Improving Consent in Trauma: Recall (ICIT: Recall)

a multicentre study protocol of consent for hip fractures

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Aims

This study investigates the effectiveness and adequacy of the informed consent process for patients undergoing hip fracture surgery. While informed consent is a legal and ethical responsibility, factors in the trauma setting can impair patients' understanding and retention of information. This study seeks to evaluate patients' recall of perioperative complications and explore their perceptions of the consent process.

Methods

A mixed-methods, multicentre cohort study will be conducted in the Southeast of Scotland. Adult patients with hip fractures will be recruited via consecutive sampling. An information recall questionnaire will be administered within 36 hours of admission to assess unprompted and prompted recall of complications. A subset of participants will then undergo a semi-structured qualitative interview postoperatively to explore their experiences and perceptions of the consent process. Data will be analyzed using a social constructivist grounded theory to assess their perceptions of consent. Ethical approval has been granted by the East of England Research Ethics Committee (reference 23/EE/0233).

Conclusion

Findings will be disseminated through peer-reviewed publications and presentations at national and international conferences. The study results will identify challenges in the consent process, particularly in how risks are communicated and understood. The data are expected to inform the development of information aids and enhance the ability of orthopaedic surgeons to provide comprehensive, patient-centred consent.

Take home message

- The study results will identify challenges in the consent process, particularly in how risks are communicated and understood.
- This is expected to inform the development of information aids, and enhance the ability of orthopaedic surgeons to provide comprehensive, patient-centred consent.

Introduction

Informed consent is a fundamental legal right for patients and an ethical obligation for surgeons. An inadequate consent process undermines the surgeon-patient relationship and can result in medicolegal consequences.[1] A review of data obtained from the NHS litigation authority between 1995 and 2012 found that the total cost of claims involving hip fractures accounted for £7 million GBP. Many were attributed to common postoperative complications, such as pressure sores, neurovascular damage, and blood clots.[2] Freedom of information requests reveal that these continue to be a large cause of claims in 2020.[3]

In 2015, the Montgomery case was a landmark ruling for surgeon-patient relationships across all specialities by shifting the focus of consent towards the specific needs and concerns of the

Table I. Inclusion and exclusion criteria for the study.

Inclusion criteria	Exclusion criteria
Patients aged ≥ 50 years, no upper age limit	Deemed to be too unwell or medically unstable to participate
All hip fracture patients who are candidates for surgery	English is not their first language
Able to provide informed consent	Under the Adult with Incapacity Act, or other detaining orders
Able to participate in a conversation without the usage of a translator	Hearing impairments
	Patients with intoxication, dementia, or delirium (4AT ≥ 4)
	Unable to provide consent

patient.[4] The ruling elevated the standards for informed consent and introduced the challenge of determining what risks are material to their patients. For consent to be valid, a surgeon is required to answer all questions relating to the course of the disease, as well as the benefits, risks, and alternatives to the intervention. The process of seeking and obtaining consent should also be an adaptive process, rather than a one-off event.[5] While many studies have audited the accuracy of consent forms or explored if patients can recall complications in the acute setting, there has been little research into exactly what complications patients attribute significance to in relation to hip fracture operations, and why.[6-8]

In emergency surgery, a patient's ability to understand and retain information is likely adversely affected by medication effects, pain, and psychological distress.[9] However, the responsibility of seeking informed consent in the acute setting is often delegated to a junior member of the orthopaedic team, sometimes with minimal formal training in the task.[10] A better understanding of what patients apply significance to in their hip fracture consent process will guide the consenting surgeon to put the Montgomery ruling into practice.

This is a multicentre, prospective mixed-methods study collecting clinical and patient-reported outcomes of patients with hip fractures in the Southeast of Scotland. It aims to identify how many complications patients are able to recall in the perioperative period, as well as what patients consider to be important during the consent process. The hypothesis is that patients will be unable to recall a significant number of complications, not understand the implications, and that there would be an important mismatch between the patient and clinician's perspective of the consent process.

Methods

Study setting

All adult inpatients with hip fractures between 1 September and 1 December 2024 in the Southeast of Scotland will be approached for recruitment into the study. Specific inclusion and exclusion criteria will be applied (Table I). Of those participants who can provide informed consent, purposive sampling will be applied to identify candidates suitable for a further postoperative interview.

Study design

This qualitative research design draws upon the social constructivist grounded theory methodology associated with Charmaz and Thornberg.[11] It is based on the belief that interviews allow co-construction of meaning through emergent interactions in a mutual exploration of the patient's perspectives and experiences, allowing interviewers to engage in reflexivity and interpret data using their own theoretical perspectives. A sequential explanatory model for data collection and analysis will be used,[12] namely the application of an information recall questionnaire for all adult trauma patients followed by the conduct and analysis of semi-structured interviews in order to give greater explanatory power. The following research questions (RQs) guided this exploration:

RQ1. How do patients who have experienced hip fractures perceive the consent process?

RQ2. How do patients perceive risks of the operation?

RQ3. What additional information is needed, and how should this additional information be relayed to improve the consent process?

Data collection: information recall questionnaire

All adult patients with hip fractures will be identified prospectively using the admissions proforma compiled daily by the admitting orthopaedic surgeon. Patient demographic data will be extracted from the hospital electronic records (TRAK) and from their consent form. Patients will be approached by the research team at an appropriate time that does not interfere with clinical care or coincide with mealtimes or visiting hours. Consent for both the information recall and postoperative interview will be completed by a member of the research team, which comprises Good Medical Practice-trained individuals. The research team will aim to complete the information recall questionnaire within 36 hours of admission.

Patient demographic data, including age, sex, postcode, type of fracture, and planned operation (arthroplasty, cannulated screws, dynamic hip screws, or intertan), will be collected from the electronic patient record, whereas the risks documented (Figure 1) will be extracted from their consent form and used to test information recall. Participants will complete a 4AT,[13] and individuals with a positive score ≥ 4 for delirium will not participate further in the study. Investigators will assess unprompted and prompted information recall for complications and details of their injury and operation using structured questionnaires. The outcome measures from prospective data collection will include rates of unprompted and prompted information recall for each complication, whether the participant lost their ability to consent within 36 hours of admission, and if the patient feels that an information leaflet would help them retain and understand the discussed complications.

Data collection: postoperative interview

Purposive sampling from participants who completed the information recall questionnaire will be used for the postoperative interview once they have reached postoperative day seven. An exploratory qualitative approach using a semi-structured interview (Table II) will be used to collect data. The goal is to provide a rich narrative focusing on the patient's thoughts, anticipations, expectations, and feelings relating to

their consent process after having had a time window to reflect on their experience. Potential probes to explore this include open questions, such as 'what does consent mean to you?', 'which of the complications discussed just now is most important to you?', 'was there any information you felt was missing during the consent process?', or 'how could the consent process be adapted to better accommodate your concerns?', and closed questions, such as, 'did you feel that some risks were more important than others?' or 'did you feel informed enough about the risks to decide about going ahead with the surgery?'. The interview will be independent of the medical team, and the interviewer will not be directly responsible or involved in the patient's care. We anticipate that interviews will last between 30 and 40 minutes. These will be conducted using a standardized transcript either face-to-face or via telephone, depending on whether they remain an inpatient by postoperative day seven.

Both the information recall and postoperative interviews will be transcribed to an electronic proforma and will be anonymized prior to transfer to the central study team. The proforma will be identical at each hospital site, allowing for ease of merging and data analysis.

Investigators

The study will be undertaken by local investigators who will identify eligible patients, gain informed consent, and administer the information recall and postoperative questionnaires. Data collection will be supervised by a consultant orthopaedic surgeon, and all investigators will complete training in undertaking the interview with patients prior to starting the study, in order to ensure standardized interview techniques.

Participant timeline

All eligible and consenting patients will complete the information recall questionnaire within 36 hours of admission and a further questionnaire one week postoperatively. Follow-up will be completed via telephone consultation if they have been discharged by this point.

Strengths and limitations

This prospective study's strengths and limitations can be seen in Table III.

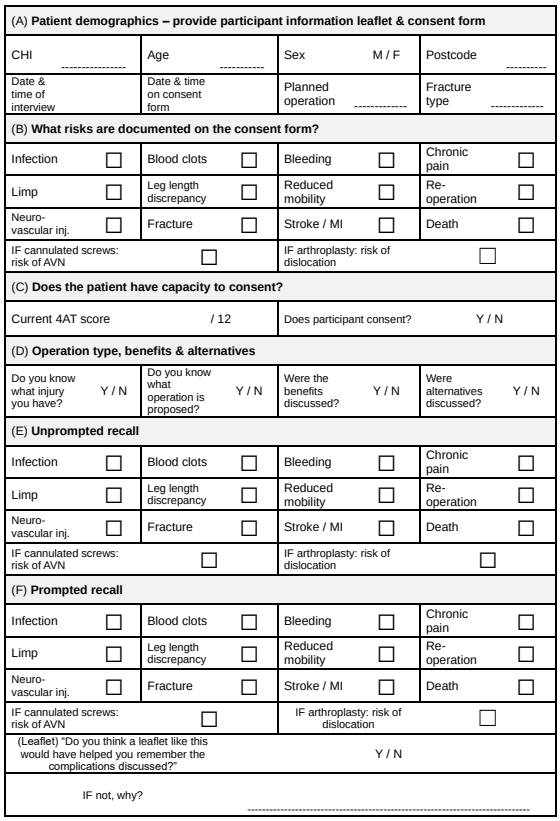
Sample size and statistical analysis

Data will be collected over a two-month period, resulting in a total of 50 hip fracture patients. From these, we anticipate 80% agreeing to participate in the study, leading to 40 participants.

Once data collection is completed, all datasets across hospital sites will be merged and analyzed at the primary site in the Southeast of Scotland. Data will be analyzed using SPSS Statistics v. 28.0 (IBM, USA). For the information recall questionnaire, continuous variables will be analyzed using mean and SD, or median and IQR, depending on whether data is normally distributed. Pearson's coefficient will be used to demonstrate the correlation between continuous variables. A p-value < 0.05 will represent statistical significance.

For the postoperative interview, an exploratory thematic analysis will be implemented based on the six-phase approach described by Braun and Clarke.[14] Thematic analysis will be used owing to its affinity with free-text patient dialogue.

Data familiarization will be completed by the lead investigators and will involve conducting, recording, fully transcribing, reading, and rereading the interviews. The data will be coded into open codes using direct quotations from the participants, and aim to be collated into themes. Data collection will continue until saturation of themes, and any disagreements in choice of coding or collation into themes will be discussed between the research team.



(A) **Patient demographics – provide participant information leaflet & consent form**			
CHI ----------	Age ----------	Sex M / F	Postcode ----------
Date & time of interview	Date & time on consent form	Planned operation ----------	Fracture type ----------
(B) **What risks are documented on the consent form?**			
Infection ☐	Blood clots ☐	Bleeding ☐	Chronic pain ☐
Limp ☐	Leg length discrepancy ☐	Reduced mobility ☐	Re-operation ☐
Neuro-vascular inj. ☐	Fracture ☐	Stroke / MI ☐	Death ☐
IF cannulated screws: risk of AVN ☐		IF arthroplasty: risk of dislocation ☐	
(C) **Does the patient have capacity to consent?**			
Current 4AT score / 12		Does participant consent? Y / N	
(D) **Operation type, benefits & alternatives**			
Do you know what injury you have? Y / N	Do you know what operation is proposed? Y / N	Were the benefits discussed? Y / N	Were alternatives discussed? Y / N
(E) **Unprompted recall**			
Infection ☐	Blood clots ☐	Bleeding ☐	Chronic pain ☐
Limp ☐	Leg length discrepancy ☐	Reduced mobility ☐	Re-operation ☐
Neuro-vascular inj. ☐	Fracture ☐	Stroke / MI ☐	Death ☐
IF cannulated screws: risk of AVN ☐		IF arthroplasty: risk of dislocation ☐	
(F) **Prompted recall**			
Infection ☐	Blood clots ☐	Bleeding ☐	Chronic pain ☐
Limp ☐	Leg length discrepancy ☐	Reduced mobility ☐	Re-operation ☐
Neuro-vascular inj. ☐	Fracture ☐	Stroke / MI ☐	Death ☐
IF cannulated screws: risk of AVN ☐		IF arthroplasty: risk of dislocation ☐	
(Leaflet) "Do you think a leaflet like this would have helped you remember the complications discussed?" Y / N			
IF not, why? ----------			

Fig. 1
Prospective data collection form and information recall questionnaire. AVN, avascular necrosis; MI, myocardial infarction.

Data management

Investigators and institutions involved in the study will permit study-related monitoring and audits on behalf of the sponsor, Research Ethics Committee review, and regulatory inspection. In the event of audit or monitoring, the investigator agrees to allow the representatives of the sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the investigator agrees to allow inspectors direct access to all study records and source documentation.

Protocol amendments

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant in

Table II. Postoperative qualitative interview guide.

Research topic	Question	Potential probes
Perception of consent	'What is your perception of the consent process for a hip fracture operation?'	• 'What does consent mean to you?' • 'What were your initial thoughts and feelings when the consent process was explained to you?' • 'How comfortable did you feel asking questions about the surgery and its risks during the consent process?' • 'Were there any parts of the consent process that you found confusing or difficult to understand?' • 'Were there any aspects of the consent process that you felt were particularly helpful or unhelpful?'
Perception of risk	'What is your perception for what the risks of a hip fracture operation are?'	• 'What were your thoughts when the surgeon discussed the risks associated with your surgery?' • 'Were there any risks that you were surprised to hear about? If so, which ones and why?' • 'Did you feel that some risks were more important than others? If yes, which ones, and why?' • 'Were there any risks that you didn't fully understand but didn't ask about? If so, why?' • 'Did you feel informed enough about the risks to decide about going ahead with the surgery?'
Information aids	'What additional information or aids do you feel would have improved the consent process?'	• 'Was there any information you felt was missing during the consent process? If so, what was it?' • 'How could the healthcare team have made the consent process clearer or easier to understand?' • 'Would an information leaflet or other written material have been helpful to you? If yes, what should it include?' • 'How could the consent process be adapted to better accommodate your concerns?'

Table III. Strengths and limitations.

Strengths	Limitations
This will be the first multicentre mixed-methods study that captures both information recall and narrative contents	Interview and narrative quality are heavily dependent on investigator skills
This study will take place in a multicentre setting	Selection and recall bias
This study will generate evidence and feedback on orthopaedic consenting to improve future treatment and trainee confidence	

the case of an urgent safety measure, must be reviewed and approved by the chief investigator. Proposed amendments will be submitted to the sponsor for classification, review, and authorization. Amendments to the protocol must be submitted in writing to the appropriate Research Ethics Committee and local research and development approval prior to implementation, and prior to participants being enrolled into the amended protocol.

Data protection

All investigators and study site staff involved with this study must comply with the requirements of the appropriate data protection legislation (including the General Data Protection Regulation and Data Protection Act) regarding the collection, storage, processing, and disclosure of personal information. Published results will not contain any personal data that could allow identification of individual participants. Completed hard-copy questionnaires and consent forms will be stored in locked filing cabinets in designated locations, accessible only to the research team. Hard copies will be transcribed immediately upon completion and converted to anonymized electronic spreadsheets on password-protected servers.

Patient confidentiality

All records will be identified in a manner designed to maintain participant confidentiality. Records will be kept in a secure storage area with limited access. Clinical information will not be released without the written permission of the participant. The investigator and study site staff involved with this study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished information, which is confidential or identifiable, and has been disclosed to those individuals for the purpose of the study. Prior written agreement from the sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.

Ethical considerations and approval

This protocol was approved by the East of England Research Ethics Committee (reference 23/EE/0233) and a letter of approval was provided on 20 November 2023. The study was registered with clinicaltrials.gov (NCT06439537). Local investigators will also be responsible for ensuring that the study has undergone appropriate information governance and clinical audit registration as appropriate for their centre. Access to the STROBE checklist for this study is available in the Supplementary Material.

Discussion

This research aims to further explore challenges in the surgical informed consent process for hip fracture operations. There are a number of factors which make adequate consent in the orthopaedic trauma setting difficult, including difficulties in retaining information, increasing expectations on surgical outcomes, and the increasing age of hip fracture patients.[9,15,16] The consequences of failing to adequately obtain informed consent can lead to poor physician-patient relationships, a poorer response to treatment, and possible litigation.

Currently, the information given to hip fracture patients at the time of consent is variable and rarely standardized, with many consent forms being incorrectly or insufficiently

completed. The most commonly cited risks on consent forms tend to be bleeding, blood clots, infection, myocardial infarction, and injury to neurovascular structures, whereas the long-term impact on mobility, such as reduced mobility, chronic pain, or leg length discrepancy, are less frequently mentioned.[8,17] Evidence also suggests that patients view signing consent forms as an administrative hurdle, feel pressured to give written consent, or are frightened to ask for more information, whereas a more exhaustive consent process, including verbal explanation or a diagram followed by evaluation of recall, could alleviate stress and anxiety.[6,18,19]

This study aims to explore the narrative content of patients and their experience of the consent process in an acute trauma setting through the usage of semi-structured questionnaires and an analysis in the prevalence and frequency of themes. The method of interview within 36 hours of admission and multicentre data collection will improve external validity in capturing narrative contents. The investigators believe that the results of this study will generate evidence to inform the design of procedure-specific information leaflets and aid the consenting orthopaedic surgeon in more confidently providing the patient with information that promotes their autonomy and decision-making.

Supplementary material

The STROBE statement: checklist of items that should be included in reports of observational studies.

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T. Feng: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Validation, Writing – original draft, Writing – review & editing.
A. Ablett: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Resources, Supervision, Validation, Writing – review & editing.
C. E. H. Scott: Conceptualization, Methodology, Project administration, Resources, Supervision, Writing – review & editing.
N. D. Clement: Conceptualization, Methodology, Project administration, Resources, Supervision, Validation, Writing – review & editing.

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Data sharing

The data that support the findings for this study are available to other researchers from the corresponding author upon reasonable request.

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Ethical review statement

This protocol was approved by the East of England Research Ethics Committee (reference 23/EE/0233), and a letter of approval was provided on 20 November 2023. The study was registered with clinicaltrials.gov (NCT06439537).