# Implementation and Evaluation of a Strategy to Improve Pre-Anesthesia Care Discussions

Study Protocol, Version 1.0

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# 1. Abstract

Patients undergoing surgery often wish to be involved in decisions about their anesthesia care; however, in practice, anesthesia teams may fail to explain risks and benefits of available anesthesia options, elicit patient preferences, and integrate such preferences into care choices. This project will evaluate the implementation of an established strategy that has been shown to improve patient-clinician communication and to increase shared decision-making at 6 participating US hospitals. The context of the study will focus on understanding and improving communication about anesthesia choices for hip fracture surgery in older adults. The quality improvement strategy involves a brief clinician training and a 1-page, clinician-administered bedside conversation aid. This tool will be formatted as a table comparing the risks and benefits of spinal vs general anesthesia. Our primary outcome will be the reach of the strategy at each of 6 hospitals, as measured by the rate of conversation aid use with eligible patients during the post-implementation and sustainment phases of the study. Additional key outcomes to assess intervention effectiveness will include patient-reported measures of shared decision-making decisional uncertainty, and patient satisfaction. We will randomize the timing of when to start using the clinical tool to evaluate the effect of the intervention.

# 2. Overall objective

The objective of this research study is to assess the implementation process for and the effectiveness of a quality improvement (QI) strategy to increase shared decision-making around anesthesia options for hip fracture surgery at 6 US hospitals. The QI strategy is to be facilitated by a clinician-administered 1-page bedside conversation aid designed to improve the quality of physician-patient communication.

# 3. Background

Surgery and anesthesia are common events in the lives of older adults. On average, a US adult will undergo 9 surgical procedures over their lifetime, most of which will require some type of anesthesia.[1] In many instances, multiple safe options for anesthesia may exist. Available data indicate that patients often want to be involved in choices about anesthesia.[2] In practice, however, anesthesia teams often fail to explain risks and benefits of anesthesia options[3] and ask about patient preferences.[4,5] These gaps highlight opportunities to improve the quality of communication between patients and clinicians about anesthesia choices.

Brief conversation aids, such as Option Grids, have been shown to improve the quality of conversations about treatment options between patients and clinicians.[6] These aids are short tabular comparisons of options, incorporating best available evidence that can be reviewed by patients and clinicians together at the bedside to facilitate efficient conversations during visits and promote deliberation about choices.[6 7-10]

In order to improve the quality of communication about anesthesia choices for surgery, we will implement a 1-page conversation aid for patients facing choices about anesthesia for hip fracture surgery (My Anesthesia Choice-Hip Fracture (My Anesthesia Choice-HF). We have demonstrated that My Anesthesia Choice-HF is both acceptable to patients and effective in improving knowledge and decisional conflict in a national simulation study.[11] This study will focus on the context of hip fracture surgery. We have selected this context because: (1) hip fracture surgery is common among older adults, occurring over 250,000 times each year in the US;[12,13] and (2) multiple options for anesthesia exist for most patients, namely spinal anesthesia or general anesthesia.[14] Spinal and general anesthesia result in similar short- and long-term outcomes.[15-18] Guidelines recommend offering a patients a choice of either anesthesia type for hip fracture surgery.[19,20]

# 4. Intervention design

## 4.1 Target population

All anesthesia clinicians (attendings, residents, and CRNAs) at study sites providing anesthesia to patients aged 50 and older undergoing surgery for hip fracture will be eligible to be trained to use the conversation aid as appropriate based on defined patient inclusion criteria and clinician judgement. Patient eligibility criteria include: age 50 and older; planned surgery to treat a hip fracture (femoral neck, intertrochanteric, or subtrochanteric fracture); absence of major contraindications to spinal anesthesia (current anticoagulant therapy or coagulopathy;[21] critical aortic stenosis; skin infection over the lumbar spine). Finally, clinicians may decline to use the conversation aid based on criteria not listed above according to their clinical judgment and professional discretion.

## 4.2. Clinician Training

At each site, we will hold an initial in-person or virtual (webinar) training session for participating anesthesia clinicians during the pre-implementation or active implementation phase (see **Implementation Schedule** below). Clinician participation will be voluntary but encouraged for all providers responsible for anesthesia care during hip fracture surgery. Clinician participation will be tracked by the lead investigator at each site. Clinicians will be permitted to opt out of training and the names of clinicians who choose to not participate will be recorded. Training sessions will be approximately 1h in duration and will be led by research team members with expertise in shared decision-making, health communication, and anesthesia for hip fracture. For clinicians who miss the initial training, a recorded training session will be available for self-learning, along with brief just-in-time facilitated training that can be delivered by the site lead investigator to clinical staff in advance of specific assignments. Refresher or repeat trainings will be made available to site teams based on ongoing assessments of the overall study principal investigators and local site teams.

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 My Anesthesia Choice-HF tool; and best practices for using the tool in practice (**Box 1**). Providers will be encouraged to use the My Anesthesia Choice-HF tool during the pre-operative assessment on all hip fracture patients deemed appropriate as above. As in typical care, clinicians will be encouraged to appropriately involve family and non-family caregivers in discussions of anesthesia options. English and Spanish language versions of the tool will be made available to sites. For individuals who speak other languages, in-person or virtual clinical medical interpreter services will be used based on local processes for obtaining clinical care consent at each site.

**Box 1:** Best practices for administration of the My Anesthesia Choice-HF tool (Adapted from Elwyn et al., 2013)

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

## 4.3. My Anesthesia Choice-HF tool

Beginning at the start of the active implementation phase (see **Implementation Schedule** below), the current English-language version of the My Anesthesia Choice-HF appears in **Appendix 1**. Prior to

implementation, the tool will be reviewed with lead investigators at all sites and finalized for use based on consensus. Minor wording modifications for clarity and accuracy, as well as updates to cited statistics based on available high-quality evidence will be permitted prior to implementation and as needed during the study. Other modifications to the tool will not be permitted. Paper copies of the finalized My Anesthesia Choice-HF tool in English and Spanish will be made available in perioperative care settings at each site. Additional copies will be made available in anesthesia team spaces to permit use during conversations occurring on the hospital floor, emergency department, or intensive care unit.

## 4.4. Clinical workflow integration

To encourage tool adoption, each site will design a local strategy for identification of potentially eligible patients prior to the pre-anesthesia evaluation and a process for encouraging the treating anesthesia team to use the My Anesthesia Choice-HF tool. Strategies for identification may include but not be limited to: 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. Nudges to remind clinicians may include but not be limited to EMR based prompts or secure email, phone or text notification of assigned anesthesia clinicians by site leads or other staff. Site plans will be documented and approved prior to study start by the overall lead investigators. Patients will be prospectively identified beginning during the pre-implementation phase to allow for collection of baseline (comparator) data (See **Section 6.1** below); clinician-facing nudges will be used at each site during active implementation phase to encourage strategy adoption. To facilitate integration into workflow, 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 to ensure project success.

## 4.5. Evaluation and ongoing feedback

Site implementation progress will be tracked by overall project PIs across all implementation stages. Prior to beginning active implementation, each site will complete an in-person or virtual pre-implementation site visit led by the overall study PI or their designee to review completion of core required elements for implementation using a standardized checklist including reviews of local implementation plans, confirmation of training completion for clinicians and project staff, confirmation of applicable regulatory documents or approvals, and verification of plans for tool availability, data collection, and other study procedures. Sites not passing this initial readiness assessment will undergo remediation as needed.

A central REDCap project database will be created to track implementation progress. Site research staff will be trained on data collection and entry (see **Study Procedures**, below), and will report into the study database on all collected data items as detailed below in the study evaluation plan. Site-level data will be monitored by the study lead investigator and the study data management team on a regular basis. Beginning in the pre-implementation phase and continuing through the end of active implementation, site lead investigators will undergo virtual meetings at least quarterly to review collected data for completeness. During the active implementation phase, these meetings will also include discussion of metrics for project reach and intervention fidelity to track implementation progress.

## 4.6. Compensation

No compensation will be offered to patients or clinicians as a component of this quality improvement intervention.

# 5. Implementation schedule and projected accrual

## 5.1. Overview of implementation schedule and study duration

Activities at each site will be divided into three phases: **Pre-Implementation; Active Implementation; and Sustainment** (**Figure 1**). Data collection will occur across all study phases at each site, although specific data elements collected will vary across phases (see **Study Procedures**). To facilitate evaluation, sites will be randomly assigned to one of three possible timing sequences for project implementation (2 sites/sequence, balanced by hip fracture volume and demographics) as shown in the study implementation diagram. The site randomization algorithm will be determined prior to project initiation by the lead study statistician and maintained on a secure server at the University of Pennsylvania.

The duration of the active implementation phase will be the same for each sequence (12 months); however, the duration of pre-implementation and sustainment phases will vary across sequences as noted below. Sequence assignment will be determined by the lead study statistician and communicated to each site at the start of the pre-implementation phase. Total project duration at each site will be 27 months.

## 5.1. Pre-implementation phase

During this phase, participating sites will finalize plans for clinician-facing nudges; engaging key stakeholders to support implementation; complete baseline data collection (See **Section 6.1** below). Clinician training (see **4.2** above) will take place during the pre-implementation phase, with the goal of carrying out training for most clinicians during the final 2 weeks of this period to ensure data collected during pre-implementation reflects typical care prior to the quality intervention. If training cannot be completed during this period due to logistical considerations or scheduling conflicts, clinician training will be permitted to continue into the active implementation phase, with the goal of all training being completed by the end of the first month of active implementation. The pre-implementation phase will last between 3 and 9 months, depending on sequence assignment.

## 5.2. Active implementation phase

During this phase, sites will implement their local My Anesthesia Choice-HF strategy developed above, with use of clinician-facing nudges to encourage adoption. As noted above, clinicians who do not complete training during the pre-implementation phase will be permitted to complete training up to one month into the active implementation phase. Refresher trainings will continue throughout this phase as noted in **4.2.** above at the discretion of the site lead investigator and the overall study PI. The duration of the active implementation phase will be 12 months at all sites.

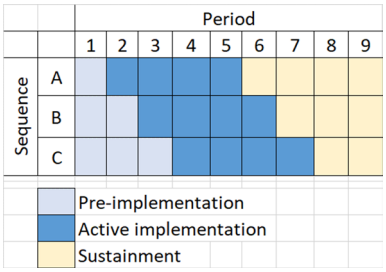


**Figure 1:** Each site will be assigned to 1 of 3 possible implementation sequences (2 sites/sequence). Pre-implementation, active implementation, and sustainment phase activities will be carried out at each site across 9 x 3-month periods according to the assigned sequence.

## 5.3. Sustainment phase

During this phase, the My Anesthesia Choice-HF tool will remain available for clinicians to use at each site for up to 6 to 12 months.

## 5.4 Projected enrollment

We anticipate that this quality improvement initiative will enroll a total of approximately 300 anesthesia clinicians and 3,548 eligible patients across all sites over the 27-month project period.

# 6. Evaluation Plan

## 6.1 Data to be collected

All study outcomes are listed in **Appendix 2**. Outcomes have been selected to address domains of the RE-AIM evaluation framework for implementation studies (Reach, Effectiveness, Adoption, Implementation and Maintenance)[22]

### 6.1.1. Primary implementation outcome

The primary implementation outcome is the reach of the intervention, assessed as the rate of use of the conversation aid during the active implementation phase at each site.

Information on the primary outcome will be collected from the attending anesthesiologist, CRNA, or resident anesthesiologist who obtained clinical consent for anesthesia for each eligible case during the active implementation period. The relevant clinical staff member will complete a brief email questionnaire within 48 hours after surgery assessing whether or not the My Anesthesia Choice-HF tool was reviewed with the patient and/or relevant family member/caregiver during the pre-anesthesia visit. For clinicians who do not complete the questionnaire on the initial attempt, site staff will follow up via email, telephone, or text to limit missing data. For visits where it was not used, clinicians will be asked to provide reasons for not using the tool. This information will be entered by site staff into the central project database.

### 6.1.2. Primary and secondary effectiveness outcomes

The primary effectiveness outcome is the change in the quality of patient-clinician communication in the pre-implementation versus active implementation periods at each site, assessed via the 4-item Shared Decision Making Process scale (SDMP; primary effectiveness outcome).[23] As a secondary effectiveness outcome, we will also assess the change in the 3-item CollaboRATE[24] patient-reported outcome measure of shared decision making. These scales will be both administered by trained research staff to patients one time after surgery between postoperative days 0 and 3 but prior to hospital discharge and entered into the study database. CollaboRATE and SDMP have each been translated into Spanish. For speakers of other languages, we will use translated versions of these instruments as available. For patients who speak languages for which translated version is not available, site teams will work with clinical translation services to conduct interviews in the patients' native language using the English-language version of each tool.

### 6.1.3. Exploratory outcomes

Exploratory outcomes will include: (1) the fraction of patients reporting decisional conflict about anesthesia pre-implementation versus active implementation periods, assessed via the 4-item SURE measure;[25] (2) patient-reported knowledge about anesthesia options pre-implementation versus active implementation periods, as assessed by a 6-item brief knowledge assessment; (3) patient satisfaction with anesthesia care pre-implementation versus active implementation periods, as assessed by a single-item "friends and family" satisfaction measure;[26] (4) the fraction of patients receiving general versus spinal anesthesia pre-implementation versus active implementation periods; (5) the fraction of patients who are able to ambulate independently (i.e. without human assistance) at first clinic follow up between 30 and 90 days after surgery; (6) fidelity of implementation to recommended best practices during active implementation and sustainment phases, assessed via the UPFRONT Fidelity Assessment (9 items)[10]; (7) the percentage of eligible patients receiving the strategy during the sustainment; (8) implementation fidelity and sustainability, as assessed via the 9-item UPFRONT Fidelity Assessment[10] 23-item NoMAD sustainability assessment;[29] (9) estimated time and resources required for project implementation.

#### *6.1.3.1. Overview of data collection for exploratory outcomes*

Items 1 through 3 above (decisional conflict, knowledge, and satisfaction) will be collected during the same visit as the effectiveness outcomes (SDMP, CollaboRATE); specifically, these assessments will each be administered by trained research staff to patients one time after surgery between postoperative days 0 and 3 but prior to hospital discharge and entered into the study database. Total time anticipated for survey completion across all items, including primary and secondary effectiveness outcomes and patient-reported exploratory outcomes will be about10 minutes. Knowledge items, and the satisfaction measure will be translated into Spanish for use as needed. For speakers of other languages, we will use translated versions of these instruments or relevant instrument items as available (https://decisionaid.ohri.ca/eval_dcs.html). For individuals who speak Spanish, we will use 4 relevant, analogous items from the Spanish-language low-literacy Decisional Conflict Scale in place of the 4-item SURE assessment, which has not been directly translated to Spanish. For patients who speak languages for which translated version is available, site teams will work with clinical translation services to conduct interviews in the native language using the English-language version of each tool.

Items 4 and 5 (anesthesia type received; ambulatory status) will be abstracted by trained research staff from the medical record using a standard data collection form and entered into the study database.

Item 6 (fidelity) will be assessed by trained research staff via direct observation of patient-clinician interactions for an approximate 10% subset of eligible cases at each site during the active implementation phase and the sustainment phase. The sampling approach and data collection procedures for these assessments are detailed below **(see 6.x, fidelity assessment procedures)**

Item 7 (use during sustainment) will be assessed for each eligible case during the sustainment phase by site staff from the attending anesthesiologist, CRNA, or resident anesthesiologist within 24 hours of surgery using the same questionnaire as for the primary outcome. Information will be collected by trained study staff and entered into the study database.

Item 8 (clinician attitudes) will be assessed via web-based surveys of participating clinicians during the active phase and the sustainment phase of the study.

Item 9 (time and resources) 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 time within approximately 4 weeks of end of active implementation phase.

## 6.1. Additional data elements to be collected

Information will also be 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); comoribidities;[30] procedure type; fracture characteristics; surgery dates; and pre-fracture function and cognitive status. Cognitive function will be assessed via the Short Blessed Test (SBT), a well-validated brief cognitive screening tool.[31,32] Patients will also complete the Single Item Literacy Screener, designed to identify patients with limited reading skills.[33] These data items will be collected across all study phases.

## 6.2. Screening, enrollment, and consent

### 6.2.1. Study database.

All study data will be entered into a study specific database on the Research Data Capture Application (RedCAP, Vanderbilt University). RedCAP is a secure web application used for building and managing online surveys and databases. Site clinical staff who are involved with study data collection will undergo training on data entry into the study database and be provided password access and granted data entry and editing permissions for data at their site. Database training and permissions for all site staff will be

tracked by the study data coordinating center at Penn. The full study database will be accessible to the overall PI, lead study statistician, and members of the study data coordinating center Penn. The study data coordinating center will carry out routine reviews of site-entered data for completeness and to assess nonsensical/outlier values. Identified missing items and potentially erroneous values will be communicated to sites for evaluation and correction as needed.

### 6.2.2. Screening and enrollment procedures

All patients undergoing hip fracture surgery at a given site during the study period (including pre-implementation, active implementation, and sustainment phases) will be identified by site research staff based on medical record review and entered into the study database. Eligibility will be determined via medical record review by trained site research staff using a standardized eligibility determination form; patients who are screened but determined to be ineligible will be tracked in the study database and reasons for ineligibility recorded in the study database. Each screened patient will be assigned a de-identified participant ID. Aside from surgical procedure dates, no direct or indirect identifiers will be recorded in the study database. A crosswalk between study IDs and patient identifiers (name, date of birth, medical record number) will be maintained at each site in a secure, separate file within the site lead investigators' office.

### 6.2.3. Consent procedures

#### *6.2.3.1. Clinicians*

All anesthesia clinicians at a given site who provide care to patients undergoing hip fracture surgery will be invited to participate. 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 the project without penalty by notifying the site lead investigator via email. A list of clinicians who opt out of participation will be maintained by the lead investigator and these clinicians will not be contacted with reminders to use the My Anesthesia Choice-HF tool or to complete study questionnaires. For clinicians who do not opt out of the overall study, participation in all aspects of the study will be voluntary; specifically, they may choose whether or not to use the My Anesthesia Choice-HF tool in a given encounter and may choose to decline participation in any of the study questionnaires without penalty.

#### *6.2.3.2. Patients*

Patients enrolled across all study phases will receive notification regarding the present study at the time of the pre-operative visit. This notification will occur via posted notices in preoperative care areas and on hard-copy versions of the My Anesthesia Choice-HF tool. Notifications will state that the site is participating in a research study focused on improving the quality of communication about anesthesia for hip fracture patients; that medical record information may be used to evaluate the reach of this intervention; that eligible patients may be approached to participate in a survey about their experiences after surgery; and that patients who wish to opt out of data collection may do so by contacting the site lead investigator. The name and contact information for the lead site investigator will be included for patients who wish to opt out of data collection. Patients who opt out of data collection will not have medical record or survey data collected beyond the date of their request to opt out; data collected prior to this request, such as screening information to determine eligibility, will be maintained in the study database for analysis. Draft notification text to be posted in clinical areas appears in **Appendix 3**.

Verbal consent will be obtained from patients at the time of the postoperative survey visit to permit continuation in the study; specifically, site research staff will present patient with an information sheet prior to the survey stating the purpose of the research and anticipated duration of the survey. Patients will be informed that survey participation is voluntary and they may choose not to participate without penalty. Patients will be informed that responses will be collected in a de-identified fashion; no identifying information other than the study participant identifier and the date of survey completion will be recorded

on the survey data collection form. Participants will also be informed that data collected in this study may be stored and shared for future research in a de-identified fashion without again seeking your consent in the future, as permitted by law. Survey administration will occur only on patients who provide verbal consent to continue in the study. Participation will be terminated at that point for patients who do not provide such consent and have not previously opted out of participation. A draft information sheet appears in **Appendix 4.**

Verbal consent for survey participation will be obtained from patients in clinical settings, such as inpatient hospital rooms and preoperative areas. All efforts will be taken to ensure privacy and sufficient time allocation to extensively review necessary recruitment materials, with recognition of contextual stressors associated with injury and acute care. Consent for the surveys will be obtained by research coordinators or site PIs. All research staff will be trained to ensure uniformity in consent procedures across sites and understanding of best practices for recruitment and consent. Where patients are themselves not able to participate in interviews, proxy respondents will be sought where appropriate and consent obtained prior to data collection as above.

#### *6.2.3.3. Justification for waiver of documentation of written informed consent.*

We request a waiver of documentation of written informed consent for enrollment of patients and physicians into the overall study and to obtain survey responses from enrolled patients. We believe that this is justified based on the level of risk involved in the study and the goals of the present research.

The research involves no incremental risks to subjects beyond what would be expected in the course of routine care. Specifically, neither clinicians nor patients are being encouraged during the intervention to alter their actual anesthesia care choices between general and spinal anesthesia. Instead, they are being provided with additional tools to support effective conversations to minimize miscommunication and maximize shared decision-making. This is no different than standard of care in which clinicians and patients each make decisions based on available information. While information is being collected on patients regarding medical care and outcomes, all possible steps will be taken to minimize the risk of unintentional disclosure or identification of patients.

Without a waiver of the requirement of written informed consent and HIPAA waiver, the initiative would still be implemented by the health system, but the study would be impracticable. Specifically, since hip fracture surgery is an urgent, non-elective procedure, pre-anesthesia evaluations may occur at unpredictable times, including weekends, off-hours, and holidays. Additionally, since anesthesia staff manage busy schedules, it may be hard to anticipate when a particular discussion of anesthesia choices may take place. As a result, a requirement to obtain written informed consent on all patients prior to discussions of anesthesia choices is impracticable in the present context, since such a requirement would lead to many patients being excluded simply based on research staff unavailability or an inability to coordinate consent documentation with the timing of anesthesia option discussions in an urgent-care context. Conversely, the population of patients who would be anticipated to provide written informed consent may not accurately reflect the full population of patients treated at a given hospital, Since the primary goal of the present study is to characterize the extent of adoption of My Anesthesia Choice-HF across all eligible patients treated at a given hospital, a requirement to obtain written informed consent would likely render the findings of the study invalid and make the execution of the present research impracticable. In contrast, the proposed model of broad notification, followed by verbal consent for continuation in the study, allows for disclosure to patients that the study is occurring along with a mechanism for patients to opt-out while also maintaining the practicability of the study regarding its primary goals.

# 7. Fidelity assessment procedures

A subset of patients during the active implementation and sustainment phases will be approached to participate in an implementation fidelity assessment. The goal of this assessment will be to determine the extent to which participating clinicians' use of the My Anesthesia Choice-HF tool aligns with recommendations for use as outlined in training. The assessment will employ structured tools as described above (see section **6.1.3.** above). Site teams will be instructed to designate specific days and time windows each week during the relevant phases to screen and enroll patients into the fidelity assessment based on research staff availability; the frequency of screening windows will be adjusted over time based on enrollment patterns and historical site case volumes to achieve enrollment of approximately 10% of eligible patients (as defined in **4.1** above) into the fidelity assessment. For patients who are selected for the fidelity assessment, research staff will perform direct observations of patient-clinician interactions to assess whether or not the conversation aid is used, and to complete a brief assessment of implementation fidelity using a structured data collection form (UPFRONT Fidelity Assessment)[10] Assessment results will be entered into the study database for analysis.

# 8. Analysis plan

## 8.1. Analyses for primary, secondary and exploratory outcomes

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 within will be analyzed according to their study phase. We will use mixed effects models to estimate the treatment effect of the My Anesthesia Choice-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;[34] interactions to capture time-cluster and time-treatment effect heterogeneity will be considered in supplemental analyses.[35] Standard errors will be adjusted for heteroscedasticity[36] and clustering using standard methods.[37] Continuous measures, such as SDMP and knowledge score, will be analyzed using linear mixed effects models. Binary outcomes such as decisional conflict and collaboRATE top score will use mixed effects logistic models.

We will assess for heterogeneity of treatment effects in the main sample population across pre-specified subgroups based on patient age, sex, race, and health literacy by introducing interaction terms to main study models to assess for differences in effects by treatment status relevant groups.[38] 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 centers and arms will be compared for all outcomes and patterns of missingness evaluated. Where missing outcome data rates are substantial (>10%), sensitivity analysis will be conducted using inverse probability weighting[39] to model the potential impact of missing data on study findings.

## 8.2. Power and Sample Size

For the sample size estimate, we assumed a conservative intra-center correlation coefficient (ICC) of 0.1, 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 center size. An average sample size of 50 per period/quarter per center 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.[35] 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 center 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 50%), and an ICC of 0.1. If the intervention group exhibits 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.[40]

# 9. Human research protection

## 9.1. Data confidentiality

Data analysis will be carried out by the study data coordinating center at the University of Pennsylvania. File transfer data to Penn staff will follow institutional standard operating procedures for ensuring confidentiality and data security. Penn's and managed systems are reviewed for compliance with internal and external regulatory requirements via internal monitoring and both internal and external auditing by specialized IT auditing firms. All study personnel that will use this data are listed on the IRB application and have completed local training in HIPAA standards and the CITI human subjects research (or its equivalent). Data access will be password protected. Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. Precautions are already in place to ensure the data are secure by using passwords and HIPAA-compliant encryption.

## 9.2. Subject confidentiality

Data will be obtained from medical records, participant interviews and direct observation of patient-clinician interactions. Any information that is obtained will be used for research purposes only. Information on patients will only be disclosed within the study team. All study staff will be reminded of the confidential nature of the data collected and contained in these databases. All study personnel that will use these data will be listed on the local site IRB application and will have completed training in HIPAA standards and the CITI human subjects research. Data access will be password protected. All data will be de-identified for analysis.

## 9.3 Data disclosure

Information on individual clinicians and patients will not be disclosed to anyone outside of the study team.

## 9.4 Data safety and monitoring

The investigators from University of Pennsylvania, Washington University in St. Louis, and each participating site will provide oversight for the study evaluation of this corporate quality improvement initiative

## 9.5 Risk/benefit

### 9.5.1. Potential study risks

The principal risk to participants concerns unintentional disclosure of personal identifying information; this risk will be minimized to the greatest extent possible by avoiding collection of patient identifiers in the study database, and via storage of all study data in highly secure physical and computing environments. Risks related to changes in clinical care resulting from the study intervention strategy are anticipated to be minimal. In theory, it is possible that use of the My Anesthesia Choice-HF could increase anxiety for some patients; on the other hand, it could also decrease anxiety by reducing uncertainty about treatment options and the magnitude of specific risks associated with treatments. As the specific approach to using the intervention will be guided by the judgement of the treating physician, and since patients already are required to provide consent for anesthesia prior to surgery, we anticipate that the risk imposed directly by the intervention will not be greater than levels of risk experienced in the course of daily life. For clinicians, the potential risks are judged to be no greater than encountered in

ordinary clinical work. The intervention is comparable to other quality improvement initiatives encountered in clinical practice. Moreover, disclosure risks related to individual clinician performance are minimized since data will not be analyzed at the clinician level and all identifiers will be removed prior to analysis.

### 9.5.2 Potential study benefits

The main potential benefit is knowledge gained on approaches that could improve the quality of communication about anesthesia choices. Patients may benefit from the intervention if it increases their satisfaction with anesthesia decision-making and decreases their decisional uncertainty. However, it is possible that patients will receive no benefit from this study. Clinicians may benefit from the study if they increase their knowledge and improve their work performance through the intervention. However, it is possible that clinicians will receive no benefit from this study.

### 9.5.3. Risk/benefit assessment

The risk/benefit ratio is favorable given the potential benefit of scientific knowledge that could be gained from increasing the level of shared decision-making for anesthesia choices. Efforts have been put into place to minimize the risk of breach of data. If favorable outcomes are found, then there is a potential to broadly disseminate findings to other physician practice groups.

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**Appendix 1:** My Anesthesia Choice-HF Tool

## Spinal or general anesthesia options for hip fracture surgery

This table is designed to help people talk to their doctor about anesthesia choices for surgery to fix a broken hip. The two most common choices are called **Spinal Anesthesia** and **General Anesthesia.** This table can help you think about what matters most to you so you can make a choice together with your doctor.

No matter which option you choose, your doctor will give you medicine to treat your pain and keep you comfortable. Your doctor will monitor you the whole time and treat any problems right away.

| | Spinal anesthesia | General anesthesia |
|---|---|---|
| **What does this involve?** | You will get an injection in your back to numb your hip joint and legs so that you do not feel pain. You will also get medicine to make you feel relaxed during surgery. | You will get medicine to keep you unconscious. You will also have a tube that goes through your mouth to help you breathe during surgery. The tube comes out when you wake up. |
| **What is the same about these two anesthesia methods?** | **Pain**<br>• There is no difference in pain in the first three days after surgery.<br><br>**New confusion (delirium)**<br>• About the same number of people (about 20 out of 100 people) feel confused for a few days or weeks after surgery.<br><br>**Recovery**:<br>• Most people leave the hospital around 3 days after surgery.<br>• About 26 out of 100 people go directly home when they leave the hospital. Others go to a rehab center first for a few days before going home.<br>• About 82 out of 100 people can walk on their own again by 2 months after surgery.<br><br>**Costs**<br>• The cost to you should be about the same.<br>• Check with your insurance company or your hospital for details. | |
| | **Spinal anesthesia** | **General anesthesia** |
| **What are the differences in the side effects?** | • About 13 out of 100 patients have a complication such as a lung infection or kidney problem.<br>• About 6 patients out of 100 have uncomfortable shivering for up to a few hours after surgery.<br>• About 2 out of 100 patients have a sore throat for a few days after surgery. | • About 15 out of 100 patients have a complication such as a lung infection or kidney problem.<br>• About 3 out of 100 patients have uncomfortable shivering for up to a few hours after surgery.<br>• About 5 out of 100 patients have a sore throat for a few days after surgery. |
| **What else should I know about each choice?** | • If you are taking **blood thinners**, this choice might be less safe for you. | • If you have **a severe lung problem**, this choice might be less safe for you. |

**Appendix 2: Study Outcome Measures.**

| **RE-AIM Dimension** | ***Outcome Measure*** | ***Data Collection Method*** | ***Timing of measurement*** | ***Relevant Study Phase(s)*** |
|---|---|---|---|---|
| **Reach (primary implementation outcome)** | Percentage of eligible patients receiving the strategy (active implementation phase; 2 items) | Clinician questionnaire administered via research staff | Postoperative day 0-3 | Active implementation |
| **Effectiveness (primary effectiveness outcome)** | Shared Decision Making Process scale (4 items)[23] | Patient-reported via survey administered by research staff | One time during postoperative day 0-3 | Pre-implementation, active implementation |
| **Effectiveness** | CollaboRATE (3 items)[41] | Patient-reported via survey administered by research staff | One time during postoperative day 0-3 | Pre-implementation, active implementation |
| **Effectiveness** | SURE measure (4 items)[25] | Patient-reported via survey administered by research staff | One time during postoperative day 0-3 | Pre-implementation, active implementation |
| **Effectiveness** | Anesthesia option knowledge assessment (6 items) | Patient-reported via survey administered by research staff | One time during postoperative day 0-3 | Pre-implementation, active implementation |
| **Effectiveness** | Friends and Family test (1 item)[26] | Patient-reported via survey administered by research staff | One time during postoperative day 0-3 | Pre-implementation, active implementation |
| **Effectiveness** | Ability to walk at clinic follow up (1 item) | Medical record review | Postoperative day 30-90 | Pre-implementation, active implementation |
| **Effectiveness** | Anesthesia type received (1 item) | Medical record review | Postoperative day 0-3 | Pre-implementation, |

| **RE-AIM Dimension** | ***Outcome Measure*** | ***Data Collection Method*** | ***Timing of measurement*** | ***Relevant Study Phase(s)*** |
|---|---|---|---|---|
| | | | | active implementation |
| **Adoption/ Implementation** | Adoption/ implementation surveys (12 items total)[42] | Site clinician/ stakeholder survey | One time within 4 weeks of end of active implementation phase | Active implementation |
| **Implementation** | UPFRONT Fidelity Assessment (9 items)[10] | Direct observation of clinical encounters | Day of surgery | Active implementation, sustainment |
| **Implementation** | Time and resources required for implementation | Site lead and site team debriefing interview | One time within 4 weeks of end of active implementation phase | Active implementation |
| **Maintenance** | Percentage of eligible patients receiving the strategy (sustainment phase vs pre-implementation; 2 items) | Clinician questionnaire administered via research staff | Postoperative day 0-3 | Sustainment |
| **Maintenance** | Perceived sustainability of the intervention (NoMAD assessment; 23 items)[29] | Site clinician/ stakeholder survey | One time within 4 weeks of end of active implementation phase active implementation; one time during final 4 weeks of sustainment phase | Active implementation, sustainment |

**Appendix 3: Study notification and opt-out information (for posting in clinical areas)**

Members of the anesthesia department at this hospital are participating in a national research study to improve the way we discuss anesthesia for patients needing surgery to repair a broken hip (hip fracture).

If you need surgery to treat a hip fracture, your health record information may be used as a part of this study; you also may be invited to complete a brief survey after surgery about your experiences.

Participation is voluntary. If you would prefer not to participate, please contact the study lead using the contact information below. There is no penalty if you choose not to join the research study, nor will you lose any benefits you may be entitled to. If you agree to participate, no additional action is needed from you today. You should ask the study team any questions you have related to the study.

Data collected in this study may be stored and shared for future research in a de-identified way. It would not be possible for future researchers to identify you.


| | |
|---|---|
| **Principal Investigator:** | Mark D. Neuman, MD, MSc<br>University of Pennsylvania Department of Anesthesiology & Critical Care<br>308 Blockley Hall, 423 Guardian Drive, Philadephia, PA 19104<br>Office: (215) 746-7468<br>Email: neumanm@pennmedicine.upenn.edu |


This research has been reviewed by the University of Pennsylvania Institutional Review Board (IRB). If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

## Appendix 4: Information sheet for patient survey participation.

**University of Pennsylvania**
**Consent for Participation in a Research Study**

| | |
|---|---|
| **Protocol Title:** | Insert Title of Research Study |
| **Principal Investigator:** | Mark D. Neuman, MD, MSc<br>University of Pennsylvania Department of Anesthesiology & Critical Care<br>308 Blockley Hall, 423 Guardian Drive, Philadelphia, PA 19104<br>Office: (215) 746-7468<br>Email: neumanm@pennmedicine.upenn.edu |

We are conducting a research study about patients' experiences making decisions about anesthesia for hip fracture surgery. The following survey should take about 10 minutes to complete.

Participation is voluntary. If you would prefer not to participate, do not complete the survey. There is no penalty if you choose not to join the research study, nor will you lose any benefits you may be entitled to. If you agree to participate, please complete the attached survey. You should ask the study team any questions you have related to participating before agreeing to join the study.

Your responses are anonymous; **we will not put your name or other identifying information on this survey**. We ask that you try to answer all questions. However, if there are any questions that you would prefer to skip, simply do not respond to that question.

Data collected in this study may be stored and shared for future research in a de-identified fashion. It would not be possible for future researchers to identify you. This can be done without again seeking your consent in the future, as permitted by law.

You must be at least 18 years old to participate. ***If you are not 18 or older, please inform the researcher and do not complete the survey.***

This research has been reviewed by the Institutional Review Board (IRB). If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

*Please keep this sheet for your reference.*