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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

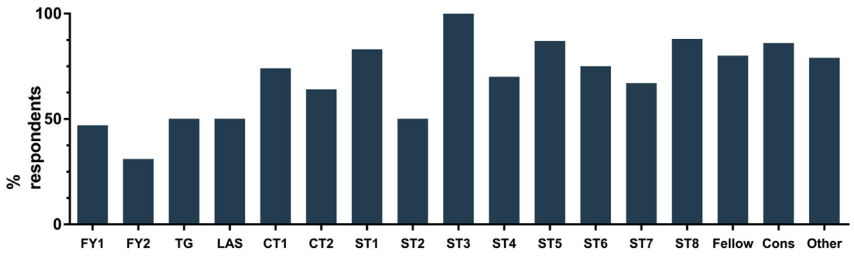

Fig. 1. Self-reported awareness of the Montgomery vs Lanarkshire Health Board ruling (2015) by training grade. Only data from respondents involved in the consent process is shown. FY – foundation year; TG-trust grade; LAS – locum appointment for service; CT – core surgical trainee; ST – speciality trainee; Fellow-post-CCT clinical fellow; Cons – consultant.

Table 1
Awareness of current UK consent law by response to knowledge test statements. *indicates correct test response.

Test statement on UK consent law	True	False
Doctors must ensure patients are aware only of those risks which are considered statistically likely or potentially very serious/ life threatening	21%	79%*
If a doctor neglects to mention a risk of a procedure deemed to be important to the patient, he or she will not be negligent if they acted in accordance with a responsible body of medical opinion	26%	74%*
A material risk is one deemed to be relevant to the patient, based on understanding of their views, beliefs and wishes	93%*	7%
Doctors should assume a patient lacks medical understanding and use their professional experience to identify the optimal treatment option for each patient	17%	83%*

a statistical or severity threshold below which a risk need not be disclosed. Regarding claims of inadequate risk disclosure, 26% of respondents believed that a doctor would not be considered negligent if they acted in accordance with a responsible body of medical opinion – the now outdated Bolam test. Surprisingly, 17% of respondents still believed that doctors should assume a patient lacks medical understanding and use their professional experience to pick the optimal treatment plan. There is no legal or regulatory guidance to support this rather paternalistic viewpoint.

3.3. Training in surgical informed consent

Formal training in the consent process has been shown to improve surgical trainees' knowledge and documentation of the consent process [12,13]. Overall, 53% of respondents had received formal training in surgical informed consent, with lower rates among more junior speciality trainees (ST1-3, 41%) compared with consultants (56%). This suggests that the provision of formal consent training in postgraduate surgical education remains limited despite the increased complexity of consent law since Montgomery.

3.4. Organisation of the consent process

To profile how surgeons obtain informed consent in NHS hospitals, we asked respondents to report on the location and timing of consent discussions. The final decision-making discussion and documentation of consent most commonly takes place in outpatient clinics, day surgery units and/or wards (Fig. 2). 19% of respondents reported use of designated pre-operative assessment clinics for consent discussions. The modal number of patient visits to discuss an operative procedure prior to signing the consent form was 2 (Fig. 3A). 49% of respondents completed consent discussions in 10 min or less and a further 45% had finished within 30 min (Fig. 3B). 24% respondents were scheduled protected time for consent discussions with patients and 52% felt that they had insufficient time for the consent process. Despite these limitations, 76% of respondents believed that their patients were satisfied with the amount of time they had to discuss their procedure before signing the consent form. Prior to signing the consent form, 73% of

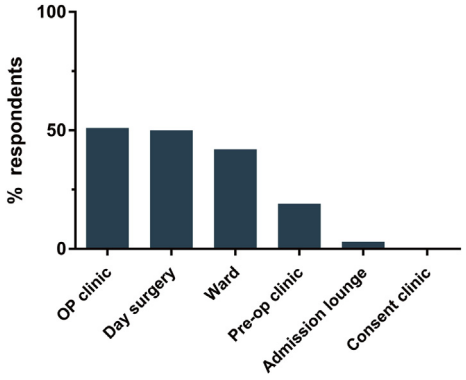

Fig. 2. Location of final decision-making discussion and documentation of consent for elective procedures. Respondents were asked to select all locations which applied. 1 respondent reported use of a dedicated consent clinic. OP clinic – outpatient clinic; Pre-op clinic - pre-operative assessment clinic; n = 507.

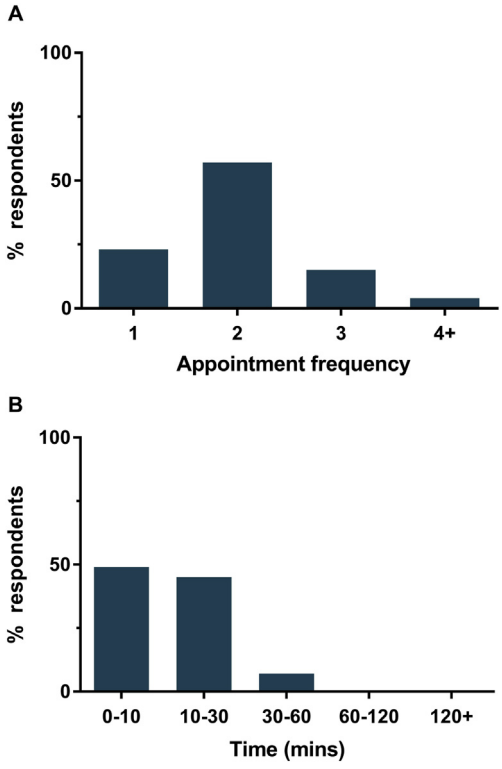

Fig. 3. Frequency and timing of consent discussions with patients. A) Number of times a patient will meet with a healthcare professional to discuss their procedure before signing a consent form. **B)** Average amount of time spent with a patient during the informed consent process; n = 507.

respondents would confirm that a patient had been given sufficient time to make their decision; 10% of these confirmations would be in the form of a written declaration.

The RCS have stipulated that the final confirmation of informed consent should be carried out by the doctor who will conduct the procedure [10]. 80% of respondents reported that this was the case in their department. In conflict with regulatory guidance, however, 22% of respondents reported that they were required to obtain consent for investigative procedures (e.g. arthroscopy, gastroscopy, and colonoscopy) or invasive procedures (e.g. insertion of percutaneous endoscopic gastrostomy or PEG) which they do not perform themselves. Examples of non-expert consent were also observed in relation to surgical trainees. 40% of doctors in training posts reported being asked to obtain consent for a procedure which they had not been trained to perform and for which they did not fully understand the nature of the operation, treatment alternatives or anticipated risks.

3.5. Content of consent discussions

Since the Montgomery ruling, doctors must ensure that they understand a patient's preferences and priorities in order to judge the volume and complexity of information to disclose during the consent process. Guidance from the RCS has stipulated that "… it is not sufficient to ask the patient if they want to know anything else, as patients cannot be expected to know what they do not know about their condition or treatment options' [10]. 57% of respondents in this study agreed or strongly agreed with this statement, 30% felt neutral and 13% disagreed or strongly disagreed. 91% reported that they routinely tailored the consent process to individual patients based on their specific views and values. In contrast, only 33% of surgical consultants who use animal-derived products in surgery (e.g. Permacol, Dura-Guard, Biodesign) routinely consented for their use. This highlights the need for greater awareness of the potential religious and cultural implications associated with these products.

Given the need for more in-depth consent discussions with patients since Montgomery, we sought to establish the current use of decision-making aids to facilitate understanding. 58% of respondents used patient information leaflets to support the consent process, whilst only 11% routinely used multimedia resources (e.g. audio/video recordings or websites).

3.6. Record of consent discussion

To demonstrate the legal validity of informed consent, doctors must be able to present a record of both sides of the consent discussion including any specific factors which led to the final decision [10]. As shown in Table 2, there was marked variation in the methods used to record consent discussions, with the most popular method being to document in the clinical notes and dictate a letter to the patient or GP. 55% of respondents used more than one method to record their consent discussion, raising doubt over the efficiency of current documentation methods.

Table 2
Ranked list of methods used to record consent discussion.

Documentation/recording method	Respondents n (%)
Clinical notes & letter	100 (20)
Clinical notes, letter & consent template	93 (18)
Consent template only	82 (16)
Clinical notes only	70 (14)
Clinical notes & consent template	42 (8)
Letter only	38 (7)
Letter & consent template	37 (7)
No documentation other than consent form	29 (6)
Clinical notes & audio recording	5 (1)
Clinical notes, letter, consent template & audio recording	4 (1)
Audio recording only	3 (1)
Clinical notes, letter & audio recording	2 (0)
Clinical notes, consent template & audio recording	1 (0)
Letter & audio recording	1 (0)

4. Discussion

In 2015, the legal standard of informed consent in the UK was redefined, requiring surgeons to personalise consent discussions to each individual patient based on their beliefs and values [7]. This study investigated UK doctors' awareness of this new legal standpoint and considered the practical challenges of updating consent practice in a modern day NHS. The majority of UK surgical trainees and consultants had good awareness and understanding of the Montgomery ruling; however a sizeable minority still believed that only a generic profile of risks, those that are most common or serious, needs to be disclosed and that the Bolam test could still defend claims of inadequate disclosure. Two years since the Montgomery judgment, most surgeons reported no noticeable change in local consent practices. Possible barriers to change included a lack of formal consent training, insufficient time for in-depth discussions with patients and the limited use of decision-making aids during the consent process. Taken together, these findings highlight the need for NHS-wide change in surgical consent policy to allow surgeons to meet the legal and regulatory standards expected of them.

4.1. Limitations

Data in the present study was obtained by invited completion of an online questionnaire by surgical doctors in the NHS. We are unable to report a survey response rate since the total number of people reached by local departmental email lists, national surgical societies and social medial platforms is unknown. Whilst the proportion of consultant and non-consultant grade doctors is similar to previously published national figures [11], our 550 survey respondents will inevitably account for a low proportion of the total number of surgical doctors working in the NHS. We acknowledge the possibility of selection bias whereby surgeons with a particular interest in consent practice were more likely to participate, over-estimating awareness of current consent law. In addition, there is likely to be an element of response bias whereby some participants selected answers based on what they 'should do' rather than their actual clinical practice. Overcoming these sources of bias would require direct observation of randomised consent discussions in surgical centres across the UK; a logistically complex study design beyond the resources available for the present study. In future, it will also be important to investigate patients' perceptions of the consent process, which were not addressed in the present study. Another possible limitation could be the lack of distinction between different NCEPOD classifications (e.g. elective vs urgent) and surgery grades (e.g. minor vs major), requiring respondents to give a generalised response based on what they 'routinely' do. This design was favoured since legal and regulatory standards of informed consent are procedure-independent. Evidence in support of this approach came from a recent study of malpractice claims in the USA, which reported that informed consent allegations were more likely to be associated with *less* severe post-operative complications [4]. In other words, good consent practice should be followed even for procedures deemed to be 'less serious'.

4.2. Awareness of consent law and regulatory guidance

The Montgomery decision had major legal consequences for doctors in the UK, opening the door to litigation claims, including retrospective cases as far back as 1999, when Nadine Montgomery was under the care of her obstetrician [5]. This prompted a warning from the RCS [that] ' … hospitals and medical staff are leaving themselves very vulnerable to expensive litigation and increased payouts by being slow to change the way the consent process happens' [14]. Indeed, some claims of failure

to obtain informed consent have already succeeded on the basis of the Montgomery ruling [5]. In the present study, approximately 1 in 5 UK doctors involved in the consent process were not aware of the Montgomery judgment and believed that doctors were only required to disclose risks deemed statistically likely or potentially very serious/life threatening. 1 in 4 respondents still believed that failure to mention a risk which was important to the patient could be defended by the outdated Bolam test. This highlights an urgent need to update clinicians' understanding of UK consent law.

Incorporating new consent guidance into all areas of clinical practice is an ongoing challenge. In the present study, two specific areas for improvement were identified. Firstly, despite attempts to personalise the consent process to individual patients, only 1 in 3 surgeons who used animal-derived products in procedures obtained specific consent for their use, which could conflict with religious or cultural beliefs. Secondly, approximately 1 in 5 surgeons are currently required to obtain consent for investigative (e.g. arthroscopy, colonoscopy) and invasive procedures (e.g. PEG insertion) which they do not perform themselves. In addition, 40% of trainees who had not yet been trained to perform a particular procedure had been asked to obtain consent when they did not fully understand the nature of the operation. These reports are in direct contradiction with RCS guidance, which states that "the surgeon discussing treatment with the patient should be suitably trained … and have sufficient knowledge of the associated risks and complications, as well as any alternative treatments …" [10].

4.3. Barriers to informed consent

The majority of respondents in this study reported no noticeable change in consent practices in their local department since Montgomery. Half of surgeons reported spending an average of just 10 min or less with a patient during the consent process (Fig. 3B), mostly in busy outpatient clinics, day surgery units or wards (Fig. 2). 76% of respondents reported that they did not receive any protected time to discuss consent with patients in their weekly schedule. The amount of time allocated to the consent process is known to be the strongest predictor of patient comprehension of their procedure [15] and must be prioritised if surgeons are to engage patients in truly shared decision-making. Surgeons in the present study reported limited use of time-saving decision-making aids, such as leaflets or multimedia, in the consent process (Section 3.5). They also reported significant variation in the documentation methods being used, with the majority of surgeons creating duplicate records of their discussion (e.g. letter and clinical notes). These findings highlight the need for innovative approaches to improve the efficiency of the consent process, in addition to simply increasing the amount of protected time allocated to surgeons.

4.4. Future strategies to improve the consent process

The present study identifies an important disparity between surgeons' awareness of informed consent guidelines and their everyday clinical practice. In order to bridge this 'knowledge-practice gap', we identify four key areas for improvement of surgical consent practice:

4.4.1. Developing a surgical consent pathway

The increased scale and complexity of the modern consent process is no longer compatible with a brief conversation on arrival in a busy day surgery unit. To meet new legal standards, NHS trusts must allocate surgeons sufficient protected time to meet with patients prior to elective procedures in dedicated pre-operative assessment clinics. A two-stage approach to consent has been proposed in which patients are first provided with information regarding their proposed procedure and treatment alternatives, before returning for a second appointment to discuss any related questions or concerns [16]. While the final consent discussion should be with the surgeon responsible for the patient's care [10], the initial appointment could be led by specialist nurses trained in the consent process. During the 'cool-off' period between appointments patients could reflect on available written information and multimedia resources to help guide their decision.

4.4.2. Use of patient decision aids

Ensuring that a patient is well-informed about a procedure can reduce anxiety [1,2], improve satisfaction [3] and even change the outcome of consent discussions [17]. Previous research has shown that the majority of patients have poor recall of surgical risks [18–21], particularly in groups with lower educational level or language competency [22,23]. Whilst written information leaflets have been shown to improve comprehension [21,22,24,25], more than a quarter of working aged adults in England have literacy levels low enough to interfere with daily tasks [26]. An alternative approach could be to develop a repository of patient decision aids (PDAs) in the form of evidence-based interactive websites with embedded multimedia (e.g. graphics, videos). A recent Cochrane review reported that PDAs help patients to gain knowledge about a procedure, improve understanding of benefits and potential risks, facilitate decision-making and promote patient autonomy [27]. By presenting information enhanced with pop-up definitions of medical terminology and links to more in-depth information, patients could tailor the level of disclosure to meet their own values and information needs [28]. They could also have the opportunity to review information on multiple occasions before completing a quiz to assess comprehension [28]. A transcript documenting any areas of misunderstanding or items flagged as being of particular importance to the patient could facilitate a later face-to-face discussion with the designated surgeon [29]. By helping patients to arrive well informed, PDAs could save time in clinic appointments, allowing surgeons to address any personal beliefs or concerns regarding treatment in depth.

Development of PDAs to facilitate surgical consent will require accurate, up-to-date content compiled from the best available research evidence. To avoid conflict of interest, we propose that PDAs should be developed by a public body such as the National Institute for Health & Care Excellence (NICE), in collaboration with the Royal College of Surgeons and national surgical specialty organisations. In addition, all content should be reviewed by patient advocates and legal experts to ensure that the information provided is accessible, easy to comprehend and in keeping with regulatory guidelines. Printed formats of PDAs should be made available for those without access to internet-enabled devices.

It is important to note that PDAs are designed to support rather than replace face-to-face consent discussions, which will remain a critical part of the consent pathway, particularly for patients with complex medical comorbidities.

4.4.3. Improving formal consent training

The consent discussion is arguably one of the most important interactions a surgeon will have with their patient and yet 47% of respondents in this study had received no formal training in how to approach it. Research from the USA has shown that informed consent training programmes improve surgical trainees' knowledge and confidence in the consent process [12,13]. In the UK, consent training could be improved by increasing coverage of consent law in the Membership of the Royal College of Surgeons (MRCS) curriculum and developing simulated consent training exercises with standardised patients in regional teaching hospitals.

4.4.4. Procedure-specific consent forms

The documentation of consent discussions on generic forms has been shown to be inherently error-prone, with significant variation in the complications listed for the same procedure and frequent omission of common and serious risks [30–32]. In addition, there is known to be significant disparity between risks discussed verbally and those detailed on consent forms [33]. The use of procedure-specific consent forms can reduce variability in documentation of complications, avoid omission of

relevant operative risks [34,35], improve patient recall [18,36] and would be expected to reduce documentation time. We propose that national surgical speciality organisations develop procedure-specific consent forms, which display core information for each procedure and allow modification to document any material risks specific to the individual. In addition to signposting the final consent discussion, the personalised end-product could act as a record of the consent discussion for the clinical notes, with copies made available to the patient and their GP.

5. Conclusions

The Montgomery judgment acknowledges that the change in legal focus from the 'reasonable doctor' to the 'reasonable patient' may create uncertainty about how much surgeons need to disclose in consent discussions [7]. With limited practical guidance on how to adopt the new legal standard of informed consent, it is unsurprising that the majority of UK surgeons in our study reported no noticeable change in local practice. In this study, we identify low rates of formal consent training, limited protected time for consent discussions and poor uptake of technology, which may represent important barriers to the upgrading of consent practices post-Montgomery. Across the NHS, the quality of surgical informed consent needs to be standardised, with adequate provision of time and resources to allow surgeons to deliver the new standard of care patients can expect of them.

Ethical approval

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.

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Author contribution

CM and APW founded the study concept. CM, APW, RF and DSL designed the online questionnaire. CM, DL and MCM collected data. CM performed data analysis/interpretation and drafted the manuscript. All authors contributed to manuscript revision and approve the final version.

Conflicts of interest

DL is a co-founder of Surgical Consent an electronic consent platform involved in the development of electronic consent forms and a surgical risk repository. No financial support or payments involved.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.ijsu.2018.05.016.

References

[1] P.J. Dawes, L. O'Keefe, S. Adcock, Informed consent: the assessment of two structured interview approaches compared to the current approach, J. Laryngol. Otol. 106 (1992) 420–424.
[2] B.M. Stanley, D.J. Walters, G.J. Maddern, Informed consent: how much information is enough? Aust. N. Z. J. Surg. 68 (1998) 788–791.
[3] J.L. Hallock, R. Rios, V.L. Handa, Patient satisfaction and informed consent for surgery, Am. J. Obstet. Gynecol. 217 (2017) 181, http://dx.doi.org/10.1016/j.ajog.2017.03.020 e1-181.e7.
[4] J. Grauberger, P. Kerezoudis, A.J. Choudhry, M.A. Alvi, A. Nassr, B. Currier, M. Bydon, Allegations of failure to obtain informed consent in spinal surgery medical malpractice claims, JAMA Surg 152 (2017) e170544, http://dx.doi.org/10.1001/jamasurg.2017.0544.
[5] S.W. Chan, E. Tulloch, E.S. Cooper, A. Smith, W. Wojcik, J.E. Norman, Montgomery and informed consent: where are we now? BMJ 357 (2017) j2224.
[6] Bolitho (Administratrix of the Estate of Patrick Nigel Bolitho (deceased)) v City and Hackney Health Authority [1997] 4 All ER 771, (n.d.).
[7] Montgomery v Lanarkshire Health Board [2015] UKSC 11, (2015).
[8] C. Dyer, Doctors should not cherry pick what information to give patients, court rules, BMJ 350 (2015) h1414, http://dx.doi.org/10.1136/bmj.h1414.
[9] Statistics » Consultant-led Referral to Treatment Waiting Times Data 2016-17, (n.d.). https://www.england.nhs.uk/statistics/statistical-work-areas/rtt-waiting-times/rtt-data-2016-17/(accessed September 28, 2017).
[10] Consent: Supported Decision-making. A Guide to Good Practice, (2016).
[11] Surgery and the NHS in numbers, R. Coll. Surg. (n.d.). https://www.rcseng.ac.uk/news-and-events/media-centre/media-background-briefings-and-statistics/surgery-and-the-nhs-in-numbers/(accessed September 27, 2017).
[12] S.E. Koller, R.F. Moore, M.B. Goldberg, J. Zhang, D. Yu, C.B. Conklin, R.E. Milner, A.J. Goldberg, An informed consent program enhances surgery resident education, J. Surg. Educ. (2017), http://dx.doi.org/10.1016/j.jsurg.2017.02.002.
[13] B.M. Thompson, R.A. Sparks, J. Seavey, M.D. Wallace, J. Irvan, A.R. Raines, H. McClure, M.A. Nihira, J.S. Lees, Informed consent training improves surgery resident performance in simulated encounters with standardized patients, Am. J. Surg. 210 (2015) 578–584, http://dx.doi.org/10.1016/j.amjsurg.2014.12.044.
[14] Trusts risk litigation payouts by not adopting full consent process, warns college | The BMJ, (n.d.). http://www.bmj.com/content/355/bmj.i5840.full.print (accessed September 28, 2017).
[15] A.S. Fink, A.V. Prochazka, W.G. Henderson, D. Bartenfeld, C. Nyirenda, A. Webb, D.H. Berger, K. Itani, T. Whitehill, J. Edwards, M. Wilson, C. Karsonovich, P. Parmelee, Predictors of comprehension during surgical informed consent, J. Am. Coll. Surg. 210 (2010) 919–926, http://dx.doi.org/10.1016/j.jamcollsurg.2010.02.049.
[16] R.A. Wheeler, Consent in surgery: is there a Montgomery effect? Clin. Risk 22 (2016) 21–24, http://dx.doi.org/10.1177/1356262216664854.
[17] E.H. Wagner, P. Barrett, M.J. Barry, W. Barlow, F.J. Fowler, The effect of a shared decisionmaking program on rates of surgery for benign prostatic hyperplasia, Pilot results, Med. Care 33 (1995) 765–770.
[18] E. Pomeroy, S. Shaarani, R. Kenyon, J. Cashman, Patient recall of informed consent at 4 Weeks after total hip replacement with standardized versus procedure-specific consent forms, J. Patient Saf. (2017), http://dx.doi.org/10.1097/PTS.0000000000000412.
[19] B.T. Olsen, C.J. Sherwood, C.K. Carrico, J.H. Priest, D.M. Laskin, Patient recall of information on a third molar informed consent video, J. Oral Maxillofac. Surg. Off. J. Am. Assoc. Oral Maxillofac. Surg (2017), http://dx.doi.org/10.1016/j.joms.2017.06.006.
[20] C. Fusetti, M. Lazzaro, M. Trobia, S. Lucchina, J. Petri, G. Garavaglia, Patients' point of view on informed consent: a prospective study in carpal tunnel surgery, Am. J. Orthop. Belle Mead NJ 42 (2013) E111–E115.
[21] J.C. Oosthuizen, P. Burns, C. Timon, The changing face of informed surgical consent, J. Laryngol. Otol. 126 (2012) 236–239, http://dx.doi.org/10.1017/S0022215111003021.
[22] A. Sherlock, S. Brownie, Patients' recollection and understanding of informed consent: a literature review, ANZ J. Surg. 84 (2014) 207–210.
[23] A. Borello, A. Ferrarese, R. Passera, A. Surace, S. Marola, C. Buccelli, M. Niola, P. Di

Lorenzo, M. Amato, L. Di Domenico, M. Solej, V. Martino, Use of a simplified consent form to facilitate patient understanding of informed consent for laparoscopic cholecystectomy, Open Med. Wars. Pol 11 (2016) 564–573, http://dx.doi.org/10.1515/med-2016-0092.

[24] E. Papsin, R. Haworth, J.M. Chorney, M. Bezuhly, P. Hong, Pediatric otoplasty and informed consent: do information handouts improve parental risk recall? Int. J. Pediatr. Otorhinolaryngol. 78 (2014) 2258–2261, http://dx.doi.org/10.1016/j.ijporl.2014.10.028.

[25] R. Ritchie, J. Reynard, Consent for surgery: time for a standardized NHS consent checklist, J. R. Soc. Med. 101 (2008) 48–49, http://dx.doi.org/10.1258/jrsm.2007.070411.

[26] M. Kuczera, S. Field, H. Windisch, Building Skills for All: a Review of England, (2016).

[27] D. Stacey, F. Légaré, N.F. Col, C.L. Bennett, M.J. Barry, K.B. Eden, M. Holmes-Rovner, H. Llewellyn-Thomas, A. Lyddiatt, R. Thomson, L. Trevena, J.H.C. Wu, Decision aids for people facing health treatment or screening decisions, Cochrane Database Syst. Rev. (2014) CD001431, http://dx.doi.org/10.1002/14651858.CD001431.pub4.

[28] C. Grady, S.R. Cummings, M.C. Rowbotham, M.V. McConnell, E.A. Ashley, G. Kang, Informed consent, N. Engl. J. Med. 376 (2017) 856–867, http://dx.doi.org/10.1056/NEJMra1603773.

[29] G. Siegal, R.J. Bonnie, P.S. Appelbaum, Personalized disclosure by information-on-demand: attending to patients' needs in the informed consent process, J. Law Med. Ethics 40 (2012) 359–367, http://dx.doi.org/10.1111/j.1748-720X.2012.00669.x.

[30] M.E. Smith, R. Lakhani, N. Bhat, Consenting for risk in common ENT operations: an evidence-based approach, Eur. Arch. Oto-Rhino-Laryngol, Off. J. Eur. Fed. Oto-Rhino-Laryngol. Soc. EUFOS Affil. Ger. Soc. Oto-Rhino-Laryngol. - Head Neck Surg 270 (2013) 2551–2557, http://dx.doi.org/10.1007/s00405-013-2464-6.

[31] D. McGrogan, D. Mark, B. Lee, M.E. O'Donnell, Content, accuracy and completeness of patient consent in a regional vascular surgery unit, Ir. J. Med. Sci. 184 (2015) 521–529, http://dx.doi.org/10.1007/s11845-014-1160-x.

[32] M.A. Mussa, T.A. Sweed, A. Khan, Informed consent documentation for total hip and knee replacement using generic forms with blank spaces, J. Orthop. Surg. Hong Kong 22 (2014) 214–217, http://dx.doi.org/10.1177/230949901402200220.

[33] D.E. Hall, B.H. Hanusa, M.J. Fine, R.M. Arnold, Do surgeons and patients discuss what they document on consent forms? J. Surg. Res. 197 (2015) 67–77, http://dx.doi.org/10.1016/j.jss.2015.03.058.

[34] E.R. St John, A.J. Scott, T.E. Irvine, F. Pakzad, D.R. Leff, G.T. Layer, Completion of hand-written surgical consent forms is frequently suboptimal and could be improved by using electronically generated, procedure-specific forms, Surg. J. R. Coll. Surg. Edinb. Irel 15 (2017) 190–195, http://dx.doi.org/10.1016/j.surge.2015.11.004.

[35] J. Crozier, A. Williams, S.T.F. Chan, G. Thompson, Randomized trial of laparoscopic cholecystectomy procedure-specific consent form, ANZ J. Surg. (2017), http://dx.doi.org/10.1111/ans.13888.

[36] M. Arnander, V. Teoh, A. Barabas, S. Umarji, A. Fleming, Improved patient awareness and satisfaction using procedure specific consent forms in carpal tunnel decompression surgery, Hand Surg. Int. J. Devoted Hand Up. Limb Surg. Relat. Res. J. Asia-Pac. Fed. Soc. Surg. Hand 18 (2013) 53–57, http://dx.doi.org/10.1142/S021881041350010X.

[37] R.A. Agha, M.R. Borrelli, M. Vella-Baldacchino, R. Thavayogan, D.P. Orgillfor the STROCSS Group, The STROCSS statement: strengthening the reporting of cohort studies in surgery, Int. J. Surg. (2017) article in press.