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Original Research

Surgical consent practice in the UK following the Montgomery ruling: A national cross-sectional questionnaire study

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ABSTRACT

Background: The Supreme Court case of Montgomery vs Lanarkshire Health Board in 2015 was a landmark case for consent practice in the UK which shifted focus from a traditional paternalistic model of consent towards a more patient-centered approach. Widely recognised as the most significant legal judgment on informed consent in the last 30 years, the case was predicted to have a major impact on the everyday practice of surgeons working in the UK National Health Service (NHS). Two years after the legal definition of informed consent was redefined, we carried out an audit of surgical consent practice across the UK to establish the impact of the Montgomery ruling on clinical practice.

Materials & methods: Data was collected by distribution of an electronic questionnaire to NHS doctors working in surgical specialities with a total of 550 respondents.

Results: 81% of surgical doctors were aware of the recent change in consent law, yet only 35% reported a noticeable change in the local consent process. Important barriers to modernisation included limited consent training, a lack of protected time for discussions with patients and minimal uptake of technology to aid decision-making/documentation.

Conclusions: On the basis of these findings, we identify a need to develop strategies to improve the consent process across the NHS and limit the predicted rise in litigation claims.

1. Introduction

Each day in the UK National Health Service (NHS), thousands of surgeons engage in complex discussions with their patients to identify which, if any, operative treatments to pursue. Central to each of these discussions is the notion of 'informed consent', whereby the surgeon discloses material information about procedures and facilitates understanding so that the patient can decide which option they favour. Consent discussions must navigate the interface between beneficence, non-maleficence and patient autonomy: a considerable challenge in a time-pressured healthcare setting. Facilitating good understanding of the indication and nature of surgical procedures can improve patient satisfaction and pre-operative anxiety levels [1–3]. In contrast, failing to engage patients in the consent discussion can lead to a loss of trust and heightens the risk of litigation in the event of post-operative complications [4].

Until recently, UK courts would judge the adequacy of information disclosure in medical negligence claims by asking whether the surgeon's conduct would be supported by a responsible body of clinicians - the so-called Bolam test under English & Welsh law, or Hunter v Hanley test in Scottish law [5] – with the qualification that the court considers this professional opinion to be reasonable and logical [6]. In 2015, this familiar legal standard was redefined by the Supreme Court ruling on Montgomery vs Lanarkshire Health Board [7]. Nadine Montgomery, a molecular biologist with type 1 diabetes and relatively short stature, gave birth to her son Sam by vaginal delivery in 1999. Her labour was complicated by shoulder dystocia which resulted in a 12 min period of acute hypoxia and Sam being born with cerebral palsy and traction-related Erb's palsy. Montgomery sued for negligence arguing that she would have requested a caesarean section had her obstetrician informed her of her personal 9–10% predicted risk of shoulder dystocia, based on known risk factors. The Supreme Court judges ruled in her

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favour and declared that doctors should ensure patients are aware of *any* risks material to them and also *any* reasonable treatment alternatives. They defined the materiality of a risk as whether "… a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it" [7]. In the post-Montgomery era, the belief that there is a percentage threshold of improbability below which a risk need not be disclosed is outdated. Consent discussions must now be tailored to the physical, emotional and spiritual needs of the individual patient, to identify which risks could hold significance.

What has been hailed as 'the most important UK judgment on informed consent for 30 years' [8], comes at a time when NHS surgeons are already struggling to tackle rising waiting times and increasing numbers of cancelled elective operations [9]. Practical advice on how surgeons can implement recommendations from the Montgomery ruling has been limited. In one of the few published guidance documents, the Royal College of Surgeons (RCS) outlined four broad principles which surgeons should adhere to [10]:

1. Tailor discussions to the individual patient by allowing time to get to know them well enough to understand their views and values
2. Explain all reasonable treatment options along with their implications
3. Discuss material risks for each of these treatment options
4. Keep written documentation of the discussion in addition to the signed consent form

The feasibility of applying these principles in a time-pressured, resource-limited NHS remains to be seen. To the best of our knowledge, there have been no published reports of the consent practices of NHS surgeons since Montgomery. The aim of the present study was therefore to perform a national survey of UK surgical trainees and consultants to establish whether the new legal and regulatory requirements have been incorporated into their everyday practice and what barriers still remain to obtaining truly informed consent.

2. Methods

2.1. Ethical consideration

NHS Research Ethics Committee approval was not required as this was a cross-sectional study of healthcare professionals who voluntarily participated in an online questionnaire. Before participating in the study, all respondents were informed that the information provided would be used for research purposes only and not in a manner which would allow identification of their individual responses.

The work has been reported in line with the STROCSS criteria [37].

2.2. Setting and participants

Between February and September 2017, a national audit of surgical consent practice was performed by inviting NHS doctors working in surgical specialities to complete an electronic questionnaire hosted at www.consentaudit2017.com. An invitation email was distributed through national surgical societies and local departmental email lists inviting doctors of any grades working in surgical specialities to participate. The questionnaire was also advertised on two social media platforms: Facebook and Twitter. To maximise the number of survey respondents and minimise non-response bias, adverts stated that all participants would be entered into a randomised draw to win one of three £50 online retail gift vouchers.

2.3. Audit questionnaire

A 36-item questionnaire was designed using the Google Forms electronic survey platform. Questions were developed by the study authors to determine compliance with RCS guidance on informed consent [10] and the Montgomery judgment [7], as well as the frequency, duration and location of consent discussions. A mixture of forced-choice yes/no, multiple choice selection and short comment question styles were used. To determine content validity, items were reviewed by a panel of experts consisting of three consultant surgeons who confirmed that all questions were comprehensive and relevant to a study of the informed consent process. A pilot study of the online questionnaire was then performed with 15 local doctors, resulting in minor amendments to phrasing and response options.

The questionnaire collected data on key participant demographics: current level of training, geographical region and surgical speciality. Respondents who were involved in the process of obtaining consent for surgical procedures were asked questions across three key domains: training in the consent process, awareness of UK consent law/regulatory guidance and current consent practice in their local hospital. Surgical trainees who had not been trained to perform the procedure(s) that they obtained consent for were given two follow-on questions relating to their previous experience of the procedure and their perceived competency to obtain informed consent. Respondents who were not currently involved in the consent process were only asked about their awareness of UK consent law/regulatory guidance. Data from incomplete responses were excluded from the analysis. A full list of survey questions is available in the Supplementary Information.

3. Results

3.1. Survey demographics

A total of 550 respondents completed the questionnaire, covering a broad range of training grades: 50.0% consultant, 25.5% speciality trainee, 6.9% core surgical trainee, 9.8% foundation year doctor, 2.2% trust grade doctor, 1.8% clinical fellow, 0.4% locum appointment for service (LAS) and 3.5% other (Supplementary Fig. 1). All NHS regions were represented in the survey: 33.1% NHS South of England, 22.0% NHS North of England, 17.1% NHS Midlands and East of England, 14.5% NHS London, 7.8% NHS Scotland, 3.8% NHS Wales and 1.6% NHS Northern Ireland (Supplementary Fig. 2). Consistent with national figures on the number of surgeons by speciality [11], the specialities with the greatest number of responses were trauma & orthopaedic surgery (24.2%) and general surgery (22.7%; Supplementary Fig. 3). Paediatric surgery and oral & maxillofacial surgery had the least representation with only 6 respondents each. 92% of respondents reported being involved in the process of obtaining consent for surgical procedures. Those not involved in the consent process were either foundation doctors (93%), core surgical trainees (5%) or 'other' grades (2%).

3.2. Awareness of consent law and regulatory guidance

81% of doctors who obtain consent for surgical procedures reported that they were aware of the Montgomery vs Lanarkshire Health Board ruling, compared with 37% of doctors not involved in the consent process. 86% of consultants, the largest group represented in our study, reported awareness of the Montgomery case (Fig. 1). 42% of respondents felt that their surgical colleagues were sufficiently aware of the impact of the Montgomery ruling on the consent process and just 35% had noticed a change in the consent process in their local department since the judgment.

To control for possible selection bias in respondents' self-reported awareness of the Montgomery case, we showed participants four statements relating to surgical informed consent and asked them to indicate whether they were true or false (Table 1). 93% of respondents correctly identified the importance of a patient's beliefs and values in determining a material risk, however 1 in 5 still incorrectly believed in