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QUALITY IMPROVEMENT

Do we achieve the Montgomery standard for consent in orthopaedic surgery?

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Abstract

Aims/Background The Montgomery v Lanarkshire Health Board (2015) case set a precedent that has driven the modernisation of consenting practice. Failure to demonstrate informed consent is a common source of litigation. This quality improvement project aimed to provide pragmatic guidance for surgeons on consent and to improve the patient experience during decision making.

Methods Elective orthopaedic patients were assessed and the quality of documented consent was recorded. Data were collected over two discrete cycles, with cycle 1 used as a baseline in practice. The following criteria were reviewed: grade of consenting clinician, alternative treatment options, description of specific risks, place and timing of consent and whether the patient received written information or a copied clinic letter. Cycle 1 results were presented to clinicians; a teaching session was provided for clinicians on the standard of consent expected and implementation of a change in practice was established with a re-audit in cycle 2.

Results There were 111 patients included in cycle 1, and 96 patients in cycle 2. Consent was undertaken mostly by consultants (54%). Specific patient risks were documented in 50% of patients in cycle 1 and 60% in cycle 2. Risks associated with a specific procedure were documented in 42% in cycle 1 and 76% in cycle 2, alternative options in 48% (cycle 1) and 66% (cycle 2). A total of 14% of patients in cycle 1 and 8% in cycle 2 had documented written information provision. Copied letters to patients was only seen in 12% of all cycles. Documentation from dedicated consenting clinics outperformed standard clinics.

Conclusions Highlighting poor documentation habits and refining departmental education can lead to improvements in practice. The use of consenting clinics should be considered and clinicians should individually reflect on how to address their own shortcomings. Other units should strongly consider a similar audit. This article provides stepwise advice to improve consent and specifics from which to audit.

Key words: Consent; Elective surgery; Medicolegal; Montgomery; Orthopaedic surgery; Quality improvement; Surgery; Trauma and orthopaedics

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Introduction

The process of acquiring and demonstrating informed consent for surgery has significantly evolved in modern times. The concept of medical paternalism has been phased out with a new era of informing the 'reasonable patient' of all management options and the individualised risk of each treatment. The Montgomery v Lanarkshire Health Board (2015) ruling paved the way for the evolution in UK consenting practice. The new method involved developing a rights-centred approach, wherein the autonomy to decide between all available treatment options rested with the informed patient. Following on from this, the Thefault v Johnston (2017) case highlighted the need for clinicians to provide 'adequate space and time' to consider the information before any surgery was undertaken. The aim of this quality improvement project was to establish the current consenting practice across a range of clinicians and to identify key areas to drive the quality up to the Montgomery standard.

Methods

This quality improvement project was undertaken at a university hospital trust with both elective and acute orthopaedic surgery performed across two sites. The trauma and

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orthopaedic service is delivered by 14 consultants who provide all aspects of orthopaedic care except for limb reconstruction, orthopaedic oncology and spinal surgery. This trust is representative of the typical case complexity undertaken at district general hospitals across the UK.

The hospital has an electronic system for storing all patient records, but the consent forms are physical documents. Clinicians use bespoke consent forms for high-volume procedures and a generic form that is used when the bespoke forms are not considered appropriate. Specific procedural risks can be recorded on the consent form as well as the individualised risks for each patient (eg a patient with diabetes will have a higher risk of infection).

Only elective procedures were included in this study, as this gave a more uniform representation of practice. Patients who lacked capacity to consent were excluded because of the intrinsic difficulties of demonstrating an evolving conversation around consent.

This quality improvement project was assessed through two cycles of data collection, each spanning 3 weeks. Consenting clinicians were blinded to the timing of the snapshots to reduce the Hawthorne effect (a known confounding consequence that occurs when the participants are aware of being assessed and modify their behaviour as a result). The following criteria were selected in order to demonstrate consenting practices within the trust. Not all criteria are mandatory, but many of them are considered as excellent practice in modern consenting, especially for complex preoperative discussions (Birch and Todd, 2020).

The criteria included:

1. Grade of consenting clinician
2. Type of surgery
3. Whether a clear diagnosis was recorded
4. If all alternative treatment options had been explored, including non-operative
5. If any specific procedural risks had been discussed (in clear language)
6. Whether patient-specific risk factors had been explained
7. If the patient had consented in the clinic
8. Provision of written information to supplement discussions
9. Employment of a dedicated ‘consenting’ clinic
10. The practice of copying the consenting letter to the patient

If any of the criteria mentioned above were not specifically documented, then it was taken as having not been discussed with the patient, in accordance with the Good Medical Practice guidelines (General Medical Council, 2013).

The first cycle of results was presented at a local departmental audit meeting, followed by the dissemination of written guidance from the Royal College of Surgeons following the Montgomery case (Royal College of Surgeons, 2016). The educational intervention used for this quality improvement project included a template for an ‘ideal standard’ of letter was created, which was then supplied to all consenting clinicians. A poster was also produced highlighting specific points that should be included in the consent letter and was displayed in clinic areas. Further departmental education of consenting standards was delivered by the authors during departmental teaching sessions. This included giving an overview of the Montgomery case, providing an ‘ideal consent’ letter example and discussing cases.

Results

The first cycle (C1) of data collection included 111 patients and the second cycle (C2) included 96 patients. The study assessed the consenting habits of 14 consultants’ elective practice. Consent was taken by a variety of clinicians (Figure 1), but most of the consenting (54%; *n*=119) was carried out by consultants in all cycles. There was no evidence of a variation in the quality of consenting according to seniority of the consenting clinician; however, consultants were responsible for some of the poorest ‘quality’ letters.

There was a wide variety of elective procedures covered across both cycles (Table 1). The most common procedure was major joint arthroplasty at 33% (*n*=69).

Documentation of surgical alternatives (Figure 2) was discussed in less than half of the cases in C1 (48%). Some of the letters had a vague mention of other management options, which included phrases such as: ‘alternative options have been exhausted’. There was a modest improvement in documentation following the educational programme, in

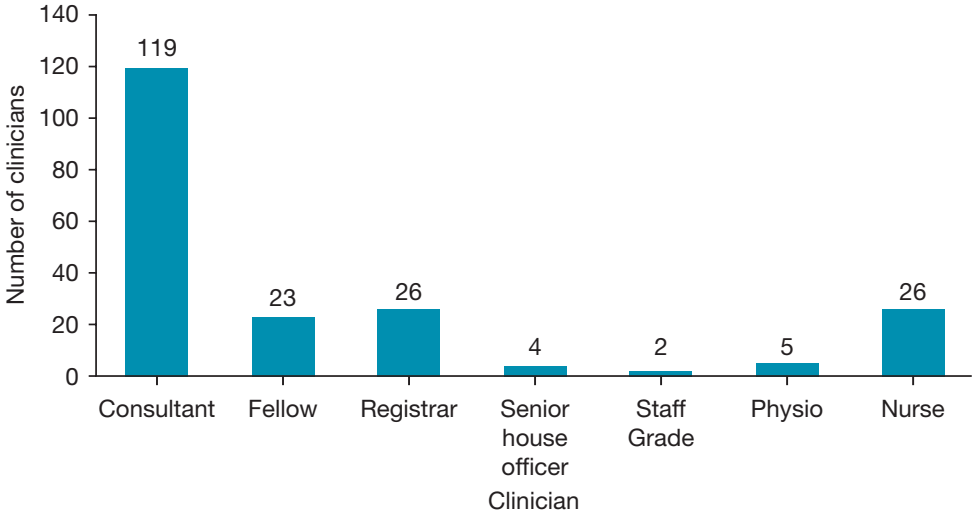

Figure 1. Graph demonstrating the different grades of consenting clinician and how often they were taking consent.

Table 1. The spectrum of elective cases undertaken in both cycle 1 and 2

Procedure	Number
Total hip replacement	38
Total knee replacement	23
Uni-compartmental knee replacement	4
Shoulder replacement	4
Joint injection	17
Joint arthroscopy	35
Anterior cruciate ligament or medial patellofemoral ligament reconstruction	12
Carpal tunnel decompression	28
Hallux surgery	8
Lesser toe surgery	8
Dupytren's surgery	4
Trigger finger release	4
Removal of metalwork	6
Other procedure	16

that 66% of the letters contained details of alternative options, compared to the baseline of 48% (Figure 2).

Risks associated with the specific procedure such as dislocation with total hip replacement and complex regional pain syndrome with carpal tunnel decompression were poorly documented in C1 but showed a significant improvement in C2 (Figure 3).

The authors felt that the primary demonstrators of informed consent were individualised, patient-specific risk factors that were clearly documented in plain language in a clinic letter and consent form. These risk factors were detrimental outcomes that could be considered as material to the patient. Examples from actual cases included: 'increased risk of infection and delayed wound healing with diabetes' and 'difficulty kneeling following a total knee replacement, which will impact the ability to work'. If these issues had been clearly documented, it inferred that sufficient time and explanation had been provided for the patient to make an informed treatment decision.

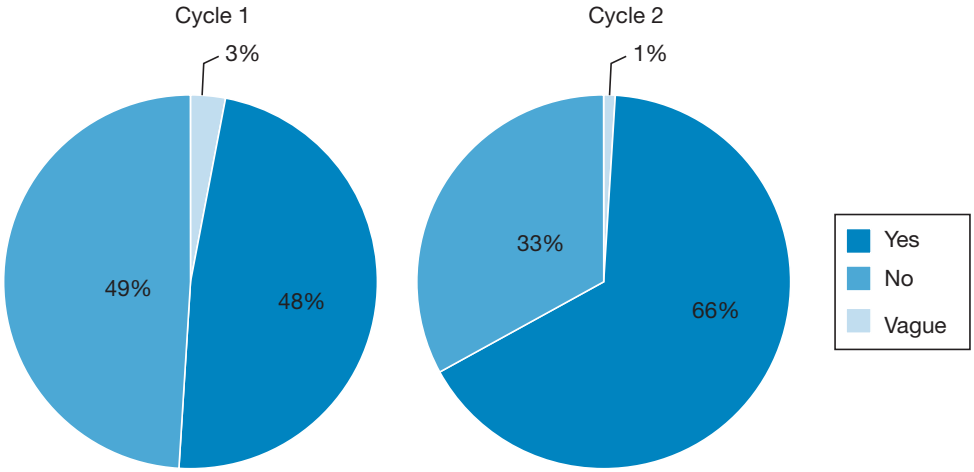

Figure 2. Charts comparing documentation of discussions of alternatives to surgical management.

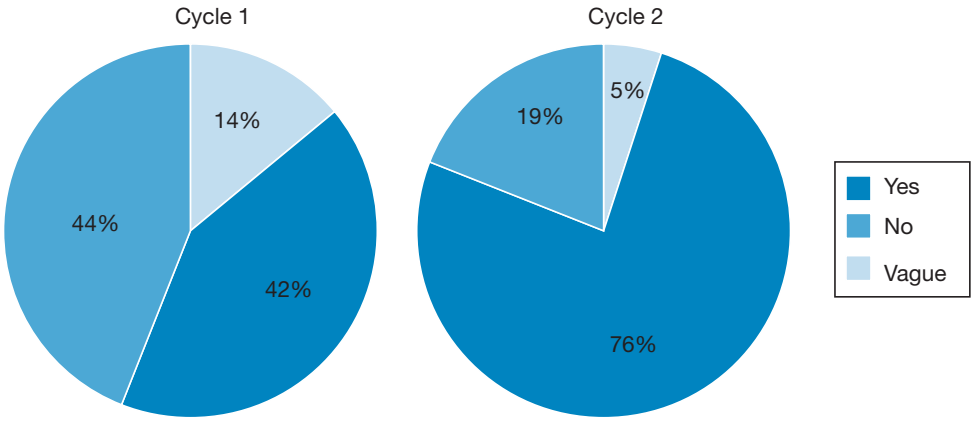

Figure 3. Charts comparing documentation of specific procedural risks.

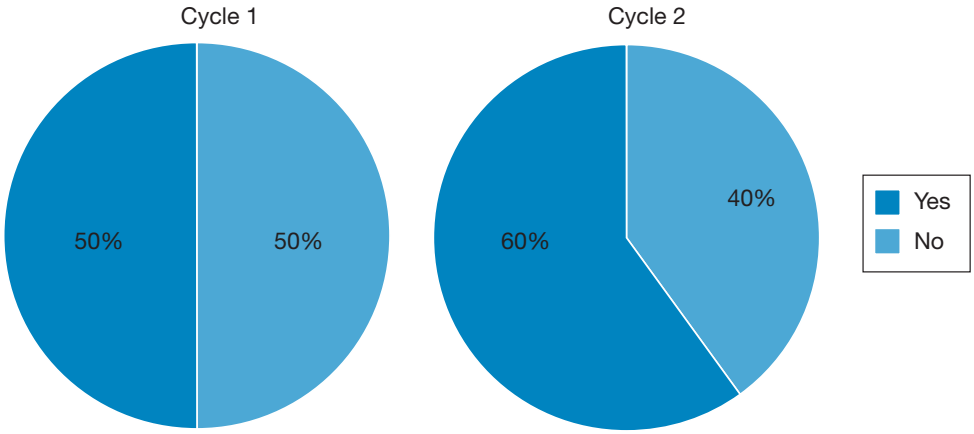

Figure 4. Charts comparing documentation of patient-specific risk factors.

The presence of the documentation of specific risks to the patient for each cycle are illustrated in Figure 4. There was a substantial improvement in documentation habits for patient specific risks between C1 and C2 (42% and 76% respectively), which reflects the educational drive that was initiated after C1.

Some of the consultants have set up 'consenting clinics' for certain patients who were either orthopaedically or anaesthetically complex. Practically, these were either clinic slots at the end of a standard elective clinic with more time allocated to that slot (20 minutes rather than 10) or a whole separate clinic solely for discussing surgery with the patient

and going through the consent form. These specific consenting clinics were only used by a small number of the consultants, and mainly for complex lower limb arthroplasty. Some of the patients were brought back for a second clinic appointment closer to their date of surgery, which was also counted as a consent clinic. A specific consenting clinic was used in 21% (n=23) of cases in C1 and 6% (n=6) in C2.

Overall, patients seen in a dedicated consenting clinic had better documentation across all domains. Patient-specific risk factors were documented in 72% (n=21) of cases, compared to just 48% (n=86) of patients in normal clinics. The majority of patients were consented in clinic before surgery (95%, n=196), with the rest being consented on the surgical admission unit on the day of surgery.

The provision of written information was rarely documented. C1 had 14% (n=15), C2 only 8% (n=8). There were no recorded incidences of patients being emailed information or signposted to online materials or mobile device applications. Copying of the consenting clinic letter to the patient address was also uncommon, only occurring in 12% (n=25) of all patients in both cycles. This low percentage did not improve with the educational intervention.

Discussion

Demonstrating consent in the modern age is a considerable challenge. Patients are becoming increasingly medically complex and have high expectations from surgeries that are aimed at improving lifestyle. In addition, the litigation landscape has seen a shift to a patient-centred approach giving autonomy exclusively to the patient. Simultaneously, consent-related litigation is on the increase. Clinicians need to be aware of how to adapt their practice to demonstrate informed consent and know how to defend themselves against 'sophisticated consent attacks' from claimants (Sokol, 2014).

By virtue of the complexity of their work, spinal surgeons are paving the way in forming robust consenting systems. The concept of the 'three-legged stool' has been adopted by the British Association of Spinal Surgeons and describes a system of consent that can be checklisted preoperatively (Powell et al, 2016; Todd, 2018). The first leg is an agreement between the patient and doctor in the outpatient clinic where the patient's diagnosis and natural history is described, along with all treatment options, and the material risks of surgery to the individual are explored. The second leg is a consenting clinic, creating space to re-discuss the risks and benefits of surgery, to explore patient understanding and to demonstrate 'time and space' for the patient to weigh up their options. The consent for the procedure is taken at this second stage. The third leg is on the day of surgery and involves the countersigning of the consent form. It is vital that documentation of the discussions is clearly recorded at each of the three stages. Failure to be able to retrospectively demonstrate each of these stages makes the metaphorical stool unstable and in practice leaves the consenting process open to criticism.

Consent training is now commonplace in hospital trusts and forms part of the junior doctor induction and consultant revalidation, and many hospital trusts have a consent lead. The current results demonstrate that institutional change is achievable but established practices can be difficult to change, even in the face of landmark legal reform. Birch and Todd (2020) have previously recommended that consenting behaviours should be integrated into undergraduate curriculum. Consent practice features on the postgraduate orthopaedic curriculum and individuals are responsible for keeping up to date with changes in consenting law. Departmental change can be achieved through education, peer pressure to reform practices and development of systems to make the process less onerous and more robust.

Describing the individualised risk of a complication to a patient in understandable terms can be difficult. The operating surgeon should also understand their own complication rate for a given operation, although this knowledge does not need to be exhaustive. The use of abbreviations or initialisms should be avoided, and clinicians should reflect on their use of language. For example, quoting the risk of infection as 1% for a total knee replacement does not communicate the detriment to quality of life for a patient who sustains deep infection. The problem with use of percentages was also highlighted in the Thefault case (Thefault v Johnston, 2017) and was fundamental in the argument against the consent process used by the claimant.

Key points

- Since the Montgomery vs Lanarkshire case, the consent landscape has shifted towards a more patient-centred approach.
- Despite consent being part of the junior doctor curriculum, poor consent practice still occurs.
- Highlighting poor documentation habits and refining departmental education can lead to improvements in practice.
- Departments should consider the use of dedicated consenting clinics to provide an optimal environment for consent.

The British Orthopaedic Association and the majority of orthopaedic sub-speciality societies in the UK provide access to good quality, patient-centred written information on a number of common orthopaedic conditions. It is important that written information uses clear language and is relevant to the patient's pathology and planned surgery. The authors recommend that the provision of written information is described within the consenting clinic letter as an additional means of demonstrating informed consent (Clearkin, 2016).

In the authors' department, it initially proved difficult to justify the personnel resources required to uniformly copy the letter from the listing clinic to the patient. Administratively, the clerical team would copy the letter to the patient if requested by the clinician, but not as a routine. This is a key area for improvement, as copying the letter to the patient has been demonstrated to improve informed consent (Howard et al, 2018).

The role of consenting clinics is not yet clearly defined. Within foot and ankle surgery, they have been shown to significantly improve the informed consent process (Howard et al, 2018). This not only allows demonstration of 'space and time' to consider the risks, but also allows the operating surgeon to re-acquaint themselves with the patient and clinical findings. Consenting clinics were exclusively used by lower limb arthroplasty surgeons and occasionally foot and ankle surgeons.

There are many challenges to uniformly achieving the ideal standard of consent. The complexity of surgery clearly has an impact on the measures taken to discuss and document the informed consent process. Clinicians must strategically balance the time and resources used to demonstrate consent. Interventions to document the consent process should be pragmatic and time-efficient where possible. The goal for each clinician should be to develop a consenting process that unifies all the recommendations mentioned in this article and to use a systematic and reproducible method to consent that can be modified for more complex cases.

The authors have written a stepwise process for clinicians to analyse their own consenting habits in an effort to drive nationwide improvement in this area (**Appendix 1**).

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Conflicts of interest

The authors declare that there are no conflicts of interest.

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Appendix 1. Recommendations for analysing consenting habits

1. Document the diagnosis and the natural history of the condition.
2. State the planned management.
3. Describe the discussion of alternative treatments and the patient's material risks of each option.
4. Describe the generic and patient specific risks of the proposed surgery in clearly understandable terms.
5. Mention any written information given (must be relevant to the patient pathology and procedure) or additional educational classes.
6. Copy the letter to the patient. Consider a point of contact to offer questions.
7. Obtain written consent in clinic – ideally a separate consenting clinic for complex cases (to demonstrate 'space and time' to consider options). Avoid divulging life-changing risks on the day of surgery without time for the patient to reconsider.
8. Develop local consent forms to provide an exhaustive generic risk profile for high volume procedures.
9. Locally audit your hospital practice to identify areas for quality improvement.
10. Use the Plan-Do-Study-Act model and use multiple small interventions to change your institution.
11. Provide targeted training for underperforming individuals as part of revalidation.
12. Consider how technology can be used in your practice to modernise information sharing with patients.