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Refining, implementing, and evaluating an anesthesia choice conversation aid for older adults with hip fracture: protocol for a stepped wedge cluster randomized trial

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Abstract

Background Hip fracture surgery under general or spinal anesthesia is a common procedure for older adults in the United States (US). Although spinal or general anesthesia can be appropriate for many patients, and the choice between anesthesia types is preference-sensitive, shared decision-making is not consistently used by anesthesiologists counseling patients on anesthesia for this procedure. We designed an Option Grid™-style conversation aid, My Anesthesia Choice—Hip Fracture, to promote shared decision making in this interaction. This study will refine the aid and evaluate its implementation and effectiveness in clinical practice.

Methods The study will be conducted over 2 phases: qualitative interviews with relevant clinicians and patients to refine the aid, followed by a stepped wedge cluster randomized trial of the intervention at 6 settings in the US. Primary outcomes will include the percentage of eligible patients who receive the intervention (intervention reach) and the change in quality of patient/clinician communication (intervention effectiveness). Secondary outcomes addressing other RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) domains will also be collected. Outcomes will be compared between baseline data and an active implementation period and then compared between the active implementation period and a sustainment period. Implementation strategies are guided by three constructs from the Practical, Robust Implementation and Sustainability Model (PRISM): *intervention*, *recipients*, and *implementation and sustainability infrastructure*.

Discussion This is a novel, large-scale trial evaluating and implementing a shared decision-making conversation aid for anesthesia choices. Strong buy-in from site leads and expert advisors will support both the success of implementation and the future dissemination of results and the intervention. Results from this study will inform the broader implementation of this aid for patients with hip fractures and can lead to the development and implementation of similar conversation aids for other anesthesia choices.

Trial registration ClinicalTrials.gov, NCT06438640

Keywords Shared decision making, Anesthesia, Hip fracture, Perioperative care, Implementation science, Patient-centered outcomes

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Contributions to the literature

- This paper describes a mixed-methods approach to refining and testing an intervention about anesthesia choices for hip fracture using qualitative interviews and a stepped wedge cluster randomized clinical trial.
- This is a large-scale trial studying the effectiveness and implementation of a conversation aid focused on anesthesia choices.
- Our strategies and results can inform future conversation aids focused on other anesthesia choices, thereby introducing shared decision-making conversation aids and best practices to these important perioperative interactions.

Background

Each year, as many as 250,000 older adults in the United States (US) undergo surgery for hip fractures with either spinal or general anesthesia [1, 2]. Across numerous randomized trials among patients with no contraindications to either anesthesia option, there are no significant differences in patient-centered outcomes such as patients' ability to walk, mortality, and delirium between either anesthesia option for hip fracture surgery [3–6].

Shared decision making is an appropriate approach for clinical situations that are preference-sensitive with tradeoffs between the benefits and drawbacks of available options [7]. Data underscore that anesthesia choice for hip fracture is one such paradigm. Perioperative tradeoffs that may be sensitive to patient preference include concerns regarding specific aspects of anesthesia administration (e.g., spinal injection, intubation), postoperative comfort, and the possibility of crossover from spinal to general anesthesia during the operation due to clinical necessity.

Patients and their family members have preferences about anesthesia options; in one clinical trial, 40% of eligible patients contacted for enrollment declined participation due to a preference for one or the other type of anesthesia, and 11% of crossovers between treatment assignments were due to patient or family member request [3, 8]. In another survey-based study, 71% of respondents indicated a desire to have some role in decisions about their anesthesia care [9]. Despite patients' and caregivers' interests in being engaged in these choices, anesthesia clinicians do not consistently approach consultations as shared decision-making conversations [10–14].

Our team developed a conversation aid, My Anesthesia Choice—Hip Fracture (MAC-HF), to help support consistent and productive shared decision-making conversations between clinicians and patients with hip fracture [15]. The MAC-HF conversation aid is based on the validated Option Grid™ format, which uses plain-language (6th-8th grade reading level) summary tables on a single page to help patients compare two clinical options [16]. Option Grids are intended to facilitate decision-making conversations rather than provide comprehensive education on a clinical topic. We adapted the Option Grid format to include visual elements, such as icons, color, and bolding of key topics. These types of visual cues have been shown to support patient engagement with complex clinical information [17–21]. MAC-HF was found to improve knowledge and reduce decisional conflict among participants imagining a choice between anesthesia options for hip fracture surgery and was perceived as acceptable and feasible to use [15].

The current protocol described in this paper is a multisite implementation study focused on Phase 1) refining the MAC-HF conversation aid, and Phase 2) training staff at study sites on shared decision making, creating site-specific implementation plans, and systematically testing the effectiveness and sustainability of the conversation aid using a stepped wedge trial design. Reporting of this protocol adheres to the Standards for Reporting Implementation Studies (StaRI); the StaRI checklist is included as additional material [22].

Methods

Overview

We will conduct a two-phase study that builds on initial work to develop the MAC-HF intervention. The intervention involves three related components: 1) provision of an evidence-informed, Option Grid-style conversation guide for clinicians and patients to use at the bedside during conversations about anesthesia options for hip fracture; 2) focused clinician training on conversation guide use and shared decision-making principles; and 3) clinician-facing nudges to encourage conversation guide use with eligible patients.

The first phase of the study (refinement) will use qualitative methods to update the aid and training approach based on clinician and patient feedback. The second phase (implementation and evaluation) will involve deploying the strategy at 6 US hospitals drawn from an existing hip fracture research network and evaluating it using RE-AIM (reach, effectiveness, adoption, implementation, maintenance/sustainment) domains via a stepped wedge cluster randomized trial.

Conceptual framework

The project will be guided by the Practical, Robust Implementation and Sustainability Model (PRISM) conceptual framework [23]. PRISM is designed to facilitate the integration of healthcare research findings into practice

by identifying factors that support successful implementation and integrating a robust measurement plan into intervention design. PRISM identifies 4 constructs: 1) the intervention (patient and organizational perspectives), 2) the recipients (patient and organizational perspectives), 3) implementation and sustainability infrastructure, and 4) the external environment. The 4 constructs comprise a total of 39 elements that can be considered during implementation. PRISM also directly incorporates RE-AIM outcome domains, which balance the measurement of patient-centered outcomes (efficacy) with the measurement of implementation success (sustainability) [24, 25]. Specific measures for this study are discussed below.

Our planned study primarily addresses the first 3 PRISM constructs, building across our phases (see Fig. 1).

Site selection and targeted clinicians

Study activities will occur at 6 US hospitals ("sites"). Sites were selected from a pool of 11 interested hospitals based on interviews and a detailed feasibility questionnaire covering annual hip fracture volume among patients aged 50 and older (>120 cases/year); support from clinical institutional leaders; performance in prior collaborations with the study teams; anticipated barriers to enrollment; and geographic, racial, and ethnic diversity. Sites were selected to include large and small hospitals, academic centers and community hospitals, and publicly and privately owned facilities.

Clinicians (attendings, residents, and certified registered nurse anesthetists (CRNAs)) at study sites providing anesthesia to patients aged 50 and older undergoing surgery for hip fracture are eligible to participate. Clinician participation at each site is encouraged, but not mandatory, and individual clinicians are permitted to opt out of participation in either or both phases of the study.

Phase 1: Refinement of the MAC-HF intervention

Phase 1 will use semi-structured interviews with clinicians, patients, and caregivers to refine the proposed

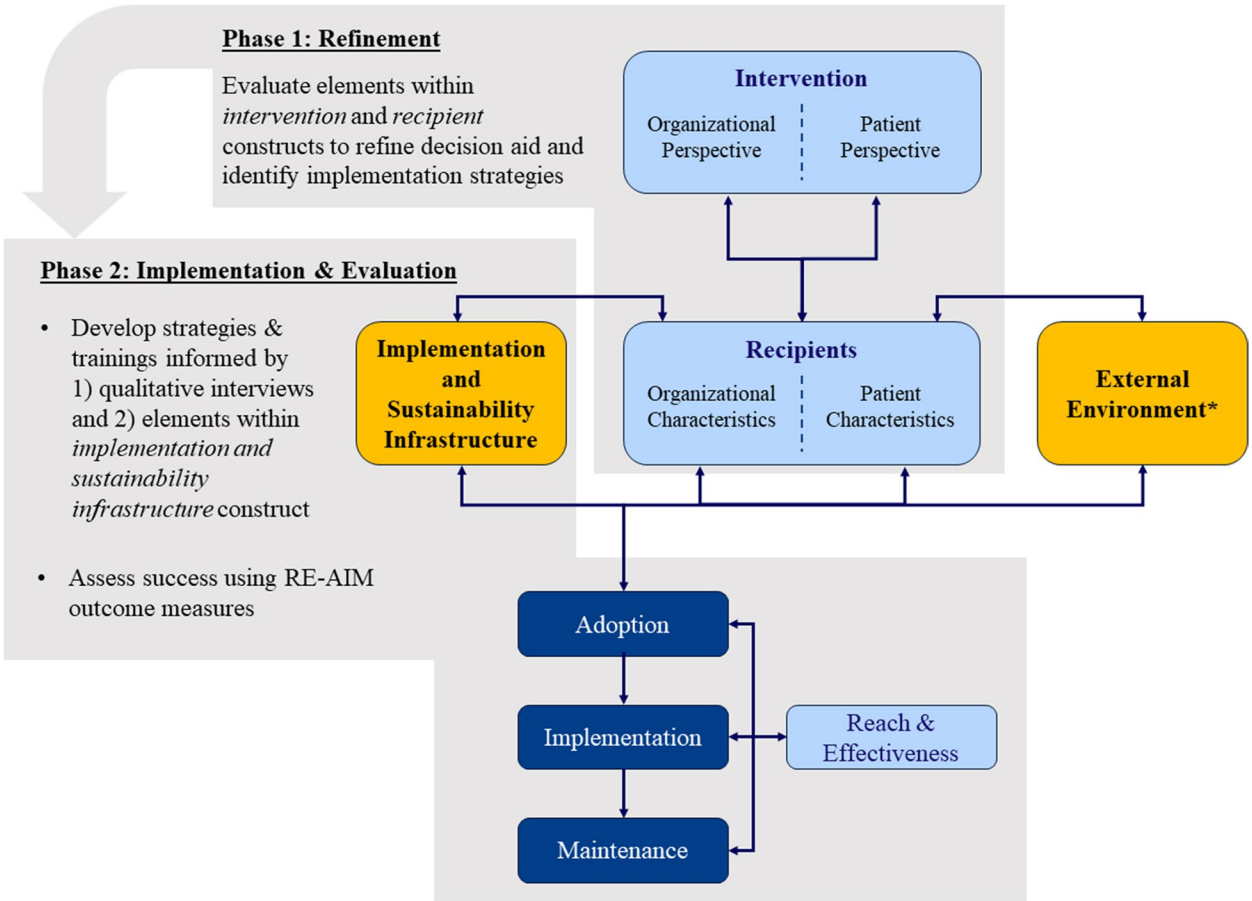

Fig. 1 Practical, Robust Implementation and Sustainability Model (PRISM) constructs to be addressed

conversation aid and assess implementation needs, including delivery timing, format, and training needed to use the intervention in routine care. We will recruit up to 40 participants in this phase with relevant experience (either clinicians treating patients for hip fracture, patients who have been treated for hip fracture, or caregivers of such patients) across study sites. Participants will review the aid and provide their opinions on format, content, benefits, disadvantages, and use within the clinical workflow. They will not use the aid to support care decisions during this phase but will provide important feedback to incorporate into Phase 2.

Interviews will be transcribed and coded using NVivo by two coders coding collaboratively on the first 5–7 transcripts to reach consensus, then separately after reaching interrater reliability (kappa $\geq$ 0.75 and $\geq$ 95% agreement) with periodic fidelity checks. The codebook will initially be based on elements from the PRISM *intervention* and *recipient* constructs that we anticipate will be relevant (see Table 1). We will refine the codebook inductively based on emerging themes from interviews.

Suggested adaptations to the aid and implementation strategies will be tracked using the Framework for Reporting Adaptations and Modifications—Expanded (FRAME) and the Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS), respectively [26, 27]. Additional informal feedback from pre-implementation site meetings will also be tracked in these frameworks. Lead investigators will discuss suggestions to reach consensus on which to implement.

Phase 2: Implementation and evaluation of the intervention

Pre-implementation, active implementation, and sustainment activities will occur at each site. During pre-implementation, sites will complete necessary training in shared decision making and the study protocol and develop local plans for conversation aid integration into clinical workflows, addressing elements from the *implementation and sustainability infrastructure* PRISM construct (Table 2). Baseline data collection on selected outcomes will also take place during this phase to allow for assessment of the efficacy of the intervention. During active implementation, the intervention will be used in routine care with support via reminders and clinician-facing nudges to maximize reach. During sustainment, the intervention will remain in use at each site without support to assess maintenance of the intervention at each site over time. We anticipate that this initiative will enroll a total of approximately 300 anesthesia clinicians and 3,548 eligible patients across all sites over the 27-month project period.

Data collection of the outcomes described below will occur across pre-implementation, active implementation, and sustainment at each site, although specific data elements collected will vary across study steps. To facilitate evaluation, sites will be randomly assigned to one of three possible timing sequences for project implementation (2 sites per sequence, balanced by hip fracture volume and demographics). The site randomization algorithm will be determined prior to project initiation by the lead study statistician and maintained on a secure server; sequence assignment will be communicated to each site at the start of the pre-implementation phase.

Pre-implementation, active implementation, and sustainment phase activities will be carried out at each site across 9 total 3-month periods according to the assigned sequence. The duration of active implementation will be the same for each sequence (12 months); however, the duration of pre-implementation and sustainment will vary across sequences (Fig. 2). Total project duration at each site will be 27 months.

Table 1 Anticipated PRISM elements to explore in Phase 1

Construct	Anticipated Relevant Elements	Relevant Interview Topics
Intervention—Organization Perspective	• Readiness • Strength of evidence • Ability to observe results • Burden • Addresses barriers of frontline staff	Usability Content & format When to deliver Where to deliver With whom to review Delivery format
Intervention—Patient Perspective	• Patient-centeredness • Provides patient choices	
Recipients—Organization Characteristics	• Support & communication • Systems & training • Expectation of sustainability	Benefits Downsides Desirability
Recipients—Patient Characteristics	• Knowledge & beliefs • Disease burden • Competing demands	

Table 2 Anticipated PRISM elements addressed in phase 2

Construct	Anticipated Relevant Elements	Planned Strategies
Implementation and Sustainability Infrastructure	• Adopter training and support • Relationship and communication with adopters (bridge researchers) • Facilitation of sharing of best practices	• Trainings on shared decision making • Continuous communication and support via site leads
	• Adaptable protocols and procedures	• Sites designing local strategies appropriate to their usual clinical workflows
	• Plan for sustainability	• Sustainment measured in a distinct study phase to assess challenges after active implementation ends

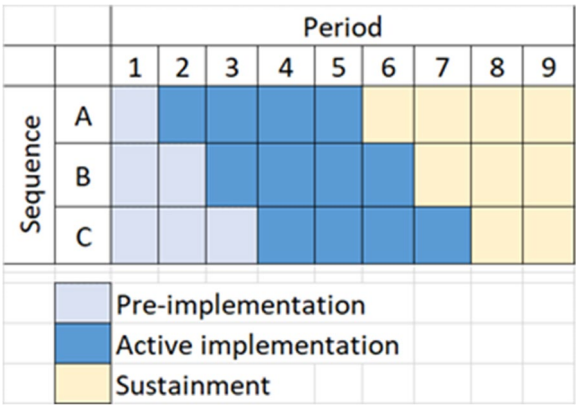

Fig. 2 Implementation sequences

Clinician training

At each site, we will hold an initial in-person or virtual (webinar) training session for participating anesthesia clinicians prior to intervention implementation. Training sessions will be approximately 1 h in duration and will be led by research team members with expertise in shared decision making, health communication, and anesthesia for hip fracture. The training session content will include a review of shared decision-making principles, evidence on shared decision making and communication in anesthesia, an overview of the MAC-HF conversation aid, and best practices for using the aid during clinical encounters (Table 3).

For clinicians who miss the initial training, a recorded training session will be available for self-directed learning, along with brief just-in-time facilitated training that will be delivered by the site lead investigator to clinical staff in advance of specific assignments. Refresher or repeat trainings will be made available to clinicians based on ongoing assessments by the overall study principal investigators and local site teams. At the time of training, all clinicians will receive information on the overall study goals and objectives, along with plans for data collection and analysis. Clinicians will be permitted to opt out of individual data collection for clinician-reported items for the project without penalty by notifying the site lead investigator via email.

Site implementation planning

Each site will design a local implementation strategy to guide intervention deployment. All sites will make the MAC-HF conversation aid available in English and Spanish versions in appropriate clinical areas in hard-copy or electronic format. Additionally, sites will develop local strategies for identifying potentially eligible patients prior to the pre-anesthesia evaluation, and sites will develop a

Table 3 Best practice steps for administration of the MAC-HF conversation aid

Step	Description *Adapted from* [16]
1. Describe	Describe that the goal of the MAC-HF conversation aid is to initiate a conversation about options, that it is organized as a table to enable comparison, and that it addresses questions that many other patients have found useful
2. Check	Check if the patients wish to read the aid themselves or whether they prefer the comparisons to be vocalized
3. Hand over	Hand over the MAC-HF aid to the patient
4. Create space	Create space by asking permission to perform other tasks if the patient wishes to read the aid, so that they do not feel 'observed' as they take time to assimilate the information
5. Encourage	Encourage questions and discussion
6. Gift	Gift a copy of the aid to the patient as a memory aid and to encourage discussing their options with others

process for encouraging the treating anesthesia team to use the MAC-HF conversation aid (Table 4). To facilitate integration into local workflows, sites will also specify plans for engaging key stakeholders and educating involved clinician groups (e.g., nursing, orthopedic surgery, geriatrics) regarding the intervention components and recommended workflows.

Patient screening and enrollment

All patients undergoing hip fracture surgery at a given site during the study period will be identified by site research staff based on medical record review. Eligibility will be determined via medical record review by trained site research staff using a standardized eligibility determination form (age ≥ 50, hip fracture, no major contraindications for either anesthesia type). Screened patients will be assigned a de-identified participant number.

Patients enrolled across study phases will receive notification regarding the study at the time of the preoperative visit and be able to opt out of data collection by contacting the site lead investigator or the overall study principal investigator (PI). Notification will occur via IRB-approved posted notices in preoperative care areas and on hard-copy versions of the MAC-HF conversation aid and will include basic study information and contact information for relevant study personnel.

Verbal consent to continue in the study will be obtained from patients using an institutional review board (IRB)-approved script at the time of the postoperative visit (described below). Survey administration will occur only with patients who provide consent to continue in the study. Patients who decline to complete the survey will end study participation and will not be contacted in the future.

Outcomes

We will use RE-AIM domains to guide the identification of study measures (Table 5) [24, 25]. Our primary implementation outcome is the percentage of eligible patients who receive the conversation aid (reach), and our primary effectiveness outcome is the change in the quality of patient/clinician communication as assessed using the Shared Decision-Making Process (SDMP) scale [28]. In addition to the primary implementation outcome, we will also assess the fraction of patients who agree to review the tool out of those offered the opportunity to do so. Measurement of all effectiveness outcomes will begin at least 3 months prior to active implementation at each site to allow for comparisons versus baseline, and measurement of effectiveness, adoption, implementation, and maintenance of the intervention will continue through the end of the sustainment phase.

Information on intervention reach will be collected from the attending anesthesiologist, CRNA, or resident anesthesiologist involved in the preoperative evaluation via email, text, telephone, or in-person interview with study research staff. This interview will take place within 48 h after surgery to determine if the MAC-HF conversation aid was reviewed with the patient and/or relevant family member or caregiver during the pre-anesthesia visit and, if applicable, to identify reasons why the aid was not reviewed. During sustainment, use with eligible cases will be assessed by site staff (attending anesthesiologist, CRNA, or resident anesthesiologist) within 24 h of surgery using the same questionnaire as for the primary outcome.

Patient-reported effectiveness outcomes (SDMP [28], CollaboRATE [29], SURE [30], anesthesia knowledge) will be collected prior to hospital discharge via in-person survey by trained research staff between postoperative days 0 and 3. If patients are themselves not able to participate in surveys (e.g., due to cognitive dysfunction), proxy respondents will be sought as appropriate; consent will be obtained prior to data collection as described above. CollaboRATE and SDMP both have been translated into Spanish. For speakers of other languages, we will use translated versions of these instruments as available. If a patient speaks a language for which a translated version is not available, site teams will work with clinical translation services to conduct the survey in the patient's native language, orally translating the English-language version of each instrument. Information on anesthesia type received and ambulatory status will be abstracted by trained research staff from the medical record using a standard data collection form and entered in the study database.

Table 4 Potential local strategies for patient identification and clinician reminders

Strategy type	Potential strategies
Patient identification	• Automated electronic medical record (EMR) algorithms • Manual review of daily operating room lists by site leads or their designees • Identification by admitting service team members at time of hospital presentation
Clinician reminders	• EMR based prompts • Secure e-mail, phone, or text notification of assigned anesthesia clinicians by site leads or other staff

Table 5 Study outcome measures by RE-AIM domain [24, 25]

Measures by RE-AIM domain [24, 25]	Implementation step		
	Pre	*Active*	*Sustainment*
Reach			
Percentage of eligible patients receiving the conversation aid (primary implementation outcome)		X	
Effectiveness			
Shared Decision-Making Process scale (SDMP; primary effectiveness outcome) [28]	X	X	X
CollaboRATE measure of shared decision making [29]	X	X	X
SURE measure of decisional conflict [30]	X	X	X
Anesthesia knowledge	X	X	X
Friends & Family Test assessment of patient experience	X	X	X
Anesthesia type received	X	X	X
Ability to walk at follow-up	X	X	X
Adoption/Implementation			
Adoption/implementation clinician survey		X	X
Implementation			
Fidelity assessment observer checklist [31]		X	X
Debriefing interview regarding time & resources required for implementation		X	X
Maintenance			
Percentage of eligible patients receiving the conversation aid (sustainment phase vs. pre-implementation)			X
NoMAD assessment of perceived sustainability		X	X

Information will also be collected via chart review and patient/caregiver surveys at the postoperative patient visit to capture demographics (age, sex, education, race/ethnicity, insurance status, household size and income, marital status); comorbidities; procedure type; fracture characteristics; surgery dates; and pre-fracture function and cognitive status. Cognitive function will be assessed via the Short Blessed Test, a well-validated brief cognitive screening measure [32, 33]. Patients will also complete the Single Item Literacy Screener, designed to identify patients with limited health literacy [34]. These data items will be collected across all study phases.

Clinician attitudes regarding sustainability will be assessed via web-based surveys of participating clinicians during the active phase and the sustainment phase of the study. Time and resources required for implementation will be assessed via a debriefing interview conducted by the overall PI and co-investigators with the site lead and study team at each project site. This debriefing will take place within approximately 4 weeks of the end of the active implementation phase at each site.

Fidelity assessment

A subset of patients during the active implementation and sustainment phases will be approached to participate in an implementation fidelity assessment. The assessment will determine the extent to which participating clinicians' use of the MAC-HF conversation aid aligns with recommendations for use as outlined in training. Depending on research staff availability, site teams will designate specific days and time windows each week during the relevant phases to screen and enroll patients into the fidelity assessment. The frequency of screening windows may be adjusted over time based on enrollment patterns and historical site case volumes with the aim of assessing interactions with approximately 10% of eligible patients. Research staff will perform direct observations of selected patient/clinician interactions to assess whether or not the conversation aid is used and will complete a brief assessment of implementation fidelity using a structured data collection form used in a similar prior study [31]. A pre-planned ancillary study under separate consent will also assess fidelity using the OPTION-5 tool based on audiorecordings of conversations between clinicians and patients [35].

Data management & safety oversight

All study data will be entered into a study specific database on the Research Data Capture (REDCap) Application by trained and credentialed staff. The full study database will be accessible to the overall PI, lead study statistician, and members of the study data coordinating site. The study data coordinating site will carry out routine reviews of site-entered data to assess completeness and nonsensical/outlier values. Identified missing items and potentially erroneous values will be communicated

to sites for evaluation and correction as needed. Principal investigators and site leads will provide oversight for safety monitoring.

Analysis & results reporting plan

Initial analyses will use descriptive statistics to examine the distribution of study variables overall and to summarize outcome data. Effectiveness outcomes will be analyzed via intention-to-treat, such that observations will be analyzed according to their study phase. We will use mixed effects models to estimate the treatment effect of the MAC-HF intervention on the effectiveness outcomes. These models will contain binary indicator variables for study phase at a given unit within a particular period; as care patterns may be similar within hospitals, we will include a random effect for the hospital. Time (study month) will be included as a fixed effect; interactions to capture time-cluster and time-treatment effect heterogeneity will be considered in supplemental analyses [36, 37]. Standard errors will be adjusted for heteroscedasticity and clustering using standard methods [38, 39]. Continuous measures, such as SDMP and knowledge score, will be analyzed using linear mixed effects models [28]. Binary outcomes such as decisional conflict and CollaboRATE top score will be analyzed using mixed effects logistic models [29, 30].

We will assess and report heterogeneity of treatment effects in the main sample population across prespecified subgroups based on patient age, sex, race, and health literacy by introducing interaction terms to main study models to examine differences in effects by these treatment status relevant groups [40]. To evaluate sustainability, we will compare outcomes during the initial 12-month active implementation period to the post-12-month sustainment period using an equivalence margin of 0.1 standard deviations (SD), where a difference of less than 0.1 SD change will be considered clinically insignificant. Missing data rates across sites and arms will be compared for all outcomes and patterns of missingness evaluated and reported as appropriate. Where missing outcome data rates are substantial (> 10%), sensitivity analysis will be conducted using inverse probability weighting to model the potential impact of missing data on study findings [41].

To ensure appropriate statistical power, we assumed a conservative intra-site correlation coefficient (ICC) of 0.1 for the sample size estimate, with lower and upper bounds of 0.05 and 0.2, respectively. We also assumed a conservative missing rate of 10% for the primary outcome, and a coefficient of variation of 0.25 for the site sizes. An average sample size of 50 per period (quarter) per site is required to have 80% power to detect a difference of 0.26 SD at a significance level of 0.05, for an ICC of 0.1, and enrollment of 2 exposed cases for each control over the active implementation phase [37]. For the binary decision conflict outcome (SURE measure), we will have over 80% power to detect a relative risk of 1.26 in the intervention group compared to the comparison group at a significance level of 0.05, given the sample size of 50 per site per period. This calculation was based on a conservative missing data rate of 10%, an estimated rate of 63% in the control group (i.e., intervention group rate of 50%). If the intervention group shows a 33% rate of decision conflict, we will achieve over 99% power. For testing maintenance of the intervention over time, our sample will provide sufficient power to exclude a change in adherence between the active implementation versus sustainment phases with a margin of 0.2 SD [42].

Discussion

We have reported the protocol for My Anesthesia Choice-Hip Fracture, a new study that will refine and implement a conversation aid for anesthesia choices. This work uses a validated implementation science framework and conversation aid format to ensure that our strategies and the MAC-HF intervention are aligned with existing best practices in these fields. Using a stepped-wedge trial design allows us to control for between-site variations in patient volume, workflows, and standards of practice for managing hip fracture because each site acts as its own control. It also allows us to make the intervention broadly available to eligible patients at each site once the active implementation phase begins, thereby supporting rapid accrual of a diverse set of end users.

In addition to these important study planning and design elements, this protocol benefits from strong logistical support and encouragement from site lead investigators, other site leadership, and patient and clinical expert advisors. We are convening regular advisory boards with patient representatives and representatives of relevant national and international clinical professional organizations to share results, elicit feedback, and seek support for dissemination activities. We anticipate that these networks, as well as our collaborations across multiple geographic areas, will act to speed and amplify the dissemination of our results. In addition to publishing our results in appropriate journals, we will seek to encourage adoption of this aid via meetings, journal supplements, podcasts, and our dedicated website.

Although we have strong buy-in from leaders at study sites, we recognize that introducing an additional element to workflows can be burdensome to already-busy clinical staff. Local strategies identified in the pre-implementation phase and the shared decision making training sessions will be important to generate interest and support from the anesthesia team at each site. We also

anticipate differences in implementation based on local practice and individual clinician preferences. We aim to identify and address major variations in implementation during the active phase through data monitoring, fidelity assessments, and clinician retraining.

Of note, our intervention and implementation strategies do not directly address PRISM's *external environment* construct. However, this project does take place within the context of a regulatory external environment in which the Centers for Medicare & Medicaid Services are beginning to explore incentivizing shared decision making through reimbursement policies [43, 44]. As shared decision making continues to become more common and expected across different clinical encounters, this research will establish evidence and strategies for designing and implementing future conversation aids for anesthesia choice in contexts beyond hip fracture.

Conclusion

Hip fracture is a common injury requiring surgery among older adults, and there are multiple reasonable options for anesthesia for hip fracture repair operations. Guidelines recommend offering patients a choice of spinal or general anesthesia, but no validated conversation aids are available for presenting this choice to patients. The intervention implemented in this study will support shared decision-making discussions between patients and clinicians about this preference-sensitive choice.

Authors' information

Not applicable.

Abbreviations

CRNA	Certified registered nurse anesthetist
EMR	Electronic medical record
FRAME	Framework for Reporting Adaptations and Modifications—Expanded
FRAME-IS	Framework for Reporting Adaptations and Modifications to Evidence-Based Implementation Strategies
ICC	Inter-site correlation coefficient
IRB	Institutional review board
MAC-HF	My Anesthesia Choice—Hip Fracture
PI	Principal investigator
PRISM	Practical, Robust Implementation and Sustainability Model
RE-AIM	Reach, effectiveness, adoption, implementation, maintenance/sustainability
SD	Standard deviation
SDMP	Shared Decision-Making Process
StaRI	Standards for Reporting Implementation Studies
US	United States

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Authors' contributions

MN, MP, JB, RF, and GE contributed to the conception and design of the protocol. The manuscript was written by EG, MP, JB, and MN with support from VS, HC, RF, SM, and KW. Funding was acquired by MN and MP. All authors have agreed both to be personally accountable for their own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which a given author was not personally involved, are appropriately investigated and resolved, with the resolution documented in the literature.

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Availability of data and materials

The datasets created, used, and/or analyzed during the study will be made available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

This study has been approved by the Washington University in St. Louis IRB (Phase 1; IRB #202402115) and the University of Pennsylvania IRB (Phase 2; IRB #855203); site reliance agreements have been executed or are in progress at participating sites for Phase 2 activities.

Consent for publication

Not applicable.

Competing interests

MP has consulted with UCB Biopharma and EPI-Q, Inc., on topics unrelated to this manuscript. GE is the Founder and Director of Sharpnet Work, LLC, which provides training for shared decision making. He provides advice in the domain of shared decision making and patient decision aids to (1) Access Community Health Network, Chicago (Adviser to Federally Qualified Medical Centers), (2) EBSCO Health for Option Grids™ patient decision aids, (3) Bind On Demand Health Insurance, (4) PatientWisdom, Inc., and (5) Abridge AI Inc. No other authors declare competing interests.

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