



Organisational risks matter and should be discussed during consent: survey of 980 neurosurgery patients from the UK

Introduction

During consent, surgeons discuss surgical and anaesthetic risks with patients. We investigated whether patients also wish to be informed about hospital organisational risks.

Methods

We used a cross-sectional survey. A questionnaire with three real-life scenarios of hospital organisational problems likely to increase the risk of surgery was given to 1,003 patients in neurosurgical departments of three United Kingdom (UK) teaching hospitals. The scenarios were: (1) computer failure in the operating room; (2) lack of surgical equipment; and (3) bed shortage or lack of operating capacity causing postponement of surgery. We quantified how strongly participants wish to be informed about organisational risks, whether this information alters a patient's decision to have surgery, and the desire of patients to discuss these risks further.

Results

In total, 980 of 1,003 (97.7%) questionnaires were returned and 84.3%–88.5% of patients wished to be informed about hospital organisational risks – more women than men (odds ratio [OR] 1.6–1.8, $p < 0.05$). Knowledge of the hospital organisational risks would influence 69.2%–70.4% of participants' decisions to have surgery; 74.9%–78.3% of participants wished to discuss the organisational risks with surgeons and 50.0%–60.8% with hospital managers before surgery. Some 69.4% of patients were concerned about organisational risks vs 77.1% who were concerned about surgical risks.

Conclusions

Most neurosurgery patients consider hospital organisational risks to be material. To comply with the Montgomery ruling in UK medicolegal case law, neurosurgeons and hospital managers should discuss with patients the organisational risks in addition to the surgical and anaesthetic risks during consent.

Keywords: Informed consent; Litigation; Medicolegal aspects; Neurosurgery

Introduction

Informed consent is a legal and ethical requirement for the practice of surgery.^{1–3} In 2015, the ruling of the United Kingdom (UK) Supreme Court in the case of *Montgomery vs the Lanarkshire Health Board* changed the practice of consent.⁴ Doctors are no longer the sole arbiter of determining what risks to discuss with patients, but doctors must take reasonable steps to ensure that patients are informed of all risks that are material to them. The test for materiality is “whether, in the circumstances of the particular case, 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 likely attach significance to it”.

UK medicolegal practice centres predominantly on the consequences of medical errors or negligence. Surgeons also generally

focus on the surgical and anaesthetic risks when discussing the chances of harm related to a procedure, and the information leaflets given to patients explaining surgical procedures describe only the surgical and anaesthetic risks.^{4–7} Managerial failures pose risks of harm during surgery, but are not normally discussed with patients during consent, and have received little medicolegal attention.^{8,9} Here, we used a survey to investigate whether patients consider hospital organisational risks to be material to them, as defined by the Montgomery ruling.

Methods

Study design

The survey, designed by neurosurgeons, solicitors and a statistician, was given to patients as a double-sided sheet with pen plus clipboard that were then returned to the

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receptionist. To avoid duplication, patients were asked whether they had already completed the survey. Sheets were numbered to allow us to establish the response rate. Replies were structured on five-point Likert scales. No free text was allowed. Patients were given the option to refuse participation and were informed that the survey was anonymous with no bearing on treatment.

Approvals

This survey was not considered research by the National Health Service (NHS) Health Research Authority online tool and thus no research ethics committee approval was required. The survey was registered with the St. George's Information Governance office as IG 2023-561.

Participant recruitment

The survey was given to patients waiting in outpatients, preassessment and to inpatients. To minimise bias, we selected clinics on different days of the week and handed the questionnaire to all patients in each clinic. Some ward patients were given the questionnaire. The data collectors were unrelated to the patients or the surgical teams looking after the patients. Recruitment was done at the neurosurgery departments of St George's Hospital in London, Charing Cross Hospital in London, and the Royal Infirmary in Edinburgh. Parents and guardians filled the survey for patients under 16 years of age.

Data collection

We chose three scenarios of hospital organisational failures that happened in real life and placed the treating surgeons in the ambiguous position whether to inform patients or proceed with the added undetermined risks. The survey had twenty-three questions: five demographic, six related to scenario 1, six related to scenario 2, four related to scenario 3, and two comparing patients' attitudes towards surgical vs organisational risks in scenarios 1–3. The questionnaire is provided Appendix 1 (available online). The three scenarios and attitude towards risk were as follows.

- Scenario 1. The surgeon cannot adequately display your scans during surgery. Surgeons look at the scans during surgery to check they are on the correct site, find an abnormality, avoid damaging structures next to the abnormality, etc. Your operation can go ahead but with higher risk.
- Scenario 2. Certain surgical equipment is not available; for example, a wound drain. The operation can go ahead, the surgeon may use an alternative or no drain, but with higher risk of developing a blood clot in the wound that may cause nerve damage.
- Scenario 3. The hospital has a bed shortage or lack of operating theatre availability and thus your surgery is rescheduled. The delay may increase the risk that you suffer nerve damage.
- Attitude towards risk. You are having a spinal operation with a 2%–3% risk of a serious complication such as paralysis. You discussed with the surgeon the treatment options and the risks + benefits of surgery. It is impossible to give you an accurate percentage for the hospital-associated risks.

Data processing and storage

The returned questionnaires were stored in a locked cabinet. Once data collection was completed, the data were manually transferred to Microsoft Excel for Mac v.16.86 (Arlington, VA, USA). One of the authors (MAJM) who did not enter data

double-checked the accuracy of data transfer in 100 randomly selected forms.

Statistical analysis

We used Microsoft Excel for Mac v.16.86, and Minitab v.22.1.0.0 (State College, PA, USA). Odds ratios (ORs), confidence intervals (CIs) and *p*-values were computed by fitting multi-variable ordinal logistic regression models to account for covariates (age, education, ethnicity, hospital, sex and surgery) on the patients' replies. CIs were computed at 95%. We used *p* < 0.05 to determine statistical significance. The findings were reported in accordance with the STROBE guidelines for cross-sectional studies.

Patient and public involvement

The survey underwent several cycles of amendments including pilot testing using lay people. The lay people provided insights into how the survey was perceived by non-clinicians including wording changes to remove technical terms.

Results

Demographics

The questionnaire was given to 1,003 participants, 74.1% (*n* = 743) at St. George's, 16.5% (*n* = 166) at Charing Cross and 9.4% (*n* = 94) in Edinburgh, between 1 October 2023 and 1 April 2024. In total, 97.7% (*n* = 980 of 1,003) of questionnaires were returned by the participants and were included in the analysis. Details of the participants are given in Appendix 2 (available online). Some 56.6% (*n* = 555) were female, 41.1% (*n* = 403) were male, and for the rest (2.2%, *n* = 22) sex was unspecified. The average age was 55.1 years (range 0.4–91); further age details are given in Appendix 3 (available online). In total, 69.0% (*n* = 676) of participants were white, followed by other ethnicities; 86.5% (*n* = 847) completed at least secondary school and the rest did not specify; 29.0% (*n* = 284) either had surgery or were scheduled for surgery, with 26.6% (*n* = 261) unsure about surgery; 9.2% (*n* = 90) were inpatients awaiting surgery; and 21.4% (*n* = 210) participants had problems with the brain or spine, with no information given for the rest.

Responses to questionnaire

Table 1 summarises the patients' responses to the three scenarios and their attitudes towards surgical risk vs organisational risk.

- Scenario 1. Some 88.5% (*n* = 867) of patients wanted to be informed of the risks posed by computer failure; 69.2% (*n* = 678) of patients stated that knowledge of these risks would change their decision to have the surgery; 43.6% (*n* = 427) of patients would consider delaying surgery, but only 21.4% (*n* = 209) would explore having surgery elsewhere. Many participants wanted to discuss these risks before surgery: 50.4% (*n* = 493) with hospital managers responsible for the computers in the operating room, and 78.3% (*n* = 768) with surgeons.
- Scenario 2. Some 86.3% (*n* = 845) of patients wanted to be informed of the risks posed by lack of equipment; 70.1% (*n* = 687) stated that knowledge of these risks would change their decision to have the surgery; 54.0% (*n* = 529) of patients would consider delaying surgery, but only 28.5% (*n* = 279) would explore having surgery elsewhere. Many participants wanted to discuss these risks before surgery: 50.0% (*n* = 490) with hospital managers responsible for operating room equipment, and 76.1% (*n* = 748) with surgeons.

Table 1 Patient responses

	Yes <i>n</i> (%)	Unsure <i>n</i> (%)	No <i>n</i> (%)	No reply <i>n</i> (%)
Scenario 1, computer failure				
I would like to be informed	867 (88.5)	31 (3.2)	20 (2.0)	62 (6.3)
Risks influence my decision	678 (69.2)	114 (11.6)	117 (12.0)	71 (7.2)
Delay surgery	427 (43.6)	282 (28.8)	189 (19.3)	82 (8.3)
Have surgery elsewhere	209 (21.4)	266 (27.1)	412 (42.0)	93 (9.5)
Discuss with manager	493 (50.4)	185 (18.9)	216 (22.0)	86 (8.7)
Discuss with surgeon	768 (78.3)	63 (6.4)	60 (6.2)	89 (9.1)
Scenario 2, equipment problem				
I would like to be informed	845 (86.3)	26 (2.7)	21 (2.1)	88 (9.0)
Risks influence my decision	687 (70.1)	108 (11.0)	86 (8.8)	99 (10.1)
Delay surgery	529 (54.0)	223 (22.8)	123 (12.6)	105 (10.6)
Have surgery elsewhere	279 (28.5)	268 (27.3)	321 (32.8)	112 (11.4)
Discuss with manager	490 (50.0)	179 (18.3)	197 (20.1)	104 (11.6)
Discuss with surgeon	748 (76.1)	68 (6.9)	56 (5.7)	108 (11.0)
Scenario 3, bed shortage or lack of operating theatre space				
I would like to be informed	826 (84.3)	29 (3.0)	29 (2.9)	96 (9.8)
Risks influence my decision	690 (70.4)	103 (10.5)	82 (8.4)	105 (10.7)
Discuss with manager	596 (60.8)	148 (15.1)	121 (12.3)	115 (11.7)
Discuss with surgeon	734 (74.9)	83 (8.5)	55 (5.6)	108 (11.0)
Surgical risks vs organisational risks				
Concern for surgical risks	756 (77.1)	49 (5.0)	72 (7.3)	103 (10.5)
Concern for hospital risks	681 (69.4)	96 (9.8)	92 (9.4)	111 (11.3)
Yes, is the sum of "definitely yes" and "probably yes" responses. No, is the sum of "definitely no" and "probably no" responses.				

- Scenario 3. Some 84.3% ($n = 826$) of patients wanted to be informed of the risks posed by postponing the surgery; 70.4% ($n = 690$) stated that knowledge of these risks would change their decision to have the surgery. Many patients wanted to discuss these risks before surgery: 60.8% ($n = 596$) with hospital managers responsible for beds and operating theatres, and 74.9% ($n = 734$) with surgeons.
- Surgical vs organisational risks. Some 77.1% ($n = 756$) of participants were concerned about the surgical risks compared with 69.4% ($n = 681$) about the hospital organisational risks.

Demographic factors associated with patient responses

We asked whether particular demographic characteristics were associated with the desire of patients to be informed of hospital organisational risks. In scenario 1, female participants were more likely than male participants (OR 1.7, 95% CI 1.1–2.4, $p < 0.05$) to want to know about organisational risks with no significant influence of the covariates age, education, ethnicity, hospital or surgery. In scenario 2, female participants were more likely than male participants (OR 1.6, 95% CI 1.0–2.4, $p < 0.05$) to want to know about organisational risks with no significant influence of the covariates age, education, ethnicity, hospital or surgery. In scenario 3, female participants were more likely than male participants (OR 1.8, 95% CI 1.2–2.6, $p < 0.05$), and those who had already had surgery less likely than others (OR 0.3,

95% CI 0.1–0.7, $p < 0.05$) to want to know about organisational risks with no significant influence of the covariates age, education, ethnicity or hospital. Details of the logistic regression models are given in Appendix 4 (available online).

Date entry error rate

In 100 randomly selected forms, 18 errors of data transfer from the paper copy to Excel were discovered from 2,700 data entry fields, thus giving a data transfer error rate of 0.6%.

Discussion

Principal findings

We showed that not only surgical risks, but also hospital organisational factors that are likely to increase the risks of surgery matter to most patients, and that patients wish to be informed of these risks. Information regarding organisational risks influences most patients' decision to have surgery. Our findings are likely generalisable because our "reasonable person in the patient's position" were many real-life patients with a wide age range, and diverse ethnicities from different hospitals.

In all scenarios, women wished to be informed of hospital organisational risks more than men, possibly because of the higher anxiety reported by women before surgery.^{10,11} In scenarios 1 and 2, most patients were likely to delay their surgery because of organisational risks, but most were unkeen to re-arrange their operations elsewhere, probably because

patients are concerned about similar organisational risks in other hospitals, about the inconvenience of moving to elsewhere (potentially further from home and having to rebuild rapport with new surgical teams) and about the delays involved in re-arrangements. Interestingly, in scenario 3, patients who already had surgery were less concerned about organisational risks (compared with patients awaiting surgery or those unsure about having surgery), likely because they considered that organisational risks no longer applied to them.

Implications

The principal implication is that, for consent to be lawful, hospital organisational risks should be discussed with the patients before surgery. At present, there is no UK medicolegal precedent that definitively rules that a surgeon must disclose organisational risks. However, the Montgomery ruling supports that, if organisational factors present material risks, they must be disclosed. Failing to do so could result in claims of negligence, breach of the duty of candour or inadequate informed consent. The trends in UK case law and regulatory guidance are moving towards greater transparency to include organisational factors.

Over the past decade, hospital organisational risks have intensified in the NHS. Many arise from competition between surgeons for limited resources (ward, high-dependency and intensive care beds, theatre space, equipment) and from managerial pressures to meet targets (for example, by prioritising long-waiters or previously cancelled patients ahead of clinically urgent ones). There is increased competition among surgeons in the same department, as a result of an increase in the number of consultants unaccompanied by an increase in infrastructure and resources (theatre space, ward space, nursing skill mix, outpatient clinic room availability, secretarial support). Such issues cause conflict between surgeons, anaesthetists, theatre staff, intensivists and managers before the start of each theatre list. The end product is last-minute changes, cancellations, operations done with inadequate equipment, elective patients prioritised over emergencies, and stressed and demoralised staff. Managerial decisions are made without the patients' knowledge or involvement, even though patients are the ones affected by the decisions. Last-minute cancellations have an adverse impact on patients and the economy, including workdays lost and health-related anxiety.¹²

A novel finding is the desire of patients to involve hospital managers in the consent process. This makes sense because managers are better informed of the organisational risks than surgeons, with several recent examples in the NHS in which managerial decisions have led to compromised patient safety including unnecessary deaths, understaffing, reduced operating, outdated equipment and limited bed capacity.^{13–16}

What constitutes an organisational risk varies between hospitals. A hospital's risk register lists organisational issues already identified by management as posing risk to patients, often accompanied by risk scores. Although the main aim of the risk register is for the hospital to internally highlight the risks and introduce measures to mitigate them, patients should be made aware of these issues during consent if the issues are thought to increase the risk of surgery. Currently, the risks listed in these registers are inaccessible to the public with a precedent of using ministerial veto to suppress disclosure.¹⁷

Based on our findings, we propose that institutions such as the General Medical Council, the Royal College of Surgeons of England, and the Royal College of Surgeons of Edinburgh alter their recommendations to recognise the importance of hospital organisational risks and the roles and responsibilities of hospital managers in the consent process.^{1–3} We also suggest that the

legal term "managerial negligence" be introduced, to complement the term "medical negligence".

Study limitations

There are important limitations to this study. First, we surveyed neurosurgical patients and thus our findings may not apply to other surgical specialties. Second, the study's cross-sectional nature means that we are unable to assess changes in patients' opinions with time. Third, we did not consider emergency operations where alternatives, such as postponing surgery or arranging surgery elsewhere, are not applicable. However, we believe that this study was well designed to address the stated aims and provide feedback on this important but underreported matter.

Conclusions

Most surveyed patients, when being consented for surgery, wish to be informed not only about surgical and anaesthetic risks, but also about hospital organisational risks. Such discussions are not current practice which, based on the Montgomery principle, leaves the consent process wanting at best, and potentially unlawful. Hospital organisational risks are complex and are best communicated to patients by a combination of surgeons and managers.

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Data availability

The data set is available from the corresponding author following reasonable request.

Author contributions

All the authors meet the International Committee of Medical Journal Editors' criteria for authorship. WYSF, MHR, PDD and VB were responsible for data collection at St. George's Hospital. YP was responsible for data collection at Edinburgh. DB was responsible for data collection at Charing Cross Hospital. MAJM was responsible for checking fidelity of data entry. MCP was responsible for conceptualisation. AKD was responsible for the study in Edinburgh Royal Infirmary. MCP was responsible for the study at St. George's Hospital. MHR was responsible for collaborator recruitment and management. MHR was responsible for project administration. MHR, HA, RV, MCP, a statistician and two solicitors were responsible for designing the survey. MCP was responsible for writing the manuscript. MCP was responsible for liaising with the statistician. All authors were responsible for editing and revising the manuscript. MCP was responsible for supervision. MCP is the guarantor. All authors have read and approved the manuscript.



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