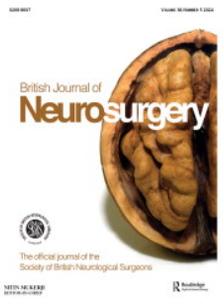

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Development and early Evaluation of a novel tool for assessment of individualised risk tolerance during surgical consent

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ABSTRACT

Purpose: The legal interpretation of consent has transitioned over the last decade. Surgeons must identify what patients value to individualise surgical consent. This presents a considerable challenge during busy ward rounds or outpatient clinics. We aimed to develop and evaluate a novel risk tolerance tool to aid surgical consent.

Methods: This prospective, longitudinal cohort study evaluated the views of adult, elective surgical patients from a single centre. Attitudes to the existing surgical consent process were assessed (n = 48) and responses underwent thematic analysis. From these responses and a stakeholder focus group, a novel risk tolerance tool was developed. The risk tool was evaluated using questionnaires in 25 pre-operative patients. Post-operatively, the same cohort were followed-up with a telephone clinic 6–8 weeks after discharge.

Results: Overall patients were satisfied with the current consent process, but negative themes emerged including that it is generalised, impersonal, and time pressured. The developed risk tool contained six domains: death, pain, loss of physical function, loss of cognitive function, need for repeat medical interventions, and social disability. Loss of physical function (mean = 34.0, SD = 12.8) and loss of cognitive function (mean = 34.0, SD = 6.1) had lowest risk tolerance, and need for repeat medical interventions (mean = 18.8, SD = 10.9) had the highest risk tolerance. Thirteen (93%) patients had a positive experience of the consent process vs 85% of patients in pre-consent tool cohort.

Conclusions: The tool demonstrated good patient acceptability and patient reported experience. The tool gathered data that may enhance understanding of patient risk tolerance and personalise the surgical consent process.

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Consent; litigation; risk; surgery

Introduction

The financial burden associated with medicolegal cases across healthcare is substantial, with NHS spending £2.4 billion on clinical negligence payments in 2021/22.[1,2] Surgery occupies 19% of overall clinical negligence claims due to the morbidity and mortality caused by procedural complications.[2–4] Inadequate consent prior to these procedures is one of the most common causes for medicolegal claims in surgery.[5–7]

The legal interpretation of consent has markedly changed over the last decade in the United Kingdom. The judgement of Montgomery v Lanarkshire Health Board (2015) moved consent from a physician centred approach (as previously described with the 'Bolam test') to a patient centred approach.[8] As a result of this ruling, informed consent should contain a discussion of all material risks of proposed and alternative treatments. The judge of materiality of a risk is whether 'a reasonable person in the patient's position would be likely to attach significance to the risk'. This is applied further in Thefaut v Johnston (2017) - in this case, following an elective lumbar spine operation, a patient was left with chronic pain and sensorimotor deficits.[9] Despite the surgeon having stated the possible risks and complications in advance of the procedure, the claimant was successful. The judge emphasises that materiality is sensitive to the characteristics of the patient. Consent should therefore include a subjective assessment of factors that may be less related to their medical condition such as a requirement to return to work or current life events which may make them more risk adverse at that time. The General Medical Council (GMC) states that 'doctors must try to find out what matters to patients so they can share relevant information about the benefits and harms of proposed options and reasonable alternatives'.[10]

A potential solution to understanding the attitudes of risk in individual patients comes from the financial advice industry, which commonly uses psychometric profiling tools to determine an individual's 'risk tolerance' profile prior to allocating funds. This is part of the due diligence process expected of regulated financial advisors when formulating investment advice for a client. An individual with a low 'risk tolerance' may have their investment allocated to a low return, but low volatility fund. Conversely, an individual with a greater appetite for risk may have their investment allocated to a more volatile, but potentially

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higher yield fund.[11] This process aims to recognise that individuals have different psychological and personal circumstances which should be accounted for when dispensing professional advice.

We hypothesised that a similar tool to the risk profiling questionnaires commonly used in the financial sector, could be developed for use in the surgical consent process. Accordingly, this study aimed to develop a risk tolerance tool to guide the consent process for surgical procedures. A formalised process to identify a patient's risk tolerance profile before undergoing a procedure will help identify what is important to the patient and allow the surgeon to put the benefits and risks of a procedure in context of each patient's circumstances.

Methodology

Overall study design

A mixed methods study design was used, with self-rated questionnaires, and subsequent thematic and quantitative analysis between October 2022 and December 2022.

The study was registered as part of a service evaluation within University College London Hospitals and approved by the Clinical Governance Committee. Informed consent was not required for this study.

The STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) checklist was followed for reporting observational studies.[12]

Development of risk tolerance tool

A preliminary view-finding questionnaire (Appendix 1) of 50 adult patients prospectively undergoing elective brain and spine surgery at a single tertiary neurosurgery hospital was done. Patients who underwent emergency operations or who were unable to answer the questionnaire were excluded. This sample size was selected based on previous thematic analyses in the literature.[13,14] A neurosurgical patient population was chosen as the morbidity and mortality associated with clinical negligence is high.[2] The questionnaire comprised of five white-space questions, which focused on the patient experience of consent. This provided a qualitative assessment of the current standard of practice regarding the consent process. Within normal working hours, patients admitted under the neurosurgery team, who were medically fit for discharge and had capacity to answer the questionnaire were identified. Patients from all neurosurgical subspecialties at our centre were included, provided they were consented by either a consultant or a registrar. Identified patients were consecutively given the view-finding questionnaire to complete until the target sample size of 50 participants was reached. The questionnaire was distributed to patients on the day of discharge and was anonymised with basic demographics and type of procedure documented. The responses gathered from this questionnaire were used for thematic analysis.

Thematic analysis was done using a previously described structured methodology with six stages: (1) data familiarisation, (2) generating codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, and (6) producing analysis report.[15] The themes derived from the analysis were discussed and agreed upon by the authorship during a weekly research meeting.

A semi-structured focus group was then conducted with key stakeholders to discuss themes raised by the initial questionnaire and to discuss the domains of risk deemed important. Stakeholders comprised of patient representatives ($n = 3$), senior medico-legal barrister ($n = 1$), and consultant neurosurgeons ($n = 3$).

Evaluation of risk tolerance tool

This novel tool was completed during a pre-operative clinic by adult patients prospectively undergoing elective brain and spine procedures (Appendix 4). Post-operatively, the patients were followed-up via telephone clinic at 6–8 weeks after discharge and asked about their experience of the novel tool, using a structured questionnaire (Appendix 3). Figure 1 shows a study flow diagram of the risk tolerance tool development.

Data analysis

Data analysis was performed on anonymised results of the risk tolerance questionnaire to demonstrate responses across the different domains with distribution curves for each, as well as overall for the patient group tested. RStudio Version 2022.07.0 + 548 was used for analysis with packages tidyverse, ggplot2, gtsummary, hrbrthemes, and viridis.

This was an early evaluation of the risk tolerance tool, in which separate cohorts completed the preliminary view-finding questionnaire and the risk tolerance tool. Prior to data collection, it was decided that we would not assess the tool for non-inferiority in comparison to the existing consent process because of the heterogeneity and low numbers in the patient cohorts.

Results

Development of risk tolerance tool

The existing consent process was assessed by prospectively surveying 50 adult patients undergoing elective brain and spine surgery. Two patients were excluded from analysis, one because they did not have surgery and one because they had emergency surgery. In the 48 patients that were analysed, 25 (52%) were male, median age was 53.5 years (IQR 25–67.75). The types of procedures performed were most commonly spine ($n = 20$, 42%), followed by brain ($n = 17$, 35%), peripheral nerve ($n = 4$, 8%), and two patients did not respond.

Q1. What was your experience of the current consent process?

Forty-one (85%) patients reported a positive experience of the current consent process. 'Clear explanation' was a theme of the positive response for example, "very thorough and detailed description of the operation." However, 10 (21%) patients commented negatively about the consent process, with the theme being the consent process is 'impersonal', for example, one patient desired " … more appreciation of the patient as a human being … ".

Q2. Do you feel that your views were listened to and understood by the surgeon?

Forty-three (90%) patients felt understood by their surgeon, for example, " … extremely understanding, and patiently answered every question and concern without judgement." A minority of patients ($n = 4$, 8%) felt listened to, but that the conversation was time pressured, for example, " … a rush."

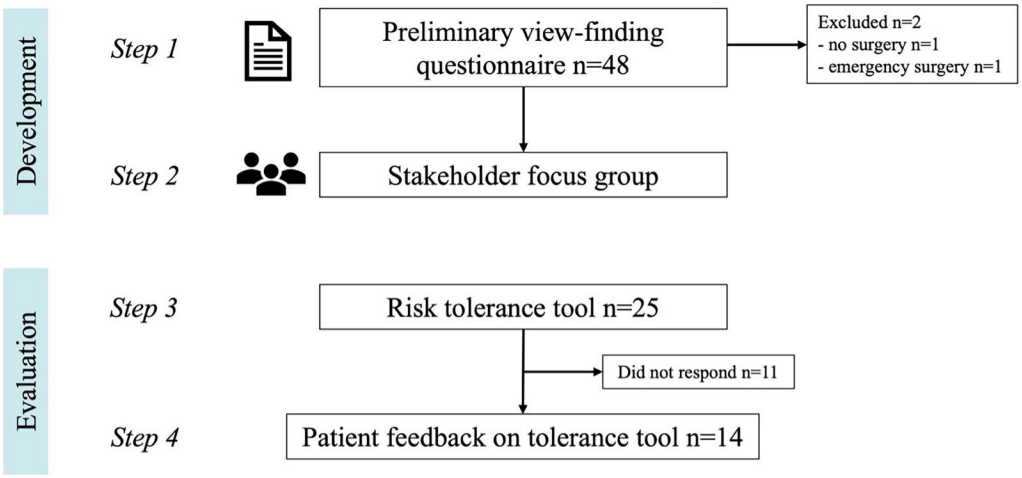

Figure 1. Study flow diagram.

Q3: Do you feel that the surgeon got to know you as an individual person prior to surgery during the process of consent and explanation?

Forty-one (85%) patients responded very positively with comments indicating consent was 'individualised', for example, "… excellent understanding of my personal situation." However, eight 18%) patients felt the consent was 'generalised' and desired more personalisation, for example, "… it felt routine" and "human touch adds invaluable insights … ".

Q4. Do you feel that you were made to understand the impact that any potential complications may have had on you as an individual?

Forty-six (96%) patients felt that the surgeon explained the impact of any potential complications to them in a detailed manner. For example, "all potential risks were explained, potential future check-ups and complications." A minor subset of two patients (4.2%) desired further explanation on the specific risks and how this would impact their life. For example, "… did not realise I would be so immobile".

Q5. How could the current process be improved?

Thirty-five (73%) patients commented that the existing process could not be improved, for example, "It couldn't! My experience has been one of reassurance, constant check of my understanding, and my complete involvement in decision making." The most common suggestion for improvement was allowing more time for the consent process to occur ($n = 4$, 8.3%). Patients commented feeling stressed by the time-pressures of the existing consent process, for example, "… meeting the previous day would have eased my stress a bit". In addition, patients ($n = 4$, 8.3%) desired more information about their procedure through use of videos/pictures, patient champions, and jargon free explanations. Three patients (6.3%) had suggestions on changing the form of consent to an online format and one patient would have like to be allocated a particular surgeon.

Based on the result of the thematic analysis and the stakeholder focus group, a novel risk tolerance tool was created to act as a risk profiling tool for patients during the consent process. The risk tolerance tool was designed to address patient concerns that the current consent process was generalised and impersonal. The following domains were included: (1) death; (2) pain; (3) loss of physical function; (4) loss of cognitive function; (5) need for repeat medical interventions; (6) social disability.

Evaluation of risk tolerance tool

The risk tolerance tool was trialled prospectively in pre-assessment clinic for 25 adult patients undergoing elective brain and spine surgery. This cohort comprised of 13 males and 12 females, with median age of 64 (IQR 51.5 – 75.5) years of age.

Risk of loss of physical function (mean = 34, SD = 12.8), loss of cognitive function (mean = 34, SD = 6.1) and social disability (mean = 33.6, SD = 7.3) had the highest mean scores indicating greater patient concerns for risk in these domains. Need for repeat medical interventions had the lowest mean score (mean = 18.8, SD = 10.9) (Figure 2).

As part of the risk tolerance tool, patients were asked to rank the five senses in order of priority. Sight was ranked of highest importance ($n = 23$, 92%), hearing as the second most important ($n = 17$, 68%), taste and touch were ranked as second or third most important for 56% ($n = 14$) and 52% ($n = 13$) of patients respectively (joint third most important senses). Smell was ranked as the least most important sense.

Patient experience of risk tolerance tool

All 25 patients who were exposed to the risk tolerance tool provided feedback. Nineteen patients (76%) felt the tool would help the surgeon understand them and 20 (80%) felt the tool would help personalise the consent process. Eighteen patients (72%) felt that a discussion about the findings of the risk tolerance tool would help facilitate a conversation during the consent process. Overall, 22 patients (88%) would be happy for the risk tolerance tool to be used during the consent process.

Impact of exposure to risk tolerance tool post-operatively

Following exposure to the risk tolerance tool 14 patients (56%) were assessed on their experience of the consent process. All questions received a higher proportion of positive responses compared to the initial cohort who were not exposed to the risk tolerance tool.

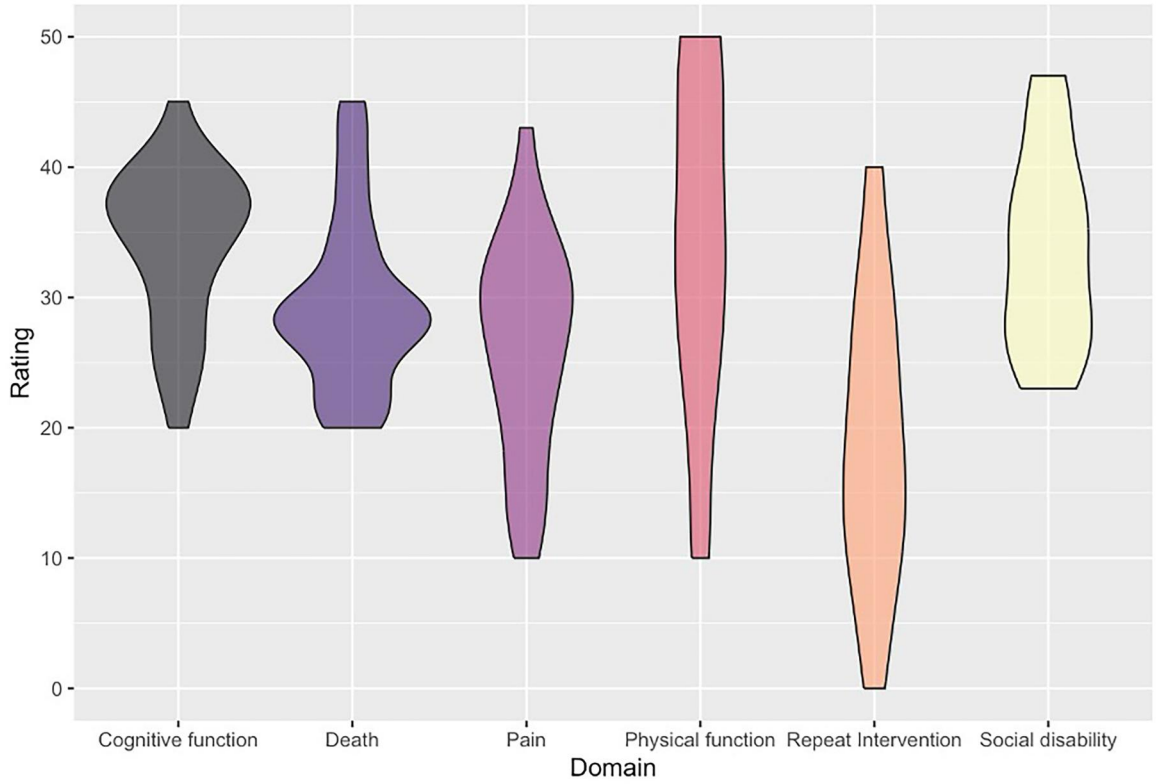

Figure 2. Violin plot of the distribution of ratings given across the different domains of the risk tolerance tool. Each domain is rated between 0-50, with higher scores indicating worse risk tolerance for each domain.

Thirteen (93%) patients had a positive experience of the consent process vs 85% of patients in pre-consent tool cohort. All 14 (100%) patients felt that their views were listened to and understood by the surgeon (90% pre-consent tool cohort). Twelve (86%) patients felt that their surgeon got to know them as an individual during the consent process (85% pre-consent tool cohort) and 13 (93%) patients felt that they were made to understand the impact of potential complications on them as an individual vs 96% in pre-consent tool cohort. We did not analyse whether the difference in consent experience was statistically significant because the cohorts differed in sample size and were asked about consent at different times (day of discharge vs. telephone follow-up). We anticipated these factors would confound the results, making statistical analysis uninformative.

Discussion

Principal findings

This is the first study exploring the application of a risk tolerance tool for augmentation of the consent process in a healthcare setting. Our initial view-finding survey and subsequent thematic analysis identified key areas for improvement in the consent process. This included allowing more time for consent and personalising the consent process. To address the themes identified, we created a novel, focus group driven, risk tolerance tool covering domains pertinent to the patient's informed consent. It was developed through patient feedback and input from key stakeholders. The risk tolerance tool has shown high levels of patient reported experience on the consent process in those exposed to the tool. It has good patient acceptability and could augment the consent process by acting as a clinical tool to facilitate greater personalisation to the consent process.

Utility of the risk tolerance tool

The risk tolerance tool developed in this study will address the requirement for personalisation of the consent process by augmenting an individualised discussion between the surgeon and patient. We envisage that the tool will be utilised by clinician's during a pre-operative clinic. The questionnaire is written in plain English and can be filled out in a timely manner, for instance in the waiting room prior to the clinic starting and the results reviewed by clinicians like how blood tests and imaging are. We found that using the risk tolerance tool encouraged patients to ask questions and express concerns about a proposed surgical procedure. It also prompted surgeons to inquire why certain risk domains were rated higher and to explore the patient's underlying fears. This allowed the surgeon to contextualise the procedure's risks based on the patient's risk profile. For instance, if the highest scoring domain during lumbar discectomy consent was the loss of physical function, the post-operative risk of neurological complications would be discussed first.

As the risk tolerance tool is used in a wider population of patients, it will be possible to compare each patient's response, to create quartiles of risk tolerance. This will provide clinicians a simple risk tolerance rating between 1–4 for each domain, to help define the risk sensitives for each patient. Comparing individual scores against a cohort addresses the issue of certain domains inherently scoring higher for all patients. For instance, loss of physical and cognitive function had the highest mean ratings in this study, indicating low risk tolerance. In contrast, the repeat intervention domain scored the lowest mean rating. Despite not having a higher absolute rating, repeat intervention may be a considerable worry for patients scoring in the highest quartile of responses. This can prompt further discussions regarding specific anxieties or characteristics that are important

in their life. It allows an understanding of materiality and supports the patient's decision making.

The active engagement with the risk tolerance tool by the patient reinforces to the patient the ownership they have of informed consent. It forces patients to question what material risks are important to them as an individual, and may prime them to have a balanced, honest, and productive consent discussion with their surgeon. Furthermore, the documentation provided by the risk tolerance tool demonstrates that the surgeon has sought to identify what matters to a patient. While this alone is unlikely to prevent future medicolegal issues, it will help surgeons discuss a procedure's benefits and risks in the context of a patient's circumstances. This was a key factor in the Thefaut v. Johnston (2017) case, where the claimant succeeded due to an inadequate consent process in which risks of a lumbar discectomy were understated and underexplored by the surgeon.[9] As an adjunct to the consent process, it is low cost, applicable across surgical specialities and if completed prior to the surgical consultation can allow more time for focused and individualised consent discussions.

Findings in context of the literature

Multiple previous studies have attempted to augment the consent process with adjuncts. Kinnersley *et al.*, in their Cochrane review identified that written information materials, audio-visual materials and decision aids were the most common adjuncts used as interventions to enhance informed consent.[16] Only two previous studies have surveyed patients in relation to risk in the context of surgical consent. Pucher *et al.* surveyed adult patients who had undergone laparoscopic cholecystectomy or hernia repair to understand the patients' attitudes towards consent and their risk tolerance.[17] Perceived risk tolerance was assessed by asking patients at what arbitrary level of risk they would be willing to consent to a procedure for a possible complication. This included theoretical risk levels of >0.1%, >1% and >10% for mild, major, severe complications and death. As expected, risk tolerance decreased with increasing severity of complications. Thiessen *et al.* assessed potential kidney donor's risk tolerance to post donation kidney failure.[18] A Likert scale expression of agreement or disagreement with stated risk in combination with a visual scale was used to assess patient's risk tolerance to post donation kidney failure. In both these studies patients have assigned a percentage of likelihood they would be willing to accept for specific risks. This provides a narrow discussion of specific risks, that does not address the requirement for understanding the individual factors that may be important to the patient in their decision making. Our risk tolerance tool builds on this previous work by providing an overview of individualised risk tolerance into six separate domains for each patient. This generalist approach will help target a more detailed conversation between patient and clinician during the consent process.

Strengths and limitations

Our patient cohort was prospectively collected and included a range of neurosurgery operations with different risk profiles. Although a heterogenous group of patients, they are from a single neurosurgical centre and results may not reflect the practices seen at other institutions or surgical disciplines. Future work aims to integrate this tool into other neurosurgical centres and other surgical specialities, to provide external validation of our results. It is important not to over interpret the results from the development of the risk tolerance tool. This is a feasibility study and therefore we are yet to ascertain if these results are applicable or would have a benefit when implemented within the consent process.

Initially, patients were surveyed post-operatively, on the day of discharge about their experience of the consent process. Responses are at risk of recall bias as the success of their surgery would have influenced their perception of the consent process. In addition, responses from patients post-operatively about the impact of the risk tolerance tool was gathered from 58% of the cohort. This selection bias may have influenced the results reported.

Conclusions

This study showcases the development of a novel risk tolerance tool that has shown non-inferiority of the patient's reported experience of the consent process after exposure to the tool. It is a unique concept within healthcare and is applicable to a diverse range of surgical procedures. This tool is designed to personalise the consent process though understanding of patient risk tolerance across multiple domains. This enhances the consent process by allowing the surgeon to have a greater understanding of what is important to the patient. Importantly, it also provides medicolegal documentation of these efforts to mitigate against future medicolegal claims. Future studies will aim to assess the implementation of the risk tolerance tool within the consent process.

Author contributions

JP conceptualisation of the study. JB, JP, NN, DR, SS, and HJM contributed to designing the study. JB, JP, and DR contributed to data extraction, curation, and analysis. JB, JP and DR, drafted the initial draft of the manuscript. JB, JP, NN, DR, SS, and HJM contributed to the review and editing of the manuscript. HJM provided supervision of the study. All authors were involved in the writing and approval of the final version of the manuscript.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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Data availability statement

Anonymised data will be made available on reasonable request by contacting the corresponding author. The thematic analysis report and RStudio script is available from GitHub repository https://github.com/bookej/Surgical-consent.git.

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