons*

The British Orthopaedic Association (2016) suggests that consent should be viewed as a process and advises not to formally obtain consent for elective surgery on the day of admission. There is a new focus on patient autonomy and the doctor's role is to support and advise (Robertson, 2016). This can only be done in the context of an

KEY POINTS

- The use of pre-printed consent forms improved legibility, completeness and consistency in the consent process.
- The pre-printed consent forms were designed to allow the surgeon to highlight those complications that would be of particular importance to that patient and constitute 'material risks'.
- To meet the new standard in surgical consent the consent forms must be used as part of an extended consent process and their customization represent an understanding of the priorities of the individual patient.

Table 5. Comparison of legibility between cycle 1 and 2

Form information		Cycle 1 (*n*=50)	Cycle 2 (*n*=62)
Mean Legibility Index		11.85	N/A
ANKLe score	Largely illegible	2%	0%
	Legible with difficulty	20%	0%
	Legible	38%	0%
	Legible and neat	40%	100%

ongoing relationship with greater dialogue between clinicians and patients, so the clinician can establish what the patient deems 'material' (Nicholas and Stephens, 2017). The clinician can then fulfil his/her responsibility to tell the patient what he/she should know and not what the clinician assumes the average patient should know. It is therefore important to acknowledge that the consent form is only part of this process and the entire consenting process needs to be clearly demonstrable and documented (*Figure 2*).

The General Medical Council (2008) guidance on recording decisions regarding consent state that 'key elements' of discussions with patients should be recorded in the medical records or on the consent form. Specifically, the information that was discussed (e.g. risks) and any 'written, visual, or audio information given to the patient' should be documented. This dialogue is often documented in the patient's letters rather than on the consent form. The authors recognize that this audit was unable to capture documentation pertinent to the consent process in the patient's notes or letters and the new consent form does not directly document this consent relationship. However, the ability to individualize the consent form to each patient is a marker of its ongoing development – the use of the tick boxes creates the opportunity to address, highlight and document the discussion of material risks for that particular patient. The authors also provide a patient guide on total hip replacement or total knee replacement to all patients and this is documented on the consent forms.

The field of consent is likely to evolve and develop and may involve practices such as testing a patient's understanding of the upcoming procedure, its risks, benefits and alternative options – perhaps if the patient does not meet certain criteria, he/she is re-tested until he/she is able to demonstrate understanding to a satisfactory level. The use of information technology is likely to result in the development of individualized documents (patient guides, consent forms) that can be specifically created for each patient. These steps may be used to further confirm that material risks to the patient have been addressed and their documentation serve as a written record of the patient's comprehension, retention and recall that this study is unable to capture.

With time, it is likely that the consent forms will be further refined in terms of the wording and risks based on the findings of the second cycle – for example, the risk 'dissatisfaction' is hand-written onto the new consent forms for total knee replacement for certain patients and is likely to be incorporated in version 2 of the form. This form is not perfect but is certainly an improvement from earlier practices – the authors believe that these consent forms are the first described in the literature that allow an element of individualization for patients.

Although not the complete solution to the challenges associated with consent the authors feel that the consent forms have been designed to cater to the individual and address some of the issues associated with use of standardized pre-printed consent forms. **BJHM**

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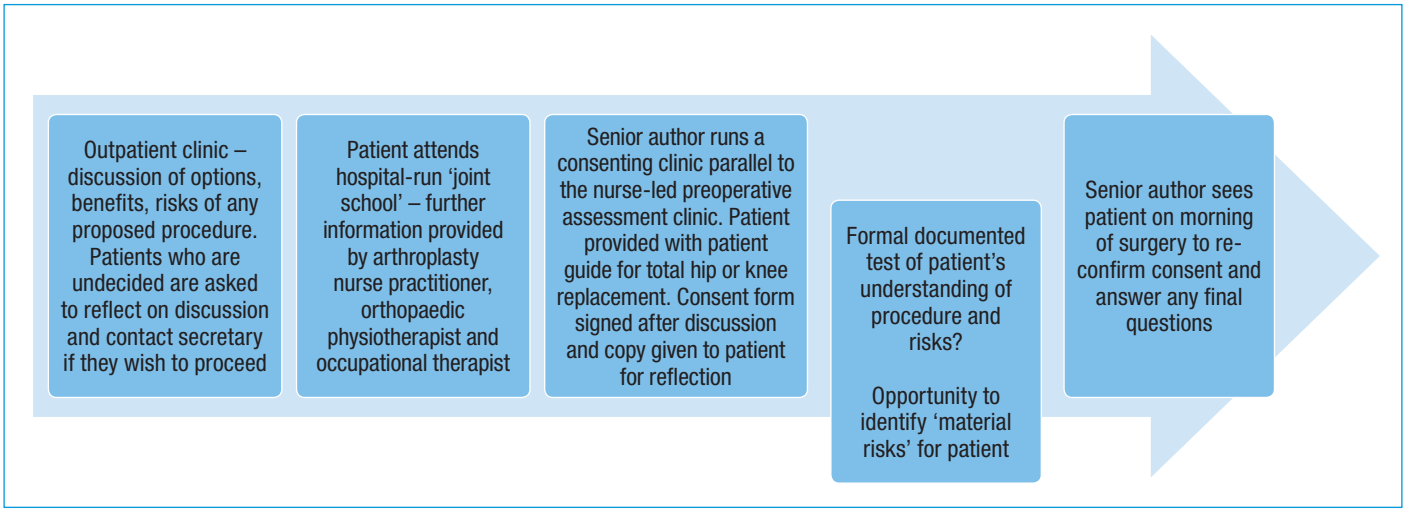
Figure 2. Flow diagram illustrating current consenting practice of senior author (DK). Is an additional step of formally testing a patient's understanding of the procedure and material risks required?



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