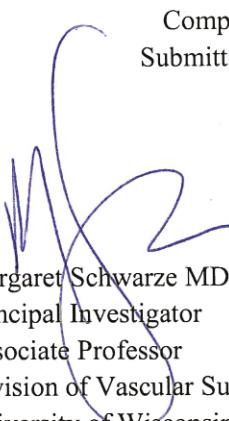


Navigating High Risk Surgery: Empowering Older Adults to Ask Questions that Inform Decisions about Surgical Treatment (PCORI-1502-27462)
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Introduction

Background and rationale

Each year, many of the 500,000 older Americans having high risk surgery^{1,2} will do so without fully understanding how it will affect them. Given trends in the number of patients 65 and older undergoing high risk surgery,^{3,4} this number is expected to grow as the U.S. population ages. High risk surgery can prolong older patients' lives and/or improve their symptoms. Yet it can also result in unwanted outcomes, including serious postoperative complications, lower quality of life,⁵ more hospitalizations,^{6,7} and potential suffering at the end of life.^{8,9} For example, of older patients who undergo coronary artery bypass grafting, nearly one in 20 will die within 30 days of surgery; those who survive are three times more likely to suffer a stroke or renal failure and nearly twice as likely to require prolonged mechanical ventilation than younger patients.¹⁰ This profile is typical of other high risk operations, including major cancer operations, vascular procedures and neurosurgeries.^{2,11} Fifty percent of older patients also have one or more chronic condition,¹² putting them at even greater risk for postoperative complications and death.^{13,14}

Because older patients are more likely to require intensive care or lengthy hospitalizations postoperatively,^{15,16} a decision to proceed with surgery can start a patient along a care trajectory that is ultimately inconsistent with his or her personal preferences and goals; for example, confinement in a nursing home or prolonged life support in intensive care. For these reasons, the decision-making process for older patients considering high risk surgery is complicated. Because the consequences of these decisions affect not only patients, but also their family members, the stakes are high.

Poor preoperative communication can lead to unwanted treatment, unanticipated postoperative challenges and conflict between surgeons and patients. Surgeons currently rely on best-practices—including informed consent—to help patients make decisions about surgery. This process is deficient because it does not provide an accessible explanation about how a patient might experience complications, or even *expected* downstream outcomes, such as the need for additional invasive treatments or predictable changes in functional status.^{17,18} Given the trade-offs between the possible benefits of surgery and the real potential for an unwanted outcome, there is no “right” treatment for each patient’s surgical problem. Patients and families need to know what the outcomes of surgery mean *for them* and how surgical treatment can be understood in the context of their overall prognosis, particularly for patients with other chronic illnesses.^{19,20} Even an “uncomplicated” recovery from a major vascular or cancer operation can impact patients’ and their family members’ wellbeing. Patients whose expectations for surgery are not met suffer as they try to make sense of their situation, feel a loss of control and assume self-blame.²¹ Items in the lay press tell stories of difficult surgical decisions,²² struggles to understand the likely outcomes of surgery,²³ and challenging negotiations with surgeons about preferences for limiting aggressive postoperative treatments.^{24,25}

These decision-making conversations can have serious implications for a modest subgroup of patients who experience life-threatening complications. From the surgeon’s perspective, the patient has agreed to

the operative procedure as well as all postoperative care anticipated by the surgeon. We call this implicitly understood contract “surgical buy-in.”^{26,27} Although surgeons perceive a mutual commitment to postoperative life-supporting treatments if necessary, this is not recognized by patients, who may desire treatment limitations and value some outcomes but not others.²⁸ This disconnect can lead to postoperative conflict between surgeons and patients, and between surgeons and other providers,^{29,30} when patients and/or their families want to withhold or withdraw treatments that the surgeon believes the patient agreed to.

We need to bridge the gap between what surgeons know and what patients understand. The structure of preoperative decision-making conversations is inadequate to assist patients in their deliberation about high risk surgery; falls short in establishing expectations for known and unexpected outcomes; and fails to accommodate patients’ preferences as they shift in the context of a specific illness or burdensome treatments. While current practices satisfy the legal requirements for informed consent, they lack essential elements for preference-sensitive decision making. Patients need surgeons to help them compare treatment options and evaluate their effectiveness by providing information about what surgery means for them. Given the gravity of these decisions—specifically, the potential for life-changing benefits and harms—simple risk disclosure and surgeon-directed deliberation is not enough. We need evidence about alternative strategies to improve these high-stakes conversations, support value-directed deliberation, set realistic postoperative expectations and avoid conflict between patients and surgeons in the setting of an unwanted outcome.

Question prompt lists have proven efficacy for improving patient-doctor communication. Question prompt list (QPL) interventions can effectively change how patients and family members communicate with physicians, improve patients’ and family members’ psychological outcomes, and better meet patients’ informational needs.³¹⁻³³ Effective QPL interventions require physicians to endorse and support the patient’s use of the question list, but do not require patient navigators or patient coaching.³⁴ For patients considering surgery³⁵ and patients with life-limiting illness³⁶ QPLs effectively increase the number of questions about prognosis and about “what to expect in the future.” QPL interventions effect behavior change in physicians (including surgeons)³⁵ so that patients receive “more evidence related to options” and more “consideration of patient of preferences.”³⁷

To address the communication problems in preoperative decision making, we worked with stakeholders to design a QPL specifically targeting the needs of patients considering high risk surgery. We developed a QPL for use in the surgical clinic by patients considering major vascular (cardiac, peripheral, neuro) and oncologic operations. It encourages patients and families to ask questions that allow them to compare treatment options and get information about what surgery means for them. More information on the rationale and development of our QPL is available in our manuscript documenting this process.³⁸

Specific aims

To answer our research question, “Could a patient-driven approach that improves decision making and informs postoperative expectations have more effectiveness than the current surgeon-directed preoperative conversation?” we will conduct a multi-site randomized controlled trial of the question prompt list intervention for high risk surgery that will:

- 1) Compare the effectiveness of the intervention relative to usual care on the extent of patient engagement in decision making for high risk surgery.
- 2) Compare the effectiveness of the intervention relative to usual care on treatment choice and on psychological well-being and post-treatment regret for patients and family members.
- 3) Compare the effectiveness of the intervention relative to usual care on interpersonal and intrapersonal conflict relating to treatment decisions and subsequent treatments received.

Our overall goals are to help patients and families 1) make treatment decisions in line with their values and goals; 2) anticipate and make sense of postoperative outcomes; and 3) experience less postoperative conflict about treatment of serious complications.

Study design

We will perform a multi-site cluster randomized trial that uses a stepped-wedged design to compare the effectiveness of our Question Prompt List (QPL) intervention to usual care for patients considering high risk vascular (peripheral, cardiac, neuro) and oncologic operations. The intervention we are testing in this study is the QPL plus a letter from the patient's surgeon endorsing its use. Effective QPL interventions require physicians to endorse and support the patient's use of the question list, but do not require patient navigators or patient coaching.³⁴ Therefore, this study involves no training or coaching.

This 24-month study will use a time-dependent cluster randomization plan within each of our five study sites. We will enroll surgeons at 5 sites whose practice is largely comprised of older adults considering high risk procedures. Then we will randomly assign time points for the surgeons to cross over from usual care to the QPL intervention. Surgeons who have crossed over to the intervention group will be notified when the QPL intervention has been implemented in their clinic and will be encouraged with bi-weekly email or text reminders to support patient use of the question list during the clinical encounters with new patients. We will enroll up to 3 patients per surgeon in each wave. To maintain enrollment we will move through each wave every 4 months or, if enrollment goals have not been met by 4 months, when sites have met 70% of their enrollment goal for each wave. Wave changes will not be made with any consideration of treatment group.

We will audiotape one preoperative clinic visit; administer questionnaires to patients and family members at three time points after that visit; and record surgical decisions, treatments received and associated outcomes via chart review. The first questionnaires will be administered by phone and the latter two may be completed by phone, mail or online survey, based on participant preference. The questionnaires include questions on concerns, self-efficacy, well-being and post-treatment regret, as shown in Table 1.

For aim 3, we will use stratified purposeful sampling to identify a subset of patients (and their family members, if applicable) in each study arm who have experienced serious complications for open-ended interviews. Open-ended interviews will occur up to 3 months after completion of the third survey. More information on the study design is available in our published protocol.³⁹

Table 1: Primary and Secondary Outcomes Measures for Aims 1 and 2.				
Construct	Specific Measure	Type; range	Source	Timing
Aim 1: patient engagement				
Engagement in decision making	Number and type of questions posed by patient and family members during T₀ consultation using a pre-defined coding scheme (Table 2) OPTION 5 (physician engagement with patient)	count; 0-25 continuous	Audio recording	T ₀
Self-efficacy in patient physician interactions	PEPPI-5-5 (perceived efficacy) HCCQ (autonomy support)	continuous continuous	Patient and family member	T ₁
Aim 2: psychological wellbeing and treatment received				
Concerns and wellbeing	MYCaW (self-identified concerns and wellbeing)	continuous	Patient and family member	T _{1-T₂} T _{1-T₃}
Post-treatment regret	"Looking back, is there anything about your treatment that you would do differently?"	Binary	Patient and family member	T ₃
Patient – psychological wellbeing, PROMIS	Psychosocial Illness Impact-Neg 4a Psychosocial Illness Impact-Pos 4a Anxiety 4a*	continuous continuous continuous	Patient	T ₂ T ₃
Family – psychological wellbeing, PROMIS	PROMIS SF Global Health Anxiety 4a	continuous continuous	Family member	T ₂ T ₃
Treatment received	Total number of operations scheduled after visit with surgeon Total number of operations scheduled and performed	count; 0-3 count; 0-3	Chart review	T ₀ T ₃

* Items in **bold** are **primary outcomes**.

T₀: Audio recorded clinic visit between patient, family member and surgeon

T₁: Phone questionnaire with patient and family member 24-48 hours after visit with surgeon

T₂: Questionnaire 1-2 weeks post-surgery or, for patients who do not have surgery, 6-8 weeks post initial visit

T₃: Questionnaire and chart review 6-8 weeks post-surgery or, for patients who do not have surgery, 12-14 weeks post initial visit

Blinding

Although we cannot blind surgeons to intervention group, based on the need for them to endorse use of the QPL during clinic visits, they will not be informed of the outcomes measured in this study. Patient and family member participants will be told that the study goal is to evaluate surgeon-patient communication and will be blinded to objectives regarding testing of the QPL intervention. We expect negligible contamination between patient participants in different study arms as the intervention requires surgeon endorsement of the QPL with a letter from the patient's surgeon and the surgeons work in different clinics on different days. Although patients in the control arm may access question lists from outside sources, we know from previous research that surgeons do not routinely ask patients about such instruments.

Study staff will not be blinded during data collection but will adhere to a study script and query about receipt of the QPL intervention as the last question in the first survey (T₁) to try to keep study staff insulated during the assessment of primary outcomes. Data will be labeled with a pseudo ID during coding to ensure that coders remain blinded to the patient's intervention status. We will provide coders with an even mix of control and intervention data during the coding period, so that they cannot impute intervention status based on the timing of coding assignments

Data and Safety Monitoring Plan

UW-Institute for Clinical and Translational Research (ICTR) has established a Data Monitoring Committee (DMC) for UW-Madison investigators conducting clinical research. This DMC provides investigators services to ensure appropriate measures are in place to promote subject safety, research integrity and compliance with federal regulations and local policies for individual clinical research protocols in need of DMC review. For this study, the UW ICTR DMC will be the primary data and safety advisory group for the PI and all study sites.

In providing oversight for the conduct of this study, the ICTR DMC will meet every 6 months during the 3-year study. Additional meetings may be scheduled as determined by the DMC. The DMC members will review protocol-specific reports created by statisticians that serve a non-voting member role on the DMC. These standard reports will include an overview of study objectives, a review of actual and projected accrual rates, an evaluation of patient demographics for balance of randomization, and a summary of the number and seriousness of adverse events. An interim analysis of study results will be performed, and source documents may be reviewed to allow the DMC to independently judge whether the overall integrity and conduct of the protocol remain acceptable based on data provided and reported by the PI. The DMC will make recommendations to the PI that could include actions of continuation, modification, suspension, or termination.

Research team members may also be involved in safety monitoring throughout the study. Although not expected, research staff will be prepared to address any negative reactions to study procedures including audio recording of the conversation with the surgeon, survey questions and open-ended interviews. All negative reactions will be reviewed to determine whether a change in protocol is necessary. The PI (Schwarze) will report any policy violations to the IRB immediately. The PI will also report any adverse events in compliance with the IRB policy for reporting. In addition to the DMC, the PI will review the research study and the accrued data on a monthly basis in project meetings so as to ensure the validity and integrity of the data and to evaluate whether changes to the anticipated benefit-to-risk ratio of study participation have occurred.

Data coding

All coding will be completed prior to unblinding.

Coding of number and types of questions will follow a pre-defined coding scheme (Table 2). We developed a detailed codebook based on an established coding scheme³¹ as noted in the PCORI proposal. Coders coded each question by speaker and question type/content area. The coding schema was tested twice, with acceptable intraclass correlation found between coders. The first round of testing drew a random sample of 45 transcripts from a prior project. Intraclass correlations were acceptable for all but one question category. We reviewed all discrepancies for this category and revised the codebook. The second round of assessment was comprised of a random set of 30 transcripts from this project. Coders were blinded to arm status of the transcripts. This sample was generated by the independent statistician who maintains our blinding procedures and synthetic study ID's. We found an acceptable ICC for all question categories, as shown in Table 3.

Table 2: Predefined coding scheme to characterize questions asked by patients and family members during surgical consultation (T₀)		
<i>Category</i>	<i>Definition</i>	<i>Example</i>
Options	Seeks to understand different treatment pathways.	"Is there another way?"
Expectations	Seeks to understand what life would look like after treatment.	"Like, you know, how long will be the recovery?"
Advance Directives	Asks about care and consequences if patient is unable to speak for him/herself.	"Then, you know, why continue?"
Risks & Complications	Seeks to understand what could go wrong, bad outcomes or hazards of surgery.	"As far as the location of the tumor that remains in those veins...is anything at risk as far as... blood flow function of any of those parts?"
Logistical & Technical	Seeks to understand the technical details about how surgical treatment is performed and how to coordinate personal needs associated with treatment.	"How long does the surgery take?"
Other	Queries regarding things external to the diagnosis, decision-making or treatment.	"How many grandkids do you have?"
Question categories in bold are primary outcomes .		

Table 3: Intraclass correlation between coders for question category coding of patient and family members during T₀ surgical consult		
<i>Category</i>	<i>ICC 1</i>	<i>ICC 2</i>
Options	0.45	0.76
Expectations	0.95	0.83
Risks & Complications	0.79	0.87
Logistical & Technical	0.93	0.92
Advance Directives	Not analyzed	Not analyzed
Other	Not analyzed	Not analyzed

Each transcript will be coded by one coder. A full codebook is provided in the Appendix. Audio recordings will be transcribed with all identifying information removed including names, dates and locations. Prior to coding, every transcript will have a thorough quality assurance check by a member of the study team to ensure the transcript fully captured what occurred during the T₀ visit, and that all questions were appropriately transcribed. Prior to categorizing each question, questions asked by patients

or family members will be identified by a Microsoft Visual Basic program, which will generate a coding sheet containing all questions asked by patients and family members during the T0 surgeon visit.

Each transcript will also be coded based on the OPTION 5 instrument, a measure of observer measured shared decision making⁴⁰ as designed by Elwyn (see Appendix). Satisfactory acceptable intraclass correlation for this measurement was difficult to attain so each transcript will be OPTION 5 scored by 2 coders and then consensus coded during group coding sessions.

Each transcript will be coded for other variables, as shown in Table 4. This coding will be done by a single coder and then consensus coded as part of group coding sessions.

Table 4: Additional variables derived from the transcribed audio recordings	
<i>Variable</i>	<i>Coding details</i>
Length of audio file	Duration of the transcribed audio recording
Number of clinicians and family members present	Presence of others in the room in addition to patient and surgeon
Any part of the transcript in a language other than English	Presence of any language other than English spoken by any person present during the audio recording
Audio-recording and transcript captured full conversation	Presence of gaps or content that appears to be missing from the surgeon's visit with the patient, pauses, lack of greetings or goodbyes
Discussion included any consideration of operative treatment/surgery and, if yes, was this a high-risk procedure or operation	Presence of a discussion about any major operative procedure
Mention that surgery had been discussed with this patient and this surgeon or another surgeon before	Reference to previous discussions or interactions with another surgeon prior
Type of indication	Presence of a discussion about a vascular or oncologic problem
Additional specific topics covered	Goals of treatment as stated by surgeon, patient goals, advance care planning, and surgeon's ambivalence about surgical intervention

Data from the “Measure Yourself Concerns and Well-being” (MYCaW) instrument will be coded using a codebook developed by the research team. The coding scheme was developed in the following way: each concern is given a primary code that best captures the essence of the concern. Up to 4 secondary codes can also be applied to each concern to capture additional themes raised. Two coders will independently code each concern, blinded to treatment arm status and site. Three study team members will meet to consensus code and resolve all discrepancies.

Data on regrets expressed by patients and family members during the T3 survey will be coded by 2 coders, blinded to intervention arm, based on a previously developed coding scheme.⁴¹ Data from this survey item will be coded for the presence or absence of regret and, when regrets are present, will be coded with one or more topic areas.

Per-Protocol Analysis of Primary Outcomes

General Analysis Plan

As described in our PCORI funded proposal, our primary analysis will compare the effectiveness of the QPL intervention relative to usual care on patient engagement for aim 1 and psychological wellbeing for aim 2. We will use an intention to treat (ITT) analysis using all available data from participants based on group assignment.

The intervention effect will be tested in the framework of generalized linear mixed effects models^{42,43} with a treatment dummy variable, surgeon random effect and site-by-time dummy variables to control site-specific secular trends.

All models will be estimated and tested using SAS version 9.3 (SAS Institute, Cary, NC), specifically PROC MIXED and PROC NLMIX.

We do not plan to impute missing data if the rate of missingness is low. Currently, our rate of missingness is quite low: 97% of patients and 92% of family members have completed T1. For T2, 88% of patients and 86% of family members have completed the survey and for T3 87% of both patients and family members have completed their survey. We plan to exclude variables for which there is no response (rather than impute these variables). Although we have a small number of incomplete audio recordings, we will treat audio recordings where less than half of the encounter with the surgeon was captured (a total of 6 recordings) as completely missing and those with more than half recorded as complete. We will perform sensitivity analysis to test whether this small loss of data impacts our findings by comparing the outcomes with and without inclusion of audio recordings that are more than half complete.

Aim-1 primary outcomes [Question Counting, PEPPi-5]

Aim 1 has five primary outcomes and as such will be analyzed with a Type I error rate of $\alpha=0.01$.

For question counting, we consider four specific types of questions and evaluate them with ordinal categories:

- Number of OPTIONS questions asked by patients and family members (0, 1, 2+)
- Number of EXPECTATION questions asked by patients and family members (0, 1, 2+)
- Number of ADVANCE DIRECTIVES questions asked by patients and family members (0, 1+)
- Number of RISKS questions asked by patients and family members (0, 1, 2+)

We will denote each question type with [Q-type], where type is either Options, Expectation, Advance Directives, or Risks. [Q-Advance Directives] is a binary variable, the other three types are three-category ordinal variables. Accordingly, a logistic random effects model will be used to analyze [Q-Advance Directives], while ordinal logistic random effects models will be used for analyzing the other three types. We have not included logistic and technical concerns and “other” questions as primary outcomes because these are not the types of questions that indicate improvement in patient activation. Logistic and technical concerns are already very commonly asked by patients and rarely provide information that would assist patients in a decision to have surgery and “other” questions are largely irrelevant to surgery or surgical decision making.^{38,44}

PEPPI-5 will be analyzed as a continuous variable based on a summary score of the entire survey. We will use linear mixed effects models for continuous responses (PEPPI-5), and ordinal logistic random effect models for ordinal variables (question categories).

Aim-2 primary outcomes [Regret, MYCaW]

Aim 2 has two primary outcomes and as such will be analyzed with a Type I error rate of $\alpha=0.025$.

Regret will be coded as a binary variable (yes/no) and analyzed with a logistic random effects model. We will evaluate regret as a binary variable where patient-family dyads are coded as 0 if neither participant expressed any regrets and 1 if either expressed regret. Responses will be coded as positive for regret if participant answered in the affirmative or if they responded “No” but then shared a regret. Responses that were characterized by dissatisfaction but not self-blame will be coded as “no regret.” Impossible, counterfactual responses, in which participants regretted or wished for something outside their control, will also be coded as “no regret.”

MYCaW: The difference in the rating of the primary concern between T1 and T2, regardless of the categorization of this concern, as reported by the patient will be treated as a continuous outcome and analyzed with a linear mixed effect model. We will accommodate the longitudinal nature of the data with a patient level random effect. Analyses will be based on a treatment difference relative to T1 at T2 in a random effects model with: a treatment difference at T1, a time (0/1) variable indicating either T1 versus T2, an intervention-by-time interaction representing the treatment difference, and a random effect at the patient level.

We will use linear mixed effects models for continuous responses (MYCaW), logistic random effects models for binary responses (regret).

Further analysis of primary endpoints generated prior to un-blinding

Updated analysis plan and modified power analysis

Rationale: Prior to unblinding (looking at treatment group assignment) and after commencement of data coding in preparation for analysis, the research team became aware of 2 issues that prompted modification

of our per-protocol analysis plan. First, reports from our DSMB demonstrate that PEPPi-5 for this cohort of patients and family members has remarkable ceiling effects (for 333 enrolled participants, mean score 21.4, IQR 20-24, scale range: 0 - 25). Thus, even if we demonstrate a significant difference it would be clinically meaningless. Second, the variability in self-reported concerns using the open-ended MYCaW instrument for patients and family members in this study is enormous. For example, some patients note concerns about parking or how the surgeon communicated with them, whereas others note concerns about removing their cancer or how they will feel after surgery. This makes it difficult to compare concerns between the entirety of the two groups and suggests a need for stratification of these outcomes in relation to the patient's clinical course, specifically whether there was a decision to have surgery. As surgical treatment is a post-randomization variable, such analysis is not appropriate for a primary outcome. In response to these 2 concerns, we recalculated our power analysis without the PEPPi-5 endpoint in aim 1 and without the MYCaW endpoint in aim 2 as these were no longer valid primary outcomes.

Power calculations for Aims 1 and 2 were updated to harmonize with the final analysis plan and the realized recruitment, which had a slight reduction in patient-level sample size (from 240/240 control/treatment to 222/221 control/treatment, given that the stepped-wedge study design wave rollover rules were not dependent on intervention assignment). The overall design is retained (relative to the submitted proposal) and the power numbers remain robust. Notably, surgeon-level sample size has not changed, and it is this sample size that is primarily driving the power. We have not modified the assumption that the between-surgeon variance accounts for 30% of the total variance. As noted previously, this is conservative considering preliminary data suggests this variance is as low as 5%.

Under our modified plan, there are four endpoints in Aim 1, the four question types. In this case, tests will be conducted with nominal $\alpha=0.05/4 = 0.0125$. Supported by our preliminary data, we assume a worst-case scenario of 65% of control patients will be in the non-activation set (the zero category). We consider an odds-ratio of improved category (moving to a higher category of questions asked) in the treatment (relative to control) of 1.3. Under these settings, we have 85% power to detect a treatment difference in [Q-Advance Directives]. For each of the other three categories, we have over 93% power to detect a difference. Under our modified protocol, regret is the only endpoint in Aim 2. In this case, testing will be conducted with nominal $\alpha = .05$. We assume the upper bound risk of regret is 0.3; we will have over 91% power to detect a regret risk difference of 0.23.

This additional analysis of our primary endpoints is otherwise unchanged from our per-protocol plan. Our modified analysis will compare the effectiveness of the QPL intervention relative to usual care on patient engagement. We will use an intention to treat (ITT) analysis using all available data from participants based on group assignment. The intervention effect will be tested in the framework of generalized linear mixed effects models with a treatment dummy variable, surgeon random effect and site-by-time dummy variables to control site-specific secular trends. Again, we will consider four specific types of questions and evaluate them with ordinal categories:

- Number of OPTIONS questions asked by patients and family members (0, 1, 2+)
- Number of EXPECTATION questions asked by patients and family members (0, 1, 2+)
- Number of ADVANCE DIRECTIVES questions asked by patients and family members (0, 1+)

-Number of RISKS questions asked by patients and family members (0, 1, 2+)

Denote each question type with [Q-type], where type is either Options, Expectation, Advance Directives, or Risks. [Q-Advance Directives] is a binary variable, the other three types are three-category ordinal variables. Accordingly, a logistic random effects model will be used to analyze [Q-Advance Directives], while ordinal logistic random effects models will be used for analyzing the other three types.

For Aim 2, there is no change to the modeling approach for regret: we will use a logistic random effects model. We will use an intention to treat analysis using all available data from participants based on group assignment. We will use a logistic random effects model with a treatment dummy variable, surgeon random effect and site-by-time dummy variables to control site-specific secular trends.

Additional considerations: Aim-1 question asking

After performing the ITT analysis, we will restrict the analysis by removing the dyads (patient and family member) where major surgery was not discussed or the patient did not have a vascular or oncologic problem. This is based on the T0 transcript of the conversation with the surgeon, which confirms whether the patient discussed surgery with the surgeon and had a vascular or oncologic problem. Specifically, we will use the subgroup analysis document, coded by the primary coder and confirmed in group consensus, to identify enrolled patients for whom surgical treatment was not discussed, or on evaluation after enrollment, the patient did not make entry criteria to be in the study, specifically, the patient did not have a diagnosis of cancer or vascular disease.

Next, we will further restrict the analysis based on penetrance of the intervention. We will identify patients in the intervention group with a clear signal that they received the QPL prior to the visit with the surgeon. This will be identified by one or more of the following criteria 1) clear presence or use of the QPL in the audio recorded conversation with the surgeon (noted in less than 20 transcripts), 2) coder identification of something that could be the QPL used during the conversation with the surgeon (coder marked this as unsure), 3) affirmative answer on the T1 survey from the patient or family member that they received something that might be the QPL from the surgeon prior to clinic visit (using a sensitivity analysis based on the certainty around receipt of the QPL within the response to this question), 4) a maybe answer on the T1 survey, 5) notes from the research coordinator that the patient was seen in clinic with a QPL.

Additional analysis will adjust for age and comorbidity. We will also evaluate a composite endpoint of all 4 question types where each of the 4 question types is categorized as binary and the composite score is ordinal (0, 1, 2, 3, 4) such that 4 signifies that a question of each type has been asked.

Additional considerations: Aim-2 regret

We will first consider regret as a binary outcome and then do additional analysis with regret considering this as a categorical variable with 0 = neither patient or family member has regret, 1 = either patient or family member has regret, 2 = both patient and family member have regret.

Stratified Analysis: Aim-2 MYCaW

The goal of evaluating MYCaW is to test how much participant-reported concerns change over time for patients who did and did not receive the QPL. Our understanding of the MYCaW measure evolved since the start of the study based on the blinded coding of MYCaW data which revealed a much wider range of problems and concerns in response to MYCaW items than our previous and current review of the literature would suggest. Because not all patients in our study will plan to have surgery after meeting with a surgeon, there is heterogeneity in the description of concerns that is dependent on their treatment plan. Without changing our pre-specified analytic plan, we believe we will have findings that are extremely difficult to interpret. Furthermore, if an effect (positive or negative) of the intervention is identified, it would be challenging to assist surgeons and patients in using these results as many different types of concerns will be lumped together. These proposed changes are responsive to the data and the setting of this trial.

As such, we will conduct a stratified analysis based on the post-randomization variable of a treatment plan to have surgical intervention as determined by the T0 conversation with the surgeon. To this end, our analysis will exclude patients whose treatment plan did not include surgery upon leaving the surgical consultation at T0, and whose treatment plan was unclear at the end of the T0 consultation (this corresponds to categories #2 and #3 below regarding the “treatment plan”).

Within the cohort of patients whose treatment plan includes surgery, we will compare intervention to control patients who noted similar concerns. We will first categorize participants (both patients and family members) by the primary (first) concern expressed and then compare the respondent-reported rating of that concern, assessing the mean score between treatment groups for each category. We will next separate respondents by type: patient and family and repeat this analysis. We will also compare the change of the respondent’s (patient or family member in separate groups) rating of that concern between T1 and T2 using a respondent-level random effects model. We will similarly analyze the change between T1 and T3.

Secondary outcomes: Aim-1: patient engagement [PEPPI-5, OPTION5, HCCQ]

PEPPI-5 and HCCQ will be analyzed as continuous variables, based on the summary score of the entire survey (PEPPI-5 scale 0 – 25, HCCQ scale 1-7). We will first analyze all respondents (patients and family members) together, and then separate respondents into patient and family outcomes.

OPTION5 will be analyzed as a continuous variable with a scale that goes from 0 – 100 based on consensus coding of each T0 transcript. This is a surgeon/patient/family score that cannot be stratified by respondent. We will compare the average score between intervention and control for the entire cohort.

Secondary outcomes: Aim-2: treatment received, well-being [PROMIS]

Treatment received will be defined as patients who had at least one major operation during the study period (identified on completion of T3 chart review).

We will also analyze this outcome according to the following classification scheme to characterize the treatment plan after meeting with a surgeon:

1. Plan for major surgery (includes plans where surgery is the treatment decision but additional tests are required)
2. Plan to not have surgery (includes a decision that no surgery will be pursued or other clear treatment plan – e.g., chemo)
3. Plan is unclear – returning to discuss later, needs more information

PROMIS: These measures will be analyzed by respondent type (patient/family), and measures will be analyzed separately dependent on time of reporting (T2 and T3).

Patient: Impact of illness – positive: continuous scale: 8-20

Impact of illness – negative: continuous scale: 8-20

Family member: SF Global Health Physical Score: continuous scale raw score: 4-20

Family member: SF Global Health Mental Score: continuous scale raw score: 4-20

Patient and family member: Anxiety 4a: continuous scale: 4-20

We will then restrict the analysis to patients who plan to have major surgery, and family members' outcomes for family members whose dyad patient has a treatment plan for surgery. We will then adjust the analysis for patients who had a major complication with surgical intervention.

For all secondary outcomes after completing the ITT analysis, we will perform a restricted analysis as described in the additional considerations section above. Specifically, we will restrict the analysis by removing the dyads (patient and family member) based on the T0 transcript of the conversation with the surgeon, which confirms whether the patient discussed surgery with the surgeon and had a vascular or oncologic problem. Next, we will further restrict the analysis based on penetrance of the intervention based on the criteria described above.

Additional important outcomes

Family member presence: We plan to compare the proportion of patients who are accompanied by a family member or “like family” friend to the visit with the surgeon between the intervention and control group as receipt of the QPL prior to a visit with a surgeon may prompt patients to bring a family member with them to the consultation visit for additional decision-making support. This binary outcome variable (yes/no family member present) will be ascertained from the T0 transcript which clearly notes number of family members/friends. Family members do not need to be enrolled in the study to be counted as present. We will use ITT analysis as well as a restricted analysis (as described above) to analyze this outcome.

Consult duration: We will compare the median consult length at T0 between groups. This is not an effectiveness outcome but rather information that clinicians and patients might want to know in considering use of the intervention in their clinic. We will also compare the median consult length within surgeon (pre/post) to account for fairly wide variation in surgeon routine (some surgeons clearly spend

45-60 minutes with patients whereas others spend 7-15 minutes with patients). Given that surgeons will have been assigned randomly to intervention wave the incidence of pre/post measurements will not be evenly distributed and may be too variable to determine real differences.

Exploratory analyses

There are several factors that might impact the effect of the intervention that we have described in our protocol for exploratory heterogeneity of treatment effect (HTE) analysis. These include insurance status (as a marker of socioeconomic status): we will use a binary variable defined by standard insurance (Medicare/private/supplemental) or (Medicaid, dual eligible, charity care, none). We will also consider oncologic indications for surgery as distinct from vascular (as identified in the T0 transcript). We will also consider extent of comorbid illnesses, stratifying patients by Charlson score and categorizing high, medium and low comorbidity.

We will perform additional analysis of OPTION 5 (shared decision making) scores, evaluating the variability in OPTION 5 scores before and after intervention, considering that these scores likely have more between surgeon variability than within surgeon variability. Specifically, we will estimate the correlation on the surgeon random effect pre- and post- intervention.

Aim-3

We will analyze qualitative data with directed content analysis⁴⁵ using a deductive theory-driven analytic framework to evaluate interpersonal and intrapersonal conflict and to compare the similarities and differences between both arms of the study. To enrich the coding process and attend to professional biases, we will include investigators with diverse clinical backgrounds (nursing, palliative care, surgery and patient advocacy). To gain understanding of the trajectory of the patient's story we will triangulate data sources by linking the audio tape of the initial surgeon-patient conversation and the patient's clinical history from chart review, with the follow-up interview. We have previously shown that surgeons see preoperative conversations as a significant event, a time when a two-way agreement is made whereby the surgeon commits to operating and the patient commits to endure potentially burdensome postoperative care.²⁷ We will use this understanding of surgical buy-in to code and analyze preoperative visit and postoperative interview transcripts with the goal of understanding how the contractual relationship that surgeons perceive is experienced by patients. We will explore how postoperative complications were discussed during the initial patient-surgeon interaction with and without the QPL and whether this interaction has impact on subsequent treatment decisions, interpersonal and intrapersonal conflict.

Investigators will independently review the transcript of each interview linked with each initial patient-surgeon conversation, generating codes to describe and classify events, processes, and concepts in the text. A team of at least three investigators will come together to jointly review each transcript in order to generate consensus and examine discord about all codes as part of the process of higher level analysis. The coding taxonomy will be revised in an iterative fashion throughout the analytic process. We will use context charts⁴⁶ to evaluate differences and similarities between control and intervention groups. We will

use qualitative research software, NVivo 10 (QSR International), to organize and store codes, facilitate comparison of cases, and access data to support themes and patterns. Using data linkage with our quantitative outcomes, specifically patient engagement and psychological wellbeing, we will mix these methods to identify trends that inform our understanding of the interaction between conflict, engagement, wellbeing and regret.

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Appendix

Pre-defined coding scheme for number and type of questions

OPTION 5 scoring sheet

QPL development paper

Published study protocol

PCORI Navigating Surgery Question Coding Manual

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General Guidance

- Do not code more than 2-3 transcripts in a single sitting
- Coding each transcript should take about 15-30 minutes
- After you've finished coding a transcript, do a final check by using the find function in Word (Ctrl-F) to locate question marks (clicking through to view all instances), ensure that you've identified all questions, and labeled speakers correctly

Step 1: Figure out what to code as a question

*What **DOES** count as a question that should be coded for this study?*

- We are only coding questions asked by patients or family members while surgeon is in the room
 - Typically, the transcripts end when the surgeon leaves the room but you may come across a transcript in which a surgeon temporarily leaves a room- this will be noted clearly in the transcript. In this case, do not code questions asked during the surgeon's absence
- It does not matter who the question is directed at, even if it is obvious the question is not directed at the surgeon
- Questions must have a question mark at the end
 - Prior to categorizing each question, questions asked by patients or family members will be identified by a Microsoft Visual Basic program, which will generate a coding sheet containing all questions asked by patients and family members during the T0 surgeon visit.
 - After you have coded the entire transcript, use "Ctrl-F" to skip from question mark to question mark to double check that you haven't missed any questions and have labeled speakers correctly
- If a question is within quotation marks (for example, if a patient is quoting someone else's question), that counts as a question and should be coded for topic area just like any other question
 - Example: "And then others go, 'what are you crazy, you're going to get it fixed?... Why would you even think about getting it fixed?'"
 - This counts as two questions
 - 1) "What are you crazy, you're going to get it fixed?"
 - 2) "...Why would you even think about getting it fixed?"

*What **DOES NOT** count as a question for this study?*

- Do not code questions asked by the surgeon or another member of the clinical care team
- Do not code questions asked by patients or family members when the surgeon is not in the room
- Do not code anything that appears question-like but lacks a question mark at the end. These utterances do not count. The following are NOT questions as they lack question marks:
 - "Is there a possibility of me getting a recording from this, because..."
 - "So in my case, you have to remove it."
 - "I don't know what the plasma is."
- Question marks that appear inside square brackets [?] refer to transcriptionist questions (usually about content that is inaudible or medical jargon) and do not count.
 - For example, the following do not count as questions:
 - [inaudible?]

- [Lovastatin?]
 - “He’s teaching me [lots? 2:49]”
- However, question marks that appear *outside* a square bracket do count as questions.
Example: “Do I have to go back to [REHAB NAME]?”

What about multi-part questions where there are 2 or more questions included in the same section of text? How many questions does this count as?

- The number of questions is based solely on the number of question marks
 - For example, this is 5 questions, each entered as its own row in the coding sheet: “But, I mean, does he make an appointment for this surgery in October? I mean, how far out are you looking? Is it really full? I mean, do you ask for that now, the appointment? Do you . . . cancel?”
- Words like “So?” or “Right?” at the end of another question count as unique questions
 - This is two questions: “So the chances of it opening up again are low? Right?”
 - See Step 3 on how to code the topic area for tag-on words like this

What if the speaker is interrupted while asking a question?

- Again, refer to the question marks for guidance. If they’re briefly interrupted (a few words at most) before finishing the question you may need to combine the two question segments together as shown below:

FAMILY: “It’s not laparoscopic . . .”

DOCTOR: “So . . .”

FAMILY: “. . . option?”

This would be coded as one question, which you would enter in your coding sheet as “It’s not laparoscopic...option?”

- On the coding sheet enter all questions from the beginning of the question to the question mark, regardless of interruptions

What do I put in the “Wording of Question” field?

- Paste the entire question into this field. If there is a 1-2 word question after a more substantive statement, include the whole thing.
 - Example: “Oh, you mentioned that he may have some pain in the L2, L3 area. Both?”
You would paste all of this, not just the “Both?” into the “wording of question” field
- If more than one question is asked in a row, paste each unique question in its own field.
 - Example: “So the chances of it opening up again are low? Right?”
You would paste “So the chances of it opening up again are low?” in one row, and “Right?” in a second, separate row; they are two separate entries.

A note on interpretation, transcription and translation and what counts as a question

- In this manual, we distinguish between *interpretation* and *translation*
 - *Interpretation* is the real-time conversion between spoken Spanish and English. This may be provided by a professional interpreter who is present in the consultation room or via a telephone interpreter service. Family members may also provide interpretation
 - *Translation* is the delayed conversion between Spanish and English provided by a transcriptionist listening to the audio file of the consult

- In a subset of transcripts for this study, a professional interpreter or family member provides interpretation between the patient/family and surgeon
- When coding this content, first consider the directionality of the question
 - DO NOT code/count any questions that are asked by the surgeon and then interpreted by an interpreter or the family back to the patient/family
 - We are only interested in questions posed by patients or family members (either questions they ask the surgeon or ask each other)
 - DO NOT code/count any questions that are posed to the surgeon by an interpreter that were not originally asked by a patient or family member
- For questions asked by patients/family members in Spanish, keep the following in mind:
 - Transcripts are fully translated at time of transcription so you may see content that presents as:
 1. Patient: Asks question in Spanish, shown as Spanish in transcript
 2. English translation of what patient just said, translated by transcriptionist
 3. Family member or interpreter: Interprets Spanish question to English for surgeon
 4. Surgeon: Answers question in English or asks a question to patient in English
 5. Family member or interpreter: Interprets English surgeon answer or question to Spanish for patient
 - The only part of the above exchange that should be coded/collected as a question to be coded is #2. Copy the transcriptionist-provided English version of this question or questions into your codebook
- It is important not to double-count these questions if the same question appears in both English and Spanish in the transcript
 - Do not code/count questions that appear in Spanish in the transcript. Do not count #1 and #3 above as questions for this reason
- It is possible that the interpreter or family member providing interpretation could misinterpret the patient/family question (for instance, condensing multiple questions into a shorter, simpler question). Since we are interested in patient/family member activation and want to count all questions they *intended* to ask we do not want to code the interpretation of their questions, only what they *actually* said, as translated by a bilingual transcriptionist. Transcriptionist-provided translation will appear in brackets or bolded text after the original text, as shown below:
 - Patient: Cuánto dura la operación? Estaré en el hospital por mucho tiempo? **[How long is the operation? Will I be in the hospital long?]**
 - Interpreter: How long will I be in the hospital?

In the example above, this would count as 2 patient questions because the patient asked 2 questions, as translated by the transcriptionist. It is not counted as just one question because we are reliant upon the transcriptionist's translation, not the interpreter's. The same would be true if a family member had been present and translating during the consult and condensed this into one question

- If a professional interpreter is present do not code/count their questions
- If a family member is providing interpretation
 - If the family member is literally relaying a surgeon's questions to a patient, or even relaying but also adding their own content beyond what the surgeon asked, do not count this as a question
 - If the family member is relaying a patient or another family member's question to the surgeon, do count this as question, as the question will separately be coded/collected as shown in #2 above
 - If a family member acting as an interpreter asks their own question to the surgeon, this is coded/collected as any other family member question would be

Step 2: Who said it? Determine the speaker

- Code all questions asked by patients or family members/loved ones while surgeon is in the room
- Do not distinguish between family members – these are all coded as “family member”
 - In some cases, a support person such as a friend may be present. Code their questions as “family member” as well
- If question speaker is unknown, count these as patient questions UNLESS transcriptionist makes a note it's a medical provider (though they are unsure of *which* provider) AND the content of the question indicates that a clinician asked it
- Do not code questions asked by the surgeon, resident(s), or other clinical staff
- Exclude questions asked while the surgeon is not present

Step 3: Code the topic area

Look for content before and after the question to determine its topic area/context. However, do not exclusively base your topic coding on how the surgeon answers the question – it is possible the surgeon may have misinterpreted the question or even ignored it. However, if the conversation seems to be consistently in one line of thought, the surgeon's response may help clue you into what the topic area should be coded as. What the patient says immediately before/after the question may also be helpful if you are struggling to identify the topic area. You may only code each question as having one topic area so carefully review the topic area codes to determine which best fits the question.

There are 6 topic area codes: OPTIONS, EXPECTATIONS, LOGISTICS AND TECHNICAL CONCERNS, RISKS/COMPLICATIONS, ADVANCE DIRECTIVES, OTHER. These are each described in more detail below. But first, here is some guidance on how to handle very short questions.

How should I code the topic area for very short questions?

- Short questions that stand all alone without any text surrounding them on that line of the transcript are always coded as “OTHER” and count as a single question. Examples:
 - “Is that right?”
 - “Really?”
 - “Huh?”
 - “Oh did he?”
 - “You know what I'm saying?”
 - “Oh, yeah?”

- Similarly, short questions that are a reiteration of what was previously said or are purely rhetorical are coded as one question with “OTHER” as the topic area. Examples:
 - “Oh really, two thirds?”
 - “It does, doesn’t it?”
 - “Now what was I going to say?”
 - *Surgeon*: “I’ve trained since 1984, so. So if you, we all do about 200 to 250 operations, 200 to 250 operations a year.”
Patient: “Wow. Since ’84?”
- If a patient or family member asks the same question twice or more with the exact same wording, code the first instance of the question based on its content and code the second/any later instances as “OTHER”. Example:
 - *Patient*: Rehab for 6 weeks? [this would be coded as “EXPECTATIONS”]
 - *Surgeon*: Yeah.
 - *Family member*: Rehab for 6 weeks? [this would be coded as “OTHER”]
 The question must be exactly the same for this rule to apply. If there are minor wording changes, code each question as you would normally. Example:
 - *Patient*: Rehab for 6 weeks? [this would be coded as “EXPECTATIONS”]
 - *Surgeon*: Yeah.
 - *Family member*: ‘He’d be in rehab for 6 weeks?’ [this would be coded as “EXPECTATIONS”]
- Short questions that are attached or directly next to a statement (in the same line of text) that is substantive (not simply re-stating what has already been said) are coded based upon the topic of the statement that precedes the short question. The short question is considered attached to the longer statement to be coded as ONE question. When filling out the coding sheet, include both the statement and the short question. This applies to short questions that are next to a statement and separated either by a comma OR a period
 - “But it’s inside the aorta, right?”
 - This question should be coded as “LOGISTICS AND TECHNICAL CONCERNS”
 - “But it’s in the aorta. No?”
 - This question should be coded as “LOGISTICS AND TECHNICAL CONCERNS”
 - “There’s no nano-technology on it yet. Right?”
 - This question should be coded as “LOGISTICS AND TECHNICAL CONCERNS”
 - “So this seems like my only option, right?”
 - This question should be coded as “OPTIONS”
- Short questions that are attached or directly next to a substantive question count as two questions ALTHOUGH the topic code for each question may be different. Usually, the short question is coded as “OTHER” while the longer question is coded according to the topic
 - “So the chances of it opening up again are low? Right?”
 - This is two questions; the first coded as “RISKS/COMPLICATIONS”, the second coded as “OTHER”

OPTIONS

“What can I do for this problem?” or “Are there other treatments apart from surgery?” are the main sentiments behind this topic area. This code should be used for questions that seek to understand what

the different treatment paths or choices are or to compare treatments. Look for words like: options, choices, alternatives

- Use this code for any questions that reference seeking additional information on possible treatment options including
 - Surgery Choice #1 vs Surgery Choice #2
 - Observation vs Surgery (Observation includes non-surgical alternatives like symptom management/medical treatment)
 - Different approaches to surgery:— open, laparoscopic, endoscopic (e.g. with catheters) (see Appendix A for examples of approaches)
 - Radiation vs chemotherapy
- Use this code for questions that are asking for recommendations: What do you think? What would you recommend?
 - Some requests for recommendations may be subtle and may sound like the patient/family member is asking for reassurance regarding a particular treatment choice
 - For example: “So there’s really no point in putting it off, right?” or “So I’m not a gambling man, but that sounds like a reasonable investment, right?”
- This includes questions about having more options if the patient does something (gains weight, stops smoking, tumor shrinks with chemo) or something happens to allow another option to be available: “If I _____, is this treatment possible?”
- Do not code questions as being “OPTIONS” if they’re about options for other things *within* the major treatment (such as whether to get a blood transfusion during surgery, what type of equipment the surgeon will use, or where an incision is made). These would instead be coded under “Logistics and Technical Concerns”
- “OPTIONS” VS “LOGISTICS” – is it about an option or a technique within an option?
 - *What vs. how* is a good way to distinguish between these two topic areas. Questions asking *what are the options* are coded as “OPTIONS” whereas questions on *how to do it* are coded as “LOGISTICS”
 - If the question is about a treatment *approach* code it as “OPTIONS”. Words that indicate a treatment *approach* is being discussed include: open, minimally invasive, laparoscopic, endoscopic, robotic, endovascular or catheter based approach (includes TAVR/TAVI, EVAR or TEVAR), single incision/single port, or any option that involves interventional radiology instead of surgery
 - However, if a question is about a technique *within* an option, code it as “LOGISTICS”. Techniques include: staples versus stitches/hand sewn, type of stent or catheter, type of graft, and reference to specific equipment/techniques – e.g. lasers, ablation, coagulation devices, ultrasound, ligasure, staplers, fluoro, dilators, scopes, cameras, specific needles or types of sutures
- “OPTIONS” VS. “EXPECTATIONS” OR “RISKS”
 - If a question is *comparing* outcomes/risks/expectations between two or more treatment options, code it as “OPTIONS”. Look for words that indicate the speaker is thinking about the relative value of things (better/worse than)
 - Example: “It’ll give it a better chance?”
 - However, if the question is asking about risks of a procedure, what life will be like within a given treatment, or after a treatment decision has been made, code this as “RISKS” or “EXPECTATIONS”. A question is NOT coded as “OPTIONS” *unless* it seeks to compare two or more options.

- Example: "So I would end up with paralysis if I didn't have the surgery?" [This is coded as OPTIONS because it's focused on *comparing* outcomes between surgery and no surgery]
Example: "How likely is it that I will be paralyzed after surgery? [This is coded as "RISKS" because it is focused on the risks of surgery only]
- "OPTIONS" examples:
 - "What is the difference between the aftereffects of radiation versus chemo as far as...the feeling?"
 - "Is there another way?"
 - "So what alternative do you think would be good?"
 - "If I was your dad, what would your advice be?"
 - "So if I, if I put weight on, and I gain some more weight, that would make a difference?" [asking if they could get a specific surgery if they put weight on]
 - "So this seems like my only option, right?"

LOGISTICS AND TECHNICAL CONCERNs

Questions about how things will work up to and through surgery. Once they hit the post-operative stage, those questions go under "EXPECTATIONS". Use the time period in the question as your guide on when to use this code.

This code includes a broad range of questions about technical or logistical aspects of surgery/treatment but also the health condition itself: Why do I have this? What's going on here?

- Includes any questions that reference surgical instruments, length of surgery, medications, surgeon expertise, surgeon practice patterns, surgical technique or procedure (see Appendix A for examples of techniques) surgery names and technique names, locations on surgery day, pre-op instructions, timing issues
- Includes specific questions about anatomy and physiology*, surgery, medications, blood products, surgeon expertise, institutional quality/expertise** practice patterns (who actually does the surgery, how many times per year this surgeon does it, etc.)
 - * These changes may include things such as cell or organ level functions/changes. Questions about physiological or anatomical changes *up to and during* the treatment are coded as logistics. Questions about these changes occurring *following* treatment are coded as expectations.
 - **Sometimes people ask about other institutions (like Mayo Clinic) but their question is not really about going there or the logistics of having treatment at another institution. What they're really asking about it is whether the procedure they do there could be done here. In this case, the question should be coded as "OPTIONS". Read questions asking about other institutions carefully as they could fall under logistics or options.
- Includes questions on location of providers and services only if they relate to the health condition and treatment being discussed
 - Example: "Is it here in this building?" would be coded as "LOGISTICS" if it's a question of where the patient's loved ones would wait for them during surgery.
 - If it was a question about where another doctor practices who is not involved in their care for the health condition being discussed with the surgeon, this would be coded as "OTHER".

- For example, if a patient and surgeon are discussing the town the patient lives in and the patient says, “Oh do you know, Dr. X? He’s my neighbor! Do you know where he works?” without any reference to Dr. X being involved in their care, this would be coded as “OTHER”.
- Includes questions about other doctors or medical personnel but only when they are related to the health condition prompting the surgical consult (questions such as “Should I let my PCP know I’m scheduled for surgery?” should be coded as “LOGISTICS” but questions about other doctors unrelated to the condition being discussed are coded as “OTHER”- an example of this would be “Do you know Dr. X?” where there is no connection between Dr. X and their condition described)
- “LOGISTICS AND TECHNICAL CONCERNs” examples:
 - “How long does the surgery take?” or “Any idea of timing?” [When will surgery be?]
 - “How will blood drain from...after you take the vein out?”
 - “Is this something like, this is not uncommon for you people?”
 - “So how many bypasses are there?”
 - “Yeah, how long do you think this has...?” [referring to discussion of blockages building up]
 - “Do you work with him a lot?” [Though note that this is coded as “LOGISTICS” only if it’s asking about a doctor involved in the treatment of their condition being discussed with the surgeon. If this was about a doctor unrelated to the health condition being discussed, this would be coded as “OTHER”]
 - “But that other way is easier to get to? [This is coded as “LOGISTICS” as opposed to is there another option]”
 - “Which valve?”
 - “What does TAVI stand for?”

EXPECTATIONS

Questions about what will happen AFTER surgery, including in the immediate, post-operative period right after surgery. Use the time period in the question as your guide on when to use this code- it must relate to something after surgery. “If we do this, what’s gonna happen after surgery?” is the main point of this topic area.

This topic area includes questions that seek to understand how the patient’s life will change or remain the same following a specific treatment option, particularly in terms of quality of life and patient reported outcomes. Look for words like: feeling, after-effect.

- Includes patient reported outcomes such as quality of life, recurrence, changes in energy levels, mobility, continence, scarring, wound-care, bags/drains/tubes after surgery, rehab details, recovery time, limitations in function or other capacity, durability of procedure (for example how long will my new heart valve last?), length of hospital stay after surgery,
- Note: questions about the length of the surgery or procedure are coded under logistic/technical concerns, NOT expectations because this question relates to the procedure itself, not what happens after
- Note: questions about physiological or anatomical changes *following a treatment* are coded under EXPECTATIONS. These changes may include things such as cell or organ level functions/changes

- “EXPECTATIONS” examples:
 - “Like, you know, how long will be the recovery?”
 - “Like my nose going to be running all the time or?”
 - “Right, but would there be any additional pain?”
 - “It like, I mean, do you have a timeline historically when it would start to . . . regenerate again or grow again?”
 - “These are maybe questions for later, but since they're on my mind now, when can he take aspirin again?”
 - “After the two weeks [post-op] or even during those two weeks, can he go visit him or not?”
 - “So how long would he need somebody with him kind of 24 hours after he gets home?”

RISKS/COMPLICATIONS

This topic area includes questions that seek to understand what could go wrong during or following the treatments options that are being discussed (operating, not operating, chemo, radiation, etc.)

Technical discussion of near-term, surgeon-defined complications (e.g. 30 days). Look for words like: risks, complications, chances, odds. Note that this includes the risks of not operating as well as risks associated with surgery or other treatment options.

- Include any questions that reference short-term, surgeon defined effects from treatment including extended hospital stay, extended recovery time, blood clotting, bleeding, etc.
- “RISKS” VS “EXPECTATIONS” code: Code any questions that reference long-term effects/outcomes including recurrence, durability of procedure as “EXPECTATIONS”, not “RISKS”
 - Be careful about the context: is the patient specifically asking about *how it's going to get done* or about *bad outcomes*? (*How it's going to get done* would go under “LOGISTICS AND TECHNICAL CONCERNS”—even if it's serious or dangerous. Whereas questions on *bad outcomes* are coded as “RISKS”)
 - If the question is *comparing* risks of two or more treatment options, code this as “OPTIONS”
- “RISKS/COMPLICATIONS” examples:
 - “How many people have to be on a ventilator after?”
 - “As far as the location of the tumor that remains in those veins and stuff, is everything, is anything at risk as far as, I don't know, blood flow function of any of those parts?”

ADVANCE DIRECTIVES

This topic area includes questions that seek information on options or preparation in the case that the patient cannot speak for him/herself. It also includes any questions that are part of a discussion of advanced care planning. This includes questions that express a preference about kinds of health states you might talk about in an advance directive: life sustaining medical treatment, feeding tubes, serious stroke, lack of independence. Look for words like: DNR, Power of Attorney (POA), living will, advance directives.

- If they are expressing preferences about what should be done if a bad outcome occurs, code this as “ADVANCE DIRECTIVES”. If they are merely discussing the risk/complications related to a surgery (likelihood of them happening), code it as “RISKS/COMPLICATIONS”.
- “ADVANCE DIRECTIVES” examples:
 - *Doctor:* “Yeah. Well if something goes terribly wrong, you’re, and you’re not able to even communicate with us, I’m assuming your wife would answer for you, and not, not, not, she would express to us what your wishes would be. I mean, normally I wouldn’t keep people going, sort of, inappropriately on life support. I think that’s a cruel thing to do.”
 - *Family Member:* “Then, you know, why continue?”
 - “What if I can’t talk after surgery, how can I make sure someone knows what I want to be done?”
 - “How do I set it up so my wife can make decisions for me if something goes wrong?”

OTHER

This topic area includes the following types of content:

- Sometimes very short questions like “Right?” are coded as “OTHER”. See guidance at the beginning of this section on how to code the topic area for very short questions
- Questions that refer to something about the patient’s health that do not fit in any of the other categories (e.g. Genetic testing, complications of *past* procedures, family history and health of others)
- Includes questions about other doctors or medical personnel *unrelated to the treatment of the health condition prompting the surgical consult*
- Includes questions on location of providers and services if they are NOT related to the health condition and treatment being discussed
- Non-health questions:
 - “Do you mind if I write too?”
 - “How many grandkids do you have?”
 - “Are you writing with a fountain pen?”
 - “Wow, you typed all of these files?”
 - “Are you in favor of this being recorded?”
 - “You need some water?”

Use caution in applying this code – do not use it as a catchall when you’re unsure of the topic area code.

Step 4: Final check for questions

Once you have read through the transcript and coded each question, go through and review to ensure that you didn’t miss any questions. This is a critical step as it is all too easy to miss a question.

Starting from the beginning, hit “Ctrl+F” to find all of the “?” marks in the transcript. Compare the questions highlighted in the transcript to the questions you have indicated on your coding sheet. Make sure you only included questions from the patient and/or family member(s), and that you have labeled the speakers correctly.

Appendix A: Approaches vs. techniques

Use the following list of approaches vs. techniques to distinguish between OPTIONS and LOGISTICS AND TECHNICAL CONCERNS

Approaches: (Typically coded as OPTIONS)

- Open
- Minimally invasive
- Laparoscopic
- Endoscopic
- Robotic
- Endovascular or catheter based approach (includes TAVR/TAVI, EVAR or TEVAR)
- Single incision/single port
- Any option that involves interventional radiology instead of surgery

Techniques within a given approach: (Typically coded as LOGISTICS AND TECHNICAL CONCERNS)

- Staples versus stitches/hand sewn
- Type of stent or catheter
- Type of graft
- Reference to specific equipment/techniques – e.g. lasers, ablation, coagulation devices, ultrasound, ligasure, staplers, fluoro, dilators, scopes, cameras, specific needles or types of sutures

“OPTIONS” vs. “LOGISTICS AND TECHNICAL CONCERNS”

- OPTIONS includes approaches to surgery (“what”)
 - Look for things like: open, minimally invasive, laparoscopic, endoscopic, robotic, endovascular or catheter based approach (includes TAVR/TAVI, EVAR or TEVAR), single incision/single port, any option that involves interventional radiology instead of surgery
- LOGISTICS AND TECHNICAL CONCERNS includes techniques within an approach (“how”)
 - Look for things like: staples versus stitches/hand sewn, type of stent or catheter, type of graft, reference to specific equipment/techniques – e.g. lasers, ablation, coagulation devices, ultrasound, ligasure, staplers, fluoro, dilators, scopes, cameras, specific needles or types of sutures

“OPTIONS” vs. “RISKS/COMPLICATIONS” or “EXPECTATIONS”

- OPTIONS includes comparison of outcomes/expectations/risks
 - Look for words like better/worse than
 - Examples
 - “It’ll give a better chance?”
 - “So I would end up with paralysis if I didn’t have the surgery?”
- RISKS or EXPECTATIONS include questions about the risks of an option or what life will look like with a certain option, without comparison to the alternative
 - Example
 - “How likely is it that I will be paralyzed after surgery?”

“LOGISTICS AND TECHNICAL CONCERNS” vs. “EXPECTATIONS”

- LOGISTICS AND TECHNICAL CONCERNS includes questions about how things will work up to and through surgery
- EXPECTATIONS includes questions about the immediate post-operative stage onward

“RISKS/COMPLICATIONS” vs. “EXPECTATIONS”

- RISKS/COMPLICATIONS includes short-term, surgeon-defined effects from treatment
- EXPECTATIONS includes any questions that reference long-term effects/outcomes including recurrence and durability of procedure

“RISKS/COMPLICATIONS” vs. “LOGISTICS AND TECHNICAL CONCERNS”

- RISKS/COMPLICATIONS includes questions on bad outcomes
- LOGISTICS AND TECHNICAL CONCERNS includes how it’s going to get done – even if it’s serious or dangerous

PCORI – OPTION 5 Scoring Sheet

TRANSCRIPT ID	
RATER	

If a resident or another clinician is present *while* the enrolled study surgeon is in the room, incorporate the other clinicians' comments into your scoring. The goal is to code a conversation about a decision and this conversation includes many things.

Item 1. For the health issue being discussed, the clinician (1) draws attention to or re-affirms that alternate treatment or management options exist or that the (2) need for a decision exists. If the patient rather than the clinicians draws attention to the availability of options, the clinician responds by agreeing that the options need deliberation.

Score	Description	Notes
0	No alternatives mentioned, no mention of need for decision at all OR doesn't respond to patient question about alternatives (If they do any of the 3 things they get higher than 0 score) (MD states need to deliberate about alts. mentioned by patient to get higher than 0 score)	
1	Get credit for doing minimal effort of any: call attention to a decision, presents alternatives or responds to patient's question about alts.	
2	Must both say there is a decision AND there are options (more than one treatment is mentioned (can include palliative care or "do nothing")	
3	MD says we need to make a decision AND alternatives have been described as valid/not ridiculous (do nothing, or you die), does not make the point that this is preference sensitive	
4	MD says we need to make a decision AND that it's preference sensitive, AND alternatives have been well described as valid/not ridiculous (do nothing, or you die)	
		Item 1 Score =

Item 2. The clinician reassures the patient, or re-affirms, that the clinician will support the patient to become informed and to deliberate about the options. If the patient states that they have sought or obtained information prior to the encounter, the clinician supports such a deliberation process.

Score	Description	Notes
0	No mention of patient partnership, helping match preferences with treatment options	
1	MD conveys empathy or any acknowledgement of patient/family emotions/fears but does not make a point of how MD will provide support. Examples: "I know this is a difficult decision." "Many families of patients in the ICU tell me this can be an overwhelming experience."	
2	ANY: Mentions partnership, working together, matching surgeon expertise with patient values/goals	
3	MD provides clear indication of support, but not specific to decision-making. Example: "Our team cares about you and will do whatever we can to help you get through this."	
4	MD provides explicit support of patient/family in deliberation. Examples: "My role is to provide you with information and to guide you" "the decision that you and I make together"	
		Item 2 Score =

PCORI – OPTION 5 Scoring Sheet

TREATMENT OPTIONS	PROS	CONS
Option 1		
Option 2		
Option 3		

Add all treatment options discussed in table (including name of surgery) – even if the pros and cons are not discussed

Treatment plan at end of consult:	
--------------------------------------	--

Item 3. The clinician gives information, or checks understanding, about the pros and cons of the options that are considered reasonable (including taking ‘no action’), to support the patient in comparing the alternatives. If the patient requests clarification, explores options, or compares options, the clinician supports the process. (we are not going to worry about check for understanding here)

Score	Description	Notes
0	No pros and cons of any treatment described	
1	Pros OR cons of one option (no second option)	
2	Pros AND cons of one option (no second option) OR says two options but only gives the pros OR cons of one of the options	
3	Pros OR cons of both (all) options	
4	Pros AND cons of both (all) options. Must state ALL to get a 4.	
		Item 3 Score =

PCORI – OPTION 5 Scoring Sheet

Item 4. The clinician makes an effort to elicit the patient's preferences in response to the options that have been described. If the patient declares their preference(s), the clinician is receptive / supportive.

Score	Description	Notes
0	No phrases for deliberation, doesn't ask if patient has questions	
1	Asks if patient has "any questions" (cursory effort)	
2	Asks a more sophisticated question about whether the patient has questions/input "does this make sense to you?"	
3	Non-specific question for deliberation in unclear context	
4	Uses a clear question for deliberation – (how are you thinking about this, what is important to you now, how does this outcome seem to you?)	
		Item 4 Score =

Item 5. The clinician makes an effort to integrate the patient's preferences as decisions are made. If the patient indicates how best to integrate their preferences as decisions are made, the clinician is supportive. (this is about the recommendation/need to make a recommendation at some point, i.e. come back and reconsider, – do they make one and is it related to the patient's preferences, "this is what we are going to do AND this is why")

Score	Description	Notes
0	Makes a decision without patient input OR doesn't make a decision AND doesn't note that the decision will be deferred	
1	"It's up to you, you decide" OR gets deferred based on another test (clinical momentum)	
2	Decision gets deferred but recognition of patient preferences incorporated somehow	
3	Surgeon makes a plan, some suggestion that this would be aligned with pts values	
4	Surgeon makes a recommendation and says that it is concordant with what is important/valuable to the patient (uses what the patient has said to promote this as the right decision; says that this is the right decision based on a specific value the patient has)	
		Item 5 Score =

TOTAL OPTION SCORE						
Item	1	2	3	4	5	Total
Score						

Engaging Patients, Health Care Professionals, and Community Members to Improve Preoperative Decision Making for Older Adults Facing High-Risk Surgery

Nicole M. Steffens, MPH; Jennifer L. Tucholka, BS; Michael J. Nabozny, MD; Andrea E. Schmick, BA; Karen J. Brasel, MD, MPH; Margaret L. Schwarze, MD, MPP

IMPORTANCE Older patients are at greater risk for postoperative complications, yet they are less likely than younger patients to ask questions about surgery.

◀ Invited Commentary
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OBJECTIVE To design an intervention to improve preoperative decision making and manage postoperative expectations.

DESIGN, SETTING, AND PARTICIPANTS A Patient and Family Advisory Council (PFAC) was created to help identify preoperative decisional needs. The PFAC included 4 men and women who had previous experience with high-risk surgery as older patients or their family members; the PFAC met monthly at a local library from May 2014 to April 2015 to examine findings from a prior qualitative study and to integrate themes with PFAC members' experiences. Patient observations included 91 recorded conversations between patients and surgeons and 61 patient interviews before and after surgery. The PFAC members and other stakeholders evaluated 118 publicly available questions and selected 12 corresponding to identified needs to generate a question prompt list (QPL). Three focus groups, including 31 community members from diverse backgrounds, were conducted at community centers in Madison and Milwaukee, Wisconsin, to refine the QPL. A clinical pilot with 42 patients considering surgery was conducted in one outpatient surgical clinic in Madison.

MAIN OUTCOMES AND MEASURES Generation of a QPL to address patients' preoperative informational and decisional needs.

RESULTS Through exploration of qualitative data, the PFAC noted 3 critical problems. Patients and family members believed surgery had to be done, were surprised that postoperative recovery was difficult, and lacked knowledge about the perioperative use of advance directives. The PFAC identified a need for more information and decisional support during preoperative conversations that included clarification of treatment options, setting postoperative expectations, and advance care planning. The following 3 question prompt categories arose: "Should I have surgery?" "What should I expect if everything goes well?" and "What happens if things go wrong?" The final list included 11 questions within these domains, was understandable in English and Spanish, and was acceptable to patients in the clinic.

CONCLUSIONS AND RELEVANCE Through direct engagement of stakeholders, a QPL was created to address core decisional and informational needs of surgical patients. Future testing will evaluate whether this list can be used to improve patient engagement and reduce postoperative regret and conflict about postoperative treatments.

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Each year, approximately 500 000 Americans 65 years or older will have a high-risk operation, such as heart bypass or major cancer surgery.¹⁻³ Although many patients benefit from high-risk surgery, it carries a real potential for mortality and serious complications, particularly for older patients with multiple comorbidities. High-risk surgery can have other unintended consequences, including postoperative suffering, conflict about additional aggressive treatments, and receipt of unwanted interventions.^{4,5} Thus, much is at stake for patients in the decision to proceed.

Surgeons play an important role helping patients make preference-sensitive decisions. However, surgeons often miss opportunities for these discussions.⁶⁻¹¹ Patients report that “explanations are rushed, issues are not explained, [and] choices are not understood.”^{12(p6-6)} Although patients generally prefer involvement in the decision-making process, they frequently do not know how to engage.^{13,14} Patients who are activated receive more patient-focused care and are more likely to take part in collaborative decision making.^{15,16} This activation is especially critical for older patients, who are less likely to ask questions and less effective in ensuring that physicians attend to their concerns than younger patients.¹⁷

In other settings, question prompt lists (QPLs) can effectively improve patient engagement.¹⁸⁻²² Standardized lists of questions to ask the physician are available, but patients who have experience with surgery rarely participate in their development. To improve patient engagement in surgical decision making, we need to bridge the gap between patients’ need to make the consequences of surgery relevant to their lives and the surgeon’s goal of setting realistic expectations. Our objective was to design an intervention to improve preoperative decision making. By formalizing a partnership among patients, family members, and researchers, our Patient and Family Advisory Council (PFAC) developed a QPL to help older adults with high-stakes surgical decisions.

Methods

Development of a PFAC

Our PFAC served as consultants to provide feedback and reflection on our research, specifically to clarify concepts from previously generated qualitative data and to integrate the PFAC’s life experiences with identified priorities. We enlisted PFAC members through clinic nurses, surgeons, and hospital patient relations departments. We invited patients and family members of older patients who had experience with high-risk surgery and purposely selected a small group with strong literacy skills who could critically interpret abstracted data. Two members previously had major surgery (cardiac and neurologic) and 2 members were primary caregivers for patients who had surgery (vascular and oncologic). This group of 2 men and 2 women met monthly at a public library and received \$1000 for attendance at twelve 90-minute meetings (May 2014 to April 2015), independent review of materials, and travel.

Collection of qualitative data was approved by the institutional review boards of the University of Wisconsin and Partners Health Care System and the research ethics board of the

Key Points

Question Can researchers engage with surgical patients and family members to develop an intervention to address preoperative decisional and informational needs?

Findings The experiences of patients and family members were integrated through observational study and direct engagement to create a question prompt list for older adults considering high-risk surgery. Three decision-making needs were addressed, including clarification of treatment options, setting postoperative expectations, and advance care planning.

Meaning This intervention was designed to overcome gaps in current practice by activating patients to promote deliberation and to prepare them for expected and unexpected outcomes.

University of Toronto. The institutional review board of the University of Wisconsin exempted the QPL clinical pilot from review. We did not pursue the boards’ approval for the work described by the PFAC or community groups because they did not have access to protected health information and are considered research advisors. All PFAC members were apprised of the extent of this project in advance and their compensation and participated voluntarily.

Origins of Qualitative Data

Before conception of our PFAC, we conducted an observational qualitative study during a 3-year period that included 91 audio-recorded preoperative conversations between patients and 11 surgeons described in-depth elsewhere.^{10,11,23} We also interviewed patients before (n = 34) and after (n = 27) surgery. We used an inductive coding strategy and deliberative adjudication process among researchers to support higher-level analysis whereby codes were expanded and refined to capture phenomena present in the data.

PFAC Process

Meeting agendas included an opening question, a statement of the meeting objectives, and a wrap-up forecasting the next steps (Table 1). Our first meetings established project goals, a timeline, and expectations. Members also shared their experience with surgery. Next, we presented themes from our qualitative analysis and linked each theme with a deidentified patient story. Members discussed their reactions and connected study data with their personal experience with high-risk surgery. This member-checking process²⁴ enriched data integration with the lived experience of members of our PFAC (Figure 1).

QPL Development

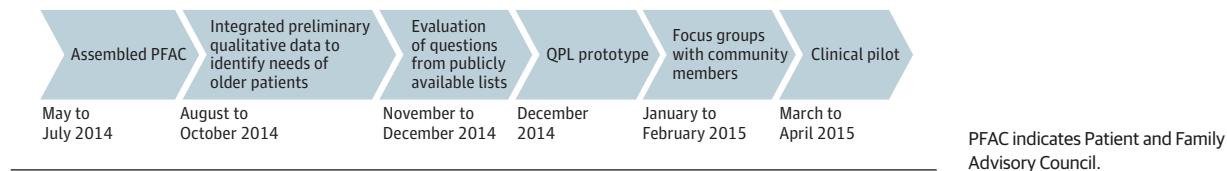
Discussions from the first 3 PFAC meetings generated key informational and decisional deficits to guide development of the QPL. We then collected 271 questions “to ask a doctor” from publicly available websites²⁵⁻²⁸ and published literature.^{21,29-31} We excluded duplicate questions and concerns irrelevant to our targets (eg, “Is there anything specific I need to bring to the hospital?”). We asked PFAC members, 2 surgeons who routinely perform high-risk operations on older patients, a pa-

Table 1. PFAC Meeting Timeline, Objectives, Activities, and Outcomes

Time, mo	Meeting	Objectives	Activities	Outcomes
1-2		Establish expectations and group harmony	<ul style="list-style-type: none"> • Introduce members • Establish standards for engagement • State project goals, timeline, and expectations • Share personal experiences with surgery 	<ul style="list-style-type: none"> • Clear understanding of group conduct, PFAC expectations, and researcher roles • Recognition that PFAC members' experience can contribute to the research project
3-5		Integrate preliminary qualitative study results with PFAC experience with high-risk surgery	<ul style="list-style-type: none"> • Learn about qualitative research methods • Reflect on study patients' stories and integrate with personal experience • Identify personally important themes extant in qualitative data 	<ul style="list-style-type: none"> • Identification of core decisional and informational needs • Identification of targets for intervention: choices, expectations, and complications
6-8		Create QPL	<ul style="list-style-type: none"> • Brainstorm questions to ask a surgeon • Discuss top 20 questions from 118 that PFAC and other stakeholders ranked in premeeting online survey • Explore question applicability to preoperative decisional needs • Provide feedback on 12-question prototype of QPL 	<ul style="list-style-type: none"> • Prototype QPL
8-12		Gain input on design for future comparative effectiveness study	<ul style="list-style-type: none"> • Assess measures and outcomes that are valuable and meaningful to patients and family members • Provide feedback on grant application • Provide feedback on study recruitment materials 	<ul style="list-style-type: none"> • Research protocol that is acceptable and relevant to stakeholders

Abbreviations: PFAC, Patient and Family Advisory Council; QPL, question prompt list.

Figure 1. Process and Activities for Engaging Patients, Family Members, and Community Members in Creating a Question Prompt List (QPL)



tient advocate, and a hospital administrator to score the remaining 118 questions on a 5-point Likert scale.

We brought the 20 highest-rated questions to the PFAC. Members deliberated about the meaning of each question, whether they could ask each question, and whether the surgeon's answer would be valuable. Using these criteria, they generated a 12-question prototype QPL.

Community Focus Groups

We presented the prototype QPL to focus groups and iteratively revised it in response to feedback. We engaged a well-established panel of 6 participants specifically trained to provide feedback to researchers and hailing from difficult-to-reach populations recruited from service programs such as food pantries and parenting groups.³² A facilitator presented each question and asked:

- "Does this question make sense?"
- "Would you feel comfortable asking this question?" and
- "If you ask this question, what information are you hoping to get?"

We brought the revised prototype to a second group of 6 participants and a Spanish version to 19 Spanish-speaking older adults who reflected on the appearance and comprehensibility of the QPL and whether they could ask a surgeon the questions. Because QPLs are effective only when physicians endorse their use,²⁰ we used this same iterative process with our stakeholders—the PFAC, 2 surgeons, and community groups—to generate a letter from the surgeon to accompany the QPL.

QPL Pilot

To evaluate the acceptability of our QPL, we tested previsit mail delivery of the QPL and surgeon letter at a local vascular surgery clinic. We then informally interviewed patients who had received the QPL about its use and ascertained their level of comfort asking the questions. We also solicited feedback from surgeons.

Results

Members of the PFAC identified informational and decision support failures in the qualitative data, including misunderstandings about treatment options and postoperative expectations. They then integrated this information with their lived experience to generate a QPL to address these deficiencies. After examining the qualitative data, PFAC members believed that patients and family members were unprepared for surgery. They were concerned that patients believed surgery had to be done, were surprised that postoperative recovery was difficult, and lacked knowledge about the use of advance directives (Table 2).

Choices

The PFAC members examined qualitative data that exposed a lack of choice about whether to have surgery. Patients in the qualitative study reported their surgeon had not presented alternatives or that the alternatives presented were unaccept-

Table 2. Informational and Decision Support Failures Identified in Qualitative Data by the PFAC

Perception	Qualitative Study ^a		
	Preoperative Interview	Postoperative Interview	PFAC Discussion
Surgery must be performed	"I didn't really decide I wanted to have it...after all those tests...sent me to the heart surgeon...he said, well it should be done."	"...there wasn't really any other options, and then so, you know, there wasn't uh, nothing to think about really."	<ul style="list-style-type: none"> Patients need more information about alternatives. Patients "already have one foot into the surgery room" because the surgical referral process implies that surgery is the only option. Patients may still conclude surgery has to be done but need to have more information about what would happen if they did not have surgery.
	"I don't know. Just get it done and go on with your life, I guess."	"But, you know, what, what's the option? Um, do you not have the surgery and wait for a heart attack and then your recovery is going to be a whole lot more complicated and probably protracted....So, to me it was like a no brainer, you know."	
Surprise that recovery is arduous	"Just to fix the problem which I am having....That is my expectation."	"Hey if I'm gonna feel like I got hit by a truck, tell me before. So it was more, it was more intensive...than I realized it would be."	<ul style="list-style-type: none"> Patients are not fully prepared for the intensity of surgery and the recovery process. Patients should know what to expect postoperatively. Patients who are surprised postoperatively may be upset with the surgeon.
	"[Surgery is] going to be the easiest, best opportunity for me to live a couple more years....It's just a little treatment here and there afterward."	"I thought it was going to be an in-and-out thing."	
Unclear advance directive	"They just know what they got to do. I don't want to be laying around being a vegetable."	"Should I let him go ahead and do the CPR? ...I didn't want to put him through that....It's the hardest decision I've ever made."	<ul style="list-style-type: none"> Patients do not have the opportunity to clearly express their preferences for postoperative life-supporting treatments. PFAC member: "There is a disconnect between what the patients want and who is the right person to tell these wishes."
	"Yeah I think [the surgeon] knows [what to do in an event of a complication]...Whatever he thinks is best."	"...if you were going to get good results, it's one thing, but if you're going to come home and do nothing...stick your finger in a light socket."	

Abbreviations: CPR, cardiopulmonary resuscitation; PFAC, Patient and Family Advisory Council.

^a Quotations are from interviews with 34 patients before and 27 patients after surgery as part of the observational qualitative study.

able. This notion was linked to the patients' belief that the surgeon felt strongly that surgery should be done or a personal understanding that their illness required surgery. These data showed patients and families had developed an understanding that the disease itself compelled the need for surgery, thereby determining the absence of alternatives.

Furthermore, in the setting of an unwanted outcome, this inextricable link between surgery and disease provided reassurance about the choice to proceed with surgery. For example, the wife of a patient whose cognitive impairment progressed markedly with surgery sought comfort with their decision:

...because we asked the doctor...because he said about the confusion [dementia], it could have been worse with the surgery. I said, well, what's my option? Does he really need the surgery...and he goes, no, he did need it.

Another patient who spent months in the hospital after resection of a benign pancreatic mass reported, "I wouldn't have had surgery if I didn't have to have the tumor removed." Belief that there was no choice or surgery had to be done appeared comforting to patients with serious illness and generated concern from the research team that this conviction should not be disrupted by efforts to improve decision making.

The PFAC members were distressed that our qualitative study patients appeared uninformed about alternatives. Simultaneously they empathized with the notion that surgery had to be done. One member told us: "[patients] already have one foot into the surgery room" before meeting a surgeon because the referral process promotes a message that surgery is essential. Still, they were clear that informed decision making was crucial for all patients, even if they ultimately con-

cluded surgery had to be done. They stressed that patients need to be "told all the ramifications and possibilities of both having [surgery] and not having it," which requires a clear explanation about what could be gained and what would happen without surgery.

These discussions generated the first decision support target for our QPL: "Should I have surgery?" Our PFAC wanted patients to deliberate about having surgery and receive explicit information about how surgery might improve symptoms or longevity. To address this need, our stakeholders selected the question prompts:

- "What are my options?"
- "What is likely to happen if I do have surgery? If I don't have surgery?"
- "Will surgery make me feel better?" and
- "Will surgery help me live longer? If so, how much longer?"

Expectations

The PFAC explored qualitative data suggesting patients were unprepared for what occurred postoperatively. For example, 1 patient noted she had been apprised of specific risks, but did not recognize this information could be used to prepare for complications or prolonged recuperation. She described how frightened she was by her slow recovery and postoperative weakness:

No, no I wasn't expecting anything. They didn't tell me there could be [complications]. They did say you could develop A-fib and they did say that after the operation you could have a stroke or heart attack....So I didn't really, I did ask questions, but I guess I didn't ask if it would be a long recovery or what could happen...I mean you're not expecting, and I don't think you know all the questions you should ask.

Although surgeons named risks and described operations under consideration as *big surgery*, patients struggled to translate this information. Patients assumed they would return to normal postoperatively: “If I can’t come back normal, I don’t want to come back.”

The PFAC expressed concern that patients underestimated the impact of surgery and had a naive outlook about the seriousness of surgery, leading to surprise or distress when recovery was arduous. This notion was familiar to PFAC members who reported feeling “blindsided” postoperatively. They worried that what was normal after surgery for the surgeon was not normal for the patient and this might cause distress when the surgeon’s expected outcome was unexpected by the patient.

This discussion generated the target: “What should I expect if everything goes well?” The PFAC chose question prompts to prepare for recovery and long-term physical changes, including:

- “How do you think my daily life will look after surgery? Right after surgery, 3 months later, 1 year later?”
- “Will I have any tubes or drains put in during or after surgery? Will I need them at home?”
- “How will this surgery affect my other health problems?” and
- “After I leave the hospital, what type of care do you think I will need?”

Complications

The PFAC reviewed qualitative data that exposed a wide variation in treatment preferences for serious postoperative complications. Patients believed the surgeon knew their wishes despite the lack of explicit discussion. For example, 1 study patient stated, “The only thing I don’t want, if I do die, I don’t want to be revived.” This type of information was not discussed with surgeons. A few patients mentioned their advance directive, but the surgeon did not explore their preferences further. Thus how to proceed in the event of a postoperative complication was unclear. Some believed family members were familiar with their preferences and could make decisions if needed.

The PFAC members were concerned that patients needed more advance care planning. They expressed dismay that patients’ treatment preferences were not communicated: “There is a disconnect between what the patients want and who is the right person to tell these wishes.” The PFAC struggled to understand how specific directives might need to be tailored to the surgical setting and were shocked by the lack of standard procedures for notifying all health care professionals about existing directives. They identified a critical need for patients to clarify their preferences with the surgeon and to discuss how directives might be interpreted during the perioperative period.

The PFAC sought questions to promote conversation about “What happens if things go wrong?” They chose the following question prompts to encourage this type of discussion:

- “Can you describe serious complications and explain what those might mean for me?”
- “If I’m too sick to speak for myself, how can I make sure you know my wishes?” and
- “If I decide to appoint someone to make medical decisions for me, what do I need to do to make those arrangements official?”

Acceptability of the QPL

English- and Spanish-speaking community members endorsed the questions on the QPL and believed that they could ask all the questions on the list. Surgeon stakeholders agreed they could answer the questions.

We iteratively revised words that community members believed were difficult to understand or to use in conversation. Community members worried that “Will surgery help me live longer?” was difficult to answer because it suggested surgeons can guarantee specific outcomes. They did not want patients to “hold doctor[s] accountable” for unreasonable information and suggested we add *in your opinion* to 3 questions. Community members praised the brochure’s clarity and understood they did not need to ask every question. They were not frightened by questions about advance care planning. Our final QPL intervention is a brochure with 11 questions (Figure 2) and a letter from the surgeon endorsing its use.

Pilot Testing

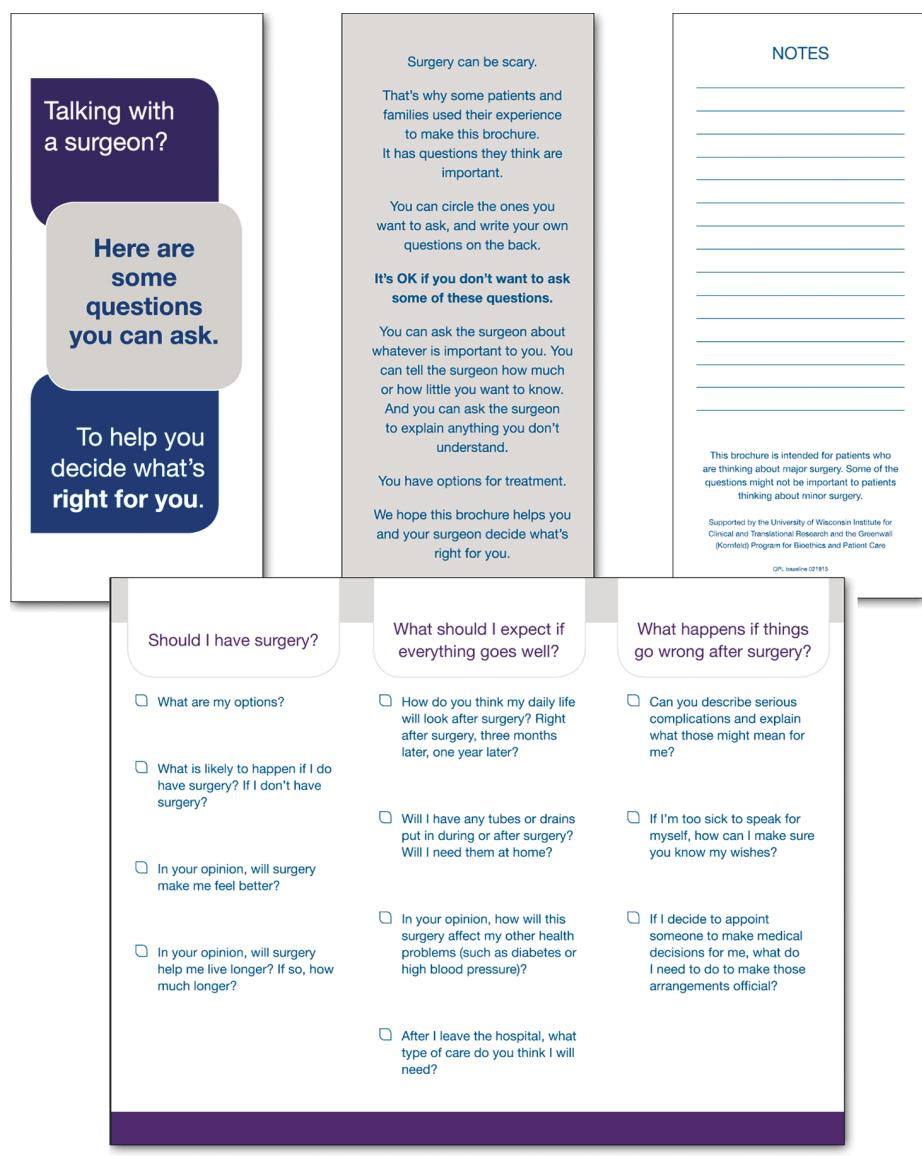
In the clinic, patients used the QPL to assist communication and felt confident that they were well informed. They noted “it puts questions in your mind,” including “questions you never would have thought to ask.” They believed they were able to explore how surgery might affect their quality of life and to secure formal designation of a health care proxy “just in case.” One patient reported nervousness on receiving the QPL because he did not know “surgery was on the table” and had inferred his problem was serious. Still, this patient understood surgical consultation was an opportunity to get his questions answered. During consultations surgeons noted that patients would pull the list out to ensure their questions were answered.

Discussion

Through engagement of patients, family members, and other stakeholders, we created a QPL to address core decisional and informational needs of patients considering high-risk surgery. The intervention, which includes the list of questions and a supportive letter from the surgeon (<https://www.hipxchange.org/SurgicalQPL>), targets elements of primary importance for informed decision making, including discussion of treatment options, clarification of goals, and preparation for expected and unexpected outcomes. Although these elements seem to be covered during traditional informed consent, this intervention is designed to rectify gaps in communication identified by patients and family members that current practices fail to address. These results have important implications for surgeons, patients, and their family members.

For surgeons, this intervention will require translating professionally defined notions of risk and benefit into patient-centered outcomes, specifically goals and expectations. Pecanac et al²³ have previously documented that surgeons skillfully describe the gravity of high-risk surgery and routinely disclose risk, yet we find it remarkable that this process inadequately supports patients as they decide whether to have surgery or prepare for expected outcomes. Although sur-

Figure 2. Patient and Family Advisory Council Question Prompt List Brochure



geons work hard to provide critical information, the meaning of *big surgery* and *risk of heart attack* is unfamiliar to patients and families who struggle to imagine how such events may be experienced. Rather than more information, they need more interpretation of the information surgeons currently provide.³³ The QPL questions are framed to help patients access surgeons' knowledge in a way that patients can understand.

For patients, the QPL aims to promote informed decision making by supporting inquiry with questions they would not have thought to ask. Traditional models of clinical decision making theorize that patient preferences for decisional control are unique and decision dependent; some prefer complete physician control whereas others want equally shared decisions or complete control.^{34,35} Newer theoretical models propose that most patients want to be involved but simply do not know how.¹⁴ This problem can be mediated by previsit edu-

cation or coaching with interventions such as the QPL. Because the patient experience is transactional (ie, determined by the actions of surgeons and patients),³⁶ patients who are motivated to be involved are more likely to participate in collaborative decision making.

Although many versions of questions to ask physicians exist, they contain questions that patients ask spontaneously. In our observation, surgeons regularly inquire whether patients have questions and patients respond with logistic or technical concerns, such as "Can my wife sleep in my room?" and "Will you use stitches or staples?"²³ Although these concerns are important to patients, they do little to engage patients in a discussion about trade-offs or to set realistic expectations for what life might be like after surgery. The QPL addresses specific needs that are not routinely queried by patients and families.

For family members, the QPL provides an opportunity to discuss unwanted outcomes at a time when the patient, surgeon, and family are together and able to communicate together. Postoperative conflict about life-supporting treatment is distressing³⁷ because patients are not always clear about their preferences preoperatively,¹¹ and surgeons are surprised when patients have not bought in to the use of prolonged life support.⁸ Although some patients may be too anxious to have such conversations before major surgery, we found many patients who desired this type of discussion.¹¹ Furthermore, respondents in our focus groups and patients in the pilot understood they did not need to ask every question.

Our study has strengths and limitations. Our qualitative data was collected in multiple sites to capture geographic variation and demonstrated robust patterns of preoperative conversation.¹⁰ However, regional differences in how surgery is presented and understood by patients may not be captured by our sample. Although we have piloted the QPL and other investigators have demonstrated the efficacy of such

interventions,¹⁸⁻²² the effectiveness of this QPL is unknown. We need evidence about how the QPL might improve these high-stakes conversations, support value-directed deliberation, set realistic postoperative expectations, and avoid conflict in the setting of an unwanted outcome. We have recently received funding from the Patient-Centered Outcomes Research Institute to test these effects in a randomized clinical trial.

Conclusions

We integrated the experiences of patients and family members through observational study and direct stakeholder engagement to create a QPL for older adults considering high-risk surgery. This intervention aims to overcome gaps in current practice by activating patients and family members before surgical consultation to promote deliberation about treatment choices and prepare patients for expected and unexpected outcomes.

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 Invited Commentary

Patient-Centered Outcomes Research—Opportunities for Novel, Innovative, and Transformative Partnerships With Patients and Their Families

Rebecca A. Aslakson, MD, PhD; Matthew Weiss, MD

The US Patient Protection and Affordable Care Act of 2010 established the Patient-Centered Outcomes Research Institute (PCORI), a national nonprofit to fund patient-centered

comparative effectiveness research and extend "the concept of patient-centeredness from health care delivery to

health care research."^{1(p1513)} As defined by PCORI, patient-centered outcomes research (PCOR) is "the evaluation of questions and outcomes meaningful and important to patients and caregivers."^{1(p1513)} Since late 2012, PCORI has directed more than \$1 billion into nearly 700 projects in 45 states, Puerto Rico, and the District of Columbia.² At least 10 surgical projects are currently funded and range from patient-reported outcomes across different types of bariatric surgery³ to advance care planning before major cancer surgery,⁴ with some groups already publishing results.⁵



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In this issue of *JAMA Surgery*, Steffens et al⁶ report PCORI-funded work to improve preoperative decision making and postoperative expectations among patients and their family members. The team developed a Patient and Family Advisory Council (PFAC), which consisted of 2 patients and 2 family members. A question prompt list (QPL) was generated by collecting questions from websites and published literature, which the PFAC members and 2 surgeons scored based on a 5-point Likert scale. The PFAC reviewed the top-scoring 20 questions and ultimately developed a 12-question prototype QPL after further evaluation by an English- and a Spanish-speaking community focus group. This prototype was piloted in a vascular surgery clinic. The final QPL includes 11 questions divided among the following 3 categories: "Should I have surgery?" "What should I expect if everything goes well?" and "What happens if things go wrong after surgery?"

BMJ Open Navigating high-risk surgery: protocol for a multisite, stepped wedge, cluster-randomised trial of a question prompt list intervention to empower older adults to ask questions that inform treatment decisions

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ABSTRACT

Introduction Older patients frequently undergo operations that carry high risk for postoperative complications and death. Poor preoperative communication between patients and surgeons can lead to uninformed decisions and result in unexpected outcomes, conflict between surgeons and patients, and treatment inconsistent with patient preferences. This article describes the protocol for a multisite, cluster-randomised trial that uses a stepped wedge design to test a patient-driven question prompt list (QPL) intervention aimed to improve preoperative decision making and inform postoperative expectations.

Methods and analysis This Patient-Centered Outcomes Research Institute-funded trial will be conducted at five academic medical centres in the USA. Study participants include surgeons who routinely perform vascular or oncological surgery, their patients and families. We aim to enrol 40 surgeons and 480 patients over 24 months. Patients age 65 or older who see a study-enrolled surgeon to discuss a vascular or oncological problem that could be treated with high-risk surgery will be enrolled at their clinic visit. Together with stakeholders, we developed a QPL intervention addressing preoperative communication needs of patients considering major surgery. Guided by the theories of self-determination and relational autonomy, this intervention is designed to increase patient activation. Patients will receive the QPL brochure and a letter from their surgeon encouraging its use. Using audio recordings of the outpatient surgical consultation, patient and family member questionnaires administered at three time points and retrospective chart review, we will compare the effectiveness of the QPL intervention to usual care with respect to the following primary outcomes: patient engagement in decision making, psychological well-being and post-treatment regret for patients and families, and interpersonal and intrapersonal conflict relating to treatment decisions and treatments received.

Ethics and dissemination Approvals have been granted by the Institutional Review Board at the University of Wisconsin and at each participating site, and a Certificate

of Confidentiality has been obtained. Results will be reported in peer-reviewed publications and presented at national meetings.

Trial registration number NCT02623335.

INTRODUCTION

Each year, many of the 500 000 older Americans having high-risk surgery^{1 2} will do so without fully understanding how it will impact them. Given operative trends for patients age 65 and older,^{3 4} this number is expected to grow as the US population ages. Although major surgery has potential to prolong life and improve symptoms, it can have unwanted outcomes for older adults, including reduced quality of life,⁵ more hospitalisations^{6 7} and potential suffering at the end of life.^{8 9} Furthermore, 50% of patients 65 and older have one or more chronic conditions,¹⁰ putting them at greater risk than younger patients for death and postoperative complications^{11 12} that necessitate intensive care or lengthy hospitalisations.^{13 14} Therefore, a decision to proceed with surgery can initiate a care trajectory that is ultimately inconsistent with personal preferences and goals, for example confinement in a nursing home or prolonged life support in an intensive care unit. Patients whose postoperative expectations are not met may suffer as they try to make sense of their situation, feel a loss of control and assume self-blame.¹⁵ For these reasons, the decision-making process for older patients considering high-risk surgery is complicated, and because



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the consequences of these decisions also affect family members, the stakes are high.

Current communication practices inadequately support preoperative decision making about major surgery. According to the Institute of Medicine,¹⁶ most patients prefer to share in decision making; however, 'they are often not afforded the chance to participate' (ch3, p38),¹⁶ and studies suggest that surgeons rarely employ a cooperative decision-making process.^{17–19} Instead, surgeons rely on best practices, specifically informed consent, to disclose procedural risks and help patients make choices. However, existing decision-making standards do not adequately engage patients in deliberation, and the process of informed consent fails to explain how a patient might actually experience complications, or even *expected* downstream outcomes, such as the need for additional invasive treatments or predictable changes in functional status.^{20 21} To make value-laden decisions, patients and families need to know what the outcomes of surgery mean *for them* and how surgical treatment can be understood in the context of their overall prognosis, particularly for patients with other chronic illnesses.^{22 23} To be successful, this process requires partnership; surgeons need patients to share what matters to them, and patients need surgeons to help them compare treatment options and evaluate their effectiveness based on patients' values and goals.

We designed a multisite, cluster-randomised trial of an intervention to improve preoperative communication between surgeons and older adults considering major vascular or oncological operations. Our study evaluates a question prompt list (QPL) intervention for use in the surgical clinic that our research group developed with input from patients, families and surgeons who have experience with high-risk surgery. The intervention aims to encourage patients and families to ask questions that allow them to compare treatment options and get information about how surgery might impact their lives. First, we discuss the rationale and theoretical foundations of the surgical QPL intervention. We then describe the research protocol together with details of study design, data collection, outcomes and analysis plan.

Current gaps in communication about high-risk surgery

To gain a better understanding of usual practice, our research group analysed over 90 preoperative conversations between surgeons and patients considering high-risk cardiovascular, oncological and neurosurgical procedures as part of a multi-institutional study.^{18 21 24} Analysis of these conversations revealed three primary barriers to decision making. One, surgeons employ a 'fix-it' model²⁵ by describing the patient's disease as an isolated abnormality linked directly with a surgical solution. This model supports an implicit message about the 'benefits' of surgery: the reason to operate is to fix what has been identified as broken, and the language implies the patient will return to 'normal' after the problem has been fixed. However, this 'fix-it' model lacks an explicit description about what surgery might mean more broadly, for example how surgery will impact the patient's functional independence or other health problems. Lack of context regarding their overall health state makes it challenging for patients to understand the need to deliberate about the value of surgery given their chronic health conditions and quality-of-life preferences.¹⁸ Two, surgeons present their own evaluation of the trade-offs associated with the proposed intervention. Surgeons struggle to elicit patient preferences, and efforts to encourage questions are often ineffective as patients regularly respond with logistical or technical concerns, for example what time surgery will take place or whether stitches or staples will be used. The result is surgeon-generated assumptions about the value of specific outcomes and acceptability of trade-offs.¹⁸ Three, informed consent requires surgeons to convey risks that are typically described as objective estimates of isolated physiological harms, for example a 45% chance of renal failure. However, this approach does not describe outcomes in a way that allows patients and families to understand what life might be like after surgery.²¹ These three barriers highlight the need to bridge the gap between what surgeons know and what patients understand about treatment outcomes. These findings complement work by Blazeby and colleagues who have observed that surgeons emphasise in-hospital

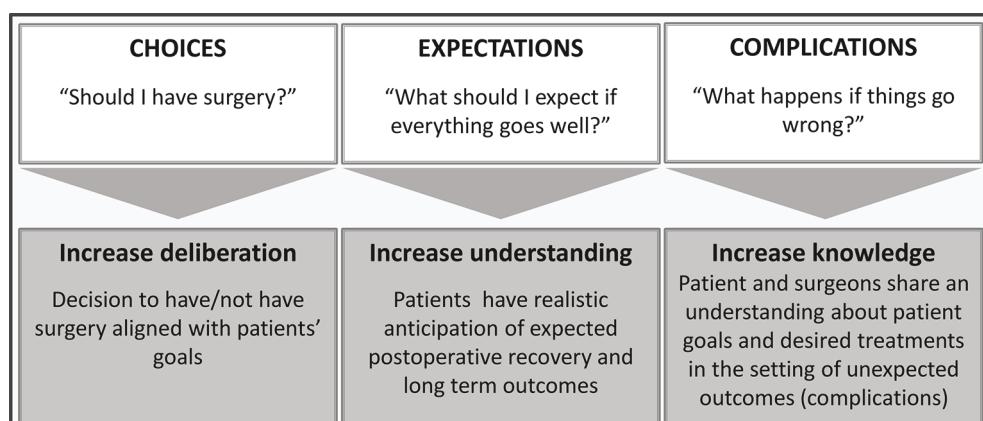


Figure 1 Patient and family stakeholder-proposed question prompt list targets and resulting goals.

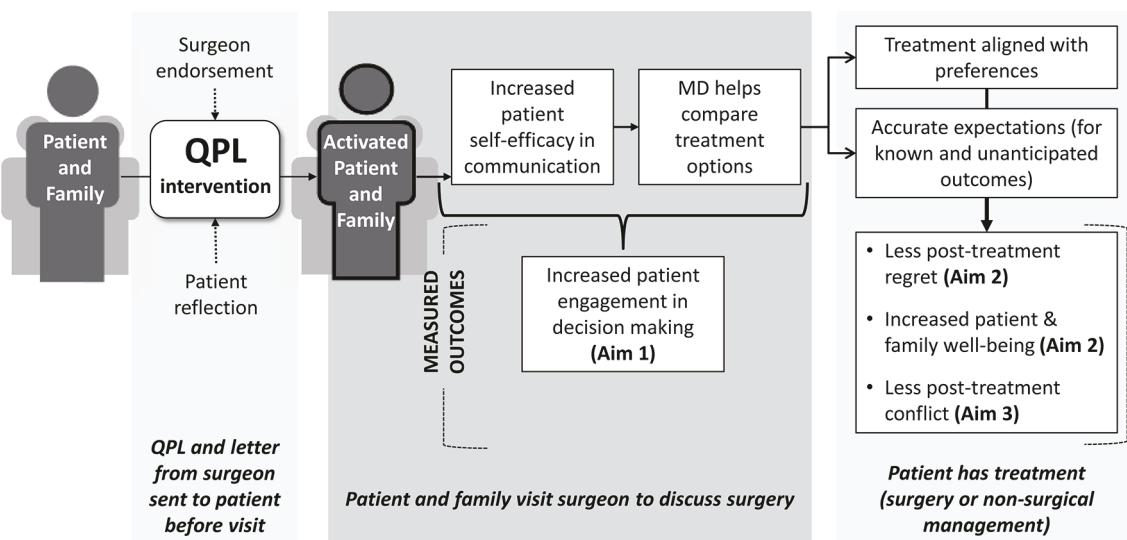


Figure 2 Theoretical framework behind the QPL intervention and the study design. MD, medical doctor; QPL, question prompt list.

risks and technical aspects of the procedure rather than long-term functional outcomes.^{26 27}

We also drew from our previous work using physician surveys²⁸⁻³¹ and qualitative interviews with surgeons³² to identify a fourth problem with preoperative communication. Our research group has previously described 'surgical buy-in', whereby surgeons operate under an assumption that the patient has agreed to both the surgical procedure as well as all postoperative care anticipated by the surgeon, including life-supporting treatments.^{28 32} While this implicit contract is understood by surgeons, it is not recognised by patients who may desire treatment limitations based on their evaluation of certain health outcomes.²⁴ This disconnect can result in postoperative conflict between surgeons, patients and families^{33 34} when patients or surrogates on behalf of patients request to forgo aggressive treatments which the surgeon believes the patient agreed to preoperatively.

Development of an intervention to improve preoperative communication

QPLs have proven efficacy for improving patient–doctor communication. QPL interventions can effectively change how patients and families communicate with physicians, improve patients' and family members' psychological outcomes, and better meet patients' informational needs.³⁵⁻³⁷ Effective QPL interventions require physicians to endorse and support the patient's use of the question list, but do not require resource-intensive adjuncts like patient navigators or patient coaching.³⁸ For patients considering surgery³⁹ and those with life-limiting illness,⁴⁰ QPLs effectively increase the number of questions about prognosis and facilitate better alignment between treatment expectations and likely outcomes. These interventions also produce behaviour change in physicians, including surgeons,³⁹ so that patients receive more information about treatment alternatives and attention to personal preferences.⁴¹

We met regularly for 10 months with a dedicated group of patients and family members to design a QPL specifically targeting the preoperative decisional needs of patients considering high-risk surgery.⁴² Our research group gathered over 300 questions from publicly available 'questions to ask your surgeon' and focused on three patient-mediated targets identified by our patient and family advisors: 'Should I have surgery?', 'What should I expect if everything goes well?', and 'What happens if things go wrong?' (figure 1). We discarded questions that were either redundant or irrelevant to these targets and used feedback from our patient, family, surgeon and hospital stakeholders to refine the list to create a surgical QPL brochure containing 11 questions. Details of the QPL development have been previously published.⁴²

Theoretical framework underlying the QPL intervention

Based on the theories of self-determination⁴³ and relational autonomy^{44 45} described by Elwyn *et al*,⁴⁶ QPLs aim to overcome structural and interactional barriers and promote patient activation, thereby increasing patient engagement in decision making. Given the transactional nature of the patient experience,⁴⁷ activated patients will receive more patient-centred care and take part in more collaborative decision making, even within the same provider. By supporting patients' need for autonomy and relatedness, interventions — such as a QPL — to help patients gain knowledge about treatment options offer a strategy to promote patients' self-perceived capacity to engage in treatment decisions.⁴⁸

Randomised comparative effectiveness study

Our intervention consists of the surgical QPL and a brief letter from the surgeon endorsing its use, mailed to the patient in advance of the clinic appointment. The intervention targets patients and family members in the preoperative period and seeks to impact (1) patient engagement in decision making for high-risk surgery,

Table 1 Stepped wedge study design: 40 surgeons at five sites

Wave	Portland	Newark	Boston	San Francisco	Madison	Total
0	0	0	0	0	0	0
1	2 (2)	1 (1)	2 (2)	1 (1)	2 (2)	8
2	3 (1)	3 (2)	3 (1)	3 (2)	4 (2)	16
3	4 (1)	4 (1)	5 (2)	5 (2)	6 (2)	24
4	5 (1)	6 (2)	6 (1)	7 (2)	8 (2)	32
5	6 (1)	7 (1)	8 (2)	9 (2)	10 (2)	40
Total number of patients per site*	72	84	96	108	120	480

*Half of all patients will have received the question prompt list intervention by the end of wave 5, for a final sample size of 240 patients in each study arm.

(2) psychological well-being and post-treatment regret for patients and family members and (3) interpersonal and intrapersonal conflict relating to treatment decisions and received treatments (figure 2). We hypothesise that through patient activation the intervention will:

- ▶ improve patient self-efficacy in communication so patients can engage with surgeons in deliberation over treatment options
- ▶ enable patients to share in decision making so that treatment decisions are aligned with their preferences
- ▶ promote accurate patient expectations for both known and unanticipated outcomes
- ▶ reduce post-treatment regret for patients and family members through increased participation in decision making
- ▶ increase patient's and family member's psychological well-being
- ▶ reduce postoperative conflict between surgeons, patients and families for patients who have an unwanted outcome.

METHODS AND ANALYSIS

Setting and design

This study is a multisite, prospective, cluster-randomised trial using a stepped wedge design⁴⁹ to compare the effectiveness of the surgical QPL intervention with usual care for older patients considering high-risk vascular and oncological procedures. We are conducting the study in the outpatient surgical clinics at five high-volume academic medical centres across the USA: University of Wisconsin Hospital and Clinics (Madison, Wisconsin), University of California San Francisco (San Francisco, California), Brigham and Women's Hospital (Boston, Massachusetts), Rutgers New Jersey Medical School/The University Hospital (Newark, New Jersey) and Oregon Health Sciences University Hospital and Clinics (Portland, Oregon). We selected these five sites to represent distinct geographical regions and demographic groups in order to capture diverse experiences with surgical decision making.

Participating surgeons from these five centres routinely perform high-risk oncological or vascular surgery. Patients and family members are invited to participate as dyads. However, patients may participate alone while family members can only enrol with a corresponding patient. We will enrol patients in each surgeon's clinic according to a stepped wedge design implemented in six 4-month waves over a 24-month period (table 1). In wave 0, all patients will receive usual care. With each subsequent wave, 8 of the 40 enrolled surgeons will cross over into the intervention group. Once a surgeon has entered the intervention arm, all patients scheduled to see that surgeon in clinic to discuss a new surgical problem will receive the QPL intervention. We will audio-record the surgeon–patient conversation in clinic, and patients and family members will complete questionnaires at three subsequent predefined time points. In addition, we will perform qualitative interviews with a subset of participants who experienced serious postoperative complications.

Participants

Attending surgeons at participating sites who routinely perform high-risk vascular (peripheral, neurological or cardiovascular) or oncological operations on older patients will be invited to participate. Eligible patients are age 65 years and older with one or more chronic health conditions who have an outpatient consultation with a study-enrolled surgeon to discuss a new surgical problem. The surgical problem must be vascular or oncological in nature and could be treated with one of the 227 ICD-9-coded procedures our research group previously defined as high risk.⁵⁰ For each enrolled patient, we will approach one family member to participate who is present during the conversation with the surgeon in clinic. Eligible participants must be English-speaking or Spanish-speaking and able to converse with the surgeon without an interpreter (aside from Spanish-speaking participants who may use an interpreter), have self-reported visual acuity and literacy skills sufficient to read a newspaper, and be able to provide written informed consent. Patients who do not have a problem that can be potentially treated with

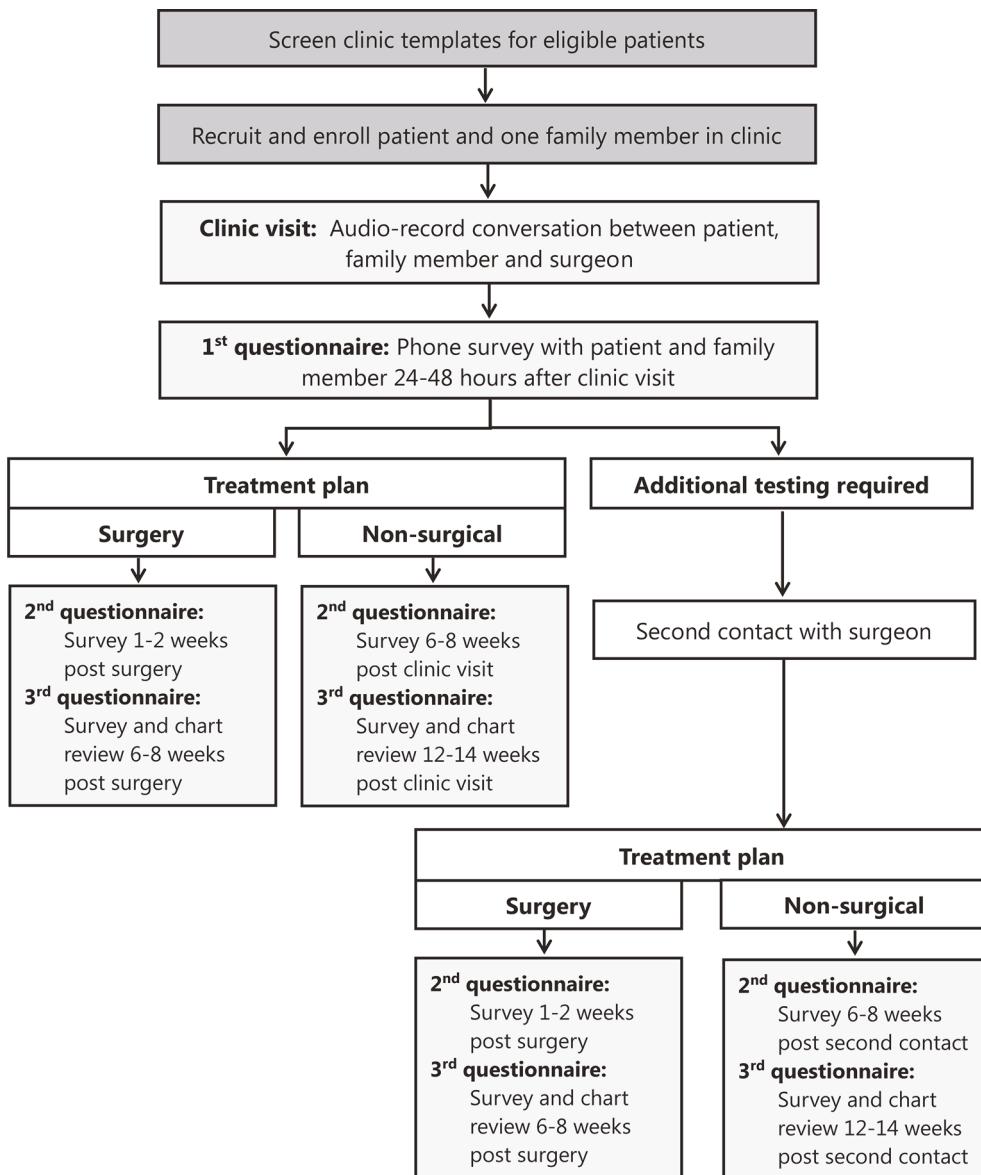


Figure 3 Screening, recruitment, enrolment and data collection points for patients in the control and intervention arms at each site.

surgery, for example an aneurysm that does not meet size guidelines for operative repair, will be excluded based on chart review or previsit determination by the surgeon.

Recruitment

At each study site, all eligible surgeons will receive an invitation via e-mail by the site principal investigator. Surgeons who do not opt out will be chosen first based on surgical subspecialty to capture variability in high-risk procedures and second by random selection of surgeons within a given subspecialty. Surgeons will not receive incentives for participation. We aim to enrol 40 surgeons in total, with the number of surgeons selected to be approximately proportional to the surgical volume at each site.

Study staff will review the clinic schedule of each enrolled surgeon and identify eligible patients based on chart review and clinic intake forms. On the day of clinic, study staff will meet with interested patients and family

members to explain the study and obtain informed consent prior to the conversation with the surgeon. Patients and family members will receive financial incentives valued at \$55 for participation. To avoid over-representation of any one surgeon, after each surgeon has two patients enrolled within the 4-month wave, recruitment will cease for that surgeon's patients until the next wave begins. We aim to enrol a total of 480 patients across all five sites, with 12 patients per surgeon.

We will use stratified purposeful sampling to identify a subset of enrolled patients (and family members, if applicable) who underwent surgery and experienced a serious postoperative complication, as determined by chart review. Serious complications include prolonged hospitalisation (more than 8 days postoperatively), prolonged length of stay in intensive care (greater than 3 days), prolonged mechanical ventilation, myocardial

Table 2 Primary and secondary outcome measures (items in bold are primary outcomes)

Construct	Specific measure	Source	Timing
Aim 1: Patient engagement			
Engagement in decision making	<ul style="list-style-type: none"> ▶ Number and type of questions using a predefined coding scheme ▶ OPTION 	Audio recording	Clinic visit
Self-efficacy in patient-physician interactions	<ul style="list-style-type: none"> ▶ PEPPI-5 (perceived efficacy) ▶ HCCQ (autonomy support) 	Patient and family member	First questionnaire
Aim 2: Psychological well-being and treatment received			
Concerns and well-being	<ul style="list-style-type: none"> ▶ MyCaW (self-identified concerns and well-being) 	Patient and family member	First to second First to third questionnaires
Post-treatment regret	<ul style="list-style-type: none"> ▶ 'Looking back, is there anything about your treatment that you would do differently?' 	Patient and family member	Third questionnaire
Psychological well-being (patient)	<ul style="list-style-type: none"> ▶ PROMISPsychosocial Illness Impact-Neg 4a ▶ Psychosocial Illness Impact-Pos 4a ▶ Anxiety 4a 	Patient	Second and third questionnaires
Psychological well-being (family)	<ul style="list-style-type: none"> ▶ PROMISSF Global Health ▶ Anxiety 4a 	Family member	Second and third questionnaires
Treatment received	<ul style="list-style-type: none"> ▶ Total number of operations scheduled after visit with surgeon ▶ Total number of operations scheduled and performed 	Chart review	Clinic visit Third questionnaire

HCCQ, Health Care Climate Questionnaire; MyCaW, Measure Yourself Concerns and Wellbeing; OPTION, Observing Patient Involvement score; PEPPI-5, Perceived Efficacy in Patient-Physician Interactions; PROMIS, Patient-Reported Outcomes Measurement Information System; SF, short form.

infarction, major cerebral vascular accident, new-onset dialysis or death.^{12 38} We will invite these patients and family members to participate in a face-to-face qualitative interview within 30 days after surgery. We will continue to interview patients until we reach saturation, meaning that data from subsequent transcripts become redundant with developed concepts. We anticipate this will occur with a sample of approximately 20 patients per study arm based on previous studies.^{18 21}

Randomisation and blinding

Surgeons will be stratified by study site and randomly assigned within each site to cross over from usual care to the QPL intervention in different study waves. On study commencement, a master's level statistician established a step-wise randomisation using a computer-generated randomisation schedule for the list of enrolled surgeons by site. The schedule determined the crossover wave for each surgeon and was designed to balance transitions to the intervention arm across sites in each wave according to the design in table 1. Surgeon crossover will occur in one direction only, and each within-site change will happen once every 4 months during the 24-month duration of the study. A 2-week hiatus in data collection at the start of the crossover will be instituted in transitioning clinics to ensure patients in the intervention group have had the opportunity to receive the QPL and endorsement letter from the surgeon. Study staff will notify enrolled

surgeons prior to the upcoming crossover as the intervention is dependent on surgeon endorsement. We expect negligible contamination between study arms as the intervention requires surgeon endorsement of the QPL. Only patients whose surgeons have crossed over into the intervention arm will receive the QPL and surgeon endorsement letter in the mail prior to consultation. Although patients in the control arm may access question lists from outside sources, our prior observational studies confirm surgeons do not routinely endorse the use of question prompts.

Whereas surgeons are not blinded to the intervention, every effort will be made to maintain blinding for patients and family members. Participants will be told the goal of the study is to evaluate communication between surgeons and patients, but they will not be informed about the distribution of the QPL. Transcriptionists and qualitative interviewers will be blinded to the intervention status of each encounter. Study staff are tasked with assuring the QPL has been sent and providing regular reminders to the surgeon to endorse the QPL with all new patients. Study staff will not know if the patient has received the QPL at the time of enrolment but will not be blinded during data collection. In an attempt to insulate study staff from group assignment during data collection, they will strictly adhere to a script and enquire about receipt of the QPL (with all patients regardless of group assignment) 1

Table 3 Mediating variables and covariates

Construct	Specific measure	Source	Timing
Variables mediating patient engagement			
Family member present	Observation: Was a family member present during clinic visit?	Audio recording	Clinic visit
MD endorsement of QPL	Observation: no endorsement, any endorsement, extensive endorsement	Audio recording	Clinic visit
QPL intervention penetrance	To patient: 'Did you receive information in the mail to prepare you for your appointment with the surgeon?' (yes/no/uncertain)	Patient	First questionnaire
Variables mediating psychological well-being			
Surgical complications	National Surgical Quality Improvement Project definition (yes/no)	Chart review	Third questionnaire
Advance directive	New advance directive completed or prior advance directive documented in patient chart (yes/no)	Chart review	Third questionnaire
DNR	New DNR order placed or existing DNR order documented in patient chart (yes/no)	Chart review	Third questionnaire
Covariates			
Comorbid illness	Charlson comorbidity score	Chart review	Clinic visit
Indication for surgery	Patient's presenting problem	Chart review	Clinic visit
MD subspecialty	Oncology or vascular subspecialty	Surgeon	Clinic visit
MD practice intensity	Average number of operations surgeon performs monthly	Operative log	3-month lead-in
Patient insurance status	Medicare, Medicare + Supplemental, Medicare+Medicaid, other	Chart review	Clinic visit
Patient demographics	Age, gender, race/ethnicity, educational attainment, health literacy	Patient	First questionnaire
MD demographics	Languages spoken, age, gender, race/ethnicity	Surgeon	Clinic visit

DNR, do not resuscitate; MD, medical doctor; QPL, question prompt list.

day after enrolment following administration of the first questionnaire. Furthermore, data collected from chart abstraction will be reviewed by a blinded clinician for 10% of the sample to ensure accuracy of data entry.

Intervention

Our intervention consists of the QPL brochure and a letter from the patient's surgeon encouraging its use. The surgical QPL contains 11 questions to help patients and families (1) make treatment decisions in line with their values and goals, (2) anticipate and make sense of post-operative outcomes and (3) experience less postoperative conflict about treatment of serious complications. Once a surgeon has crossed over into the intervention arm, all of his or her patients with a new vascular or oncological problem will receive the QPL intervention via US mail prior to the scheduled clinic appointment. To ensure that there is sufficient time for patients to receive the QPL intervention, we will only recruit patients who have been identified as eligible at least 5 days in advance of their appointment. This timeframe will remain consistent for

both control and intervention patients as those who are scheduled more urgently may be systematically different.

Data collection

Audio recording

We plan to audio-record and transcribe verbatim one conversation between the attending surgeon, patient and accompanying family member(s). In order to capture the primary decision-making conversation, this may occur during either the first or second clinic visit depending on the usual practice pattern of each surgeon. Prior to study commencement, each surgeon will select their usual approach: either (1) treatment decisions are typically made during the first clinical encounter, or (2) treatment decisions are typically made during the second clinic visit.

Patient and family member questionnaires

After the primary decision-making conversation with the surgeon, patients and family members will receive three questionnaires. Study staff will conduct follow-up phone interviews to administer the first questionnaire

within 24–48 hours of the patient's clinic visit. Patients and family members will complete these questionnaires independently. Administration of two subsequent questionnaires will be linked to the treatment plan and administered via phone or e-mail based on patient preference. For patients who receive surgery, questionnaires will be administered at 1–2 weeks and 6–8 weeks postoperatively. For those who undergo medical management or observation, questionnaires will be given at 6–8 weeks and 12–14 weeks following the clinic visit. We deliberately chose this timing to create similar administration schedules regardless of whether the patient pursues surgery (figure 3). We allow for up to six contact attempts at each time point.

Chart review

Study staff will use chart review to record clinical data, treatments received and outcomes of treatment. Data collected will be limited to clinical information pertaining to surgical care from the initial visit through to administration of the final survey. Data collected from chart review and questionnaires will be stored using the REDCap (Research Electronic Data Capture) software hosted at the University of Wisconsin.⁵¹

Qualitative interviews

For patients who suffer serious postoperative complications, a trained interviewer from each centre will perform a face-to-face interview with the patient, if able, and/or the family member. Interviews will be audio-recorded and transcribed verbatim.

Outcomes

Aim 1: patient engagement

To assess patient engagement in decision making, we will use direct observation and patient report measured using a coding scheme established by Walczak and colleagues³⁵ and the Perceived Efficacy in Patient–Physician Interactions (PEPPI-5) scale as our primary outcome measures. From transcriptions of the clinic conversations, two blinded and trained coders will independently count all questions, cues and concerns mentioned by the patient and all family members, friends or other caregivers present during the conversation. Our secondary outcomes for patient engagement include the Observing Patient Involvement score^{52 53} used for the recorded conversation, and the Health Care Climate Questionnaire (HCCQ)⁵⁴ administered to patients and family members at the time of the first questionnaire 24–48 hours after the visit with the surgeon. We adapted both the PEPPI-5 and the HCCQ for use by family members (table 2).

Aim 2: psychological well-being

We selected psychological well-being as an important outcome based on feedback from our patient and family stakeholders who reported significant emotional harm; specifically they felt 'blindsided' when surgical results did not match their expectations. The primary outcome measures to assess psychological well-being are the

Measure Yourself Concerns and Wellbeing (MYCaW) and patient-reported post-treatment regret. MYCaW is a patient-reported outcome measure originally designed for patients with cancer and their family members, which we have adopted for use with patients who have vascular disease. MYCaW allows patients and family members to identify their own most pressing health concerns and rate their well-being. We will administer the MYCaW at the three time points. Patients and family members will report their initial responses to the MYCaW at the time of the first questionnaire, 24–48 hours after the clinic visit. Participants will independently rescore their initial concerns and well-being at the two subsequent time points corresponding to the second and third questionnaires; the difference in scores describes improvement or deterioration in their well-being. To assess treatment-associated regret, we will ask patients and family members at the time of the third and final questionnaire — 'Looking back, is there anything about your treatment/your family member's treatment that you would do differently?' — and transform responses into a dichotomous variable (regret, no regret) for analysis.⁵⁵ We will also analyse these responses qualitatively.

Secondary outcome measures include validated measures from the Patient-Reported Outcomes Measurement Information System (PROMIS) to assess the psychological impact of illness from the patient's perspective.⁵⁶ Patients will receive the Psychosocial Illness Impact-Neg 4a, Psychosocial Illness Impact-Pos 4a and Anxiety 4a; family members will be asked to complete Anxiety 4a and PROMIS short form (SF) Global Health. Because studies of other interventions that support shared decision making show that in some situations informed patients elect more conservative treatment,⁵⁷ we will compare the total number of operations scheduled and performed on enrolled patients by their study surgeon between the control and intervention groups. We will also collect information about potential mediating variables and covariates described in table 3.

Aim 3: postoperative conflict

In qualitative interviews with a subset of participants who suffered a serious postoperative complication, we will use questions designed to explore the content of patient and family experience with perioperative conflict. The interview guide is structured around open-ended questions about perioperative events, including 'Tell me the story of your experience with surgery'.⁵⁸ The interviewer will follow up the respondents' narrative description with probing on the following domains: patient and family values and goals, decision making, interpersonal relationships (between surgeons and patients/family members, between treating physicians and between family members) and intrapersonal conflict (relating to post-treatment regret and self-blame). We will use feedback during concurrent coding and analysis to prompt additional questioning on emerging themes and trends.

Planned analyses

Quantitative analyses

Our primary analysis will compare the effectiveness of the QPL intervention relative to usual care in regard to patient engagement and patient psychological well-being. We will use an intention-to-treat analysis with all available data from participants based on group assignment. The intervention effect will be tested in the framework of generalised linear mixed-effects models^{59 60} with a treatment dummy variable, surgeon random effect and site-by-time dummy variables to control for site-specific secular trends. We will use linear mixed-effect models for continuous responses such as self-efficacy (PEPPI-5) and well-being (MYCaW), logistic random-effects models for binary responses such as post-treatment regret, and log-linear random-effect models for count-dependent variables such as the number and type of questions asked during the preoperative visit. For linear models, we will adjust for prespecified covariates to increase the statistical precision of our treatment effect estimation.

Our secondary analyses will examine other patient endpoints such as psychological well-being (PROMIS measures) and nature of treatment received. These analyses will also test for intervention effects in family member outcomes such as PEPPI-5, HCCQ, MYCaW, post-treatment regret and psychological well-being. We will use the generalised linear mixed modelling framework used in primary analyses for these outcomes. All models will be estimated and tested using PROC MIXED or PROC NLMIX in SAS V.9.3.

We will perform additional analyses to test and quantify whether and to what extent the effect of the QPL intervention on patient engagement outcome measures is mediated by the presence of a family member during the visit with the surgeon. Exploratory analysis of family-reported outcomes will occur independently of patient-reported outcomes. To accomplish this, we will compare the indirect effect with the total effect in joint linear structural equation models for the endpoint and the mediator, including correlated random surgeon effects for each of the mediator and endpoint parts of the models. In addition, we anticipate treatment effect could vary across subpopulations defined by the following covariates: indication for surgery, patient comorbid illness and insurance status. Therefore, we will test the effect of treatment separately in subpopulations defined by these variables.

To decrease missing data, we limited the number of questions in the follow-up questionnaires and will provide a bonus incentive for participants who complete all three questionnaires. At the time of analysis, we will develop a comprehensive description of the missingness patterns and develop a plan for imputation that leverages the available data and concentrates on the data most heavily subject to missingness. If data are missing on predictor variables of interest, values will be imputed using multiple imputation techniques (ie, chained equations imputations).^{61 62} If dropout is substantial, we will again use

multiple imputation, including exploiting responses from the first two time points (day of clinic visit and 24–48 hours postvisit), to impute responses from the final two questionnaires, to maximise statistical efficiency and to minimise bias.

Sample size and power calculation

Each arm will contain 240 patients, for a total of 480 patient participants. Based on our prior work, we expect about 70%–80% of patients will have a family member present who will participate. Therefore, we estimate 384 family members from all sites will partake, although we will enrol up to 480 family members if all patients have a family member interested in participating. Assuming all enrolled patients enrol with a family member, the maximum number of all possible participants (surgeons, patients and family members) is 1000.

For each quantitative aim, we desire a family-wise two-sided type I error rate of $\alpha=0.05$; under a Bonferroni correction, tests will be conducted with nominal $\alpha=0.05/2=0.025$ because there are two primary endpoints for aim 1 and aim 2 (table 2). Using patient satisfaction data at one site, we found that between-surgeon variance accounts for only 5% of the total variance. Because power in the stepped wedge design is slightly degraded with greater variance between (vs within) surgeons, we assumed a worst-case scenario between-surgeon variance of 30%. We interpreted this as the interclass correlation between multiple patients of the same surgeon at a given site and included a surgeon-level random effect in our calculation, anticipating between 5% and 30% of the total variance to be accounted for by surgeon effects (ie, interclass correlation (ICC) =0.05–0.30). Extending the information-based method of computing power for a basic stepped wedge design⁴⁹ to the case of our multisite stepped wedge design, we custom-programmed power calculations using R V.3.2.1 (R Foundation for Statistical Computing).

With this method, we computed power of 82% to detect small-to-medium and 93% to detect medium effect sizes of Cohen's $d=0.425$ and $d=0.5$, respectively. Assuming the SD for PEPPI-5 within each treatment arm is 4.3,⁶⁴ we will have 93% power to detect effects as small as 2.15 points. For the number of patient questions, we assumed a mean difference of 1.4 questions between arms.⁴⁰ Assuming overdispersion of two relative to Poisson data, within arm SD=2.7, yielding $d=1.4/2.7=0.52$, which we are well powered to detect. For the MYCaW well-being scale, Jolliffe *et al*⁶⁵ found SD=1.26 at 6 weeks, and a 6-week versus baseline mean difference of 0.59. We will also have 93% power to detect an MYCaW difference as small as $0.5\times1.26=0.63$, comparable with the difference over time in Jolliffe *et al*.⁶⁵ For regret, we assume the upper bound risk of the presence of regret is 0.3,⁵⁵ yielding SD=0.46; we will have over 90% power to detect a regret risk difference of 0.23. Nearly identical power results were obtained via a continuous latent liability model for a binary event (regret).⁶⁶ To account for clustering within sites, this

calculation includes fixed effects terms for site, time (wave) and site-by-time, reflecting our a priori analysis plan.

Qualitative analysis

We will use directed content analysis⁶⁷ to compare interpersonal and intrapersonal conflict between study arms as it relates to the phenomenon of surgical buy-in.^{28 32 68} To gain understanding of the trajectory of each patient's story, we will triangulate data sources by linking the audio tape of the surgeon–patient decision-making conversation and the patient's clinical history from chart review with the follow-up interview. We have previously shown that surgeons see preoperative conversations as a significant event, a time when a two-way agreement is made whereby the surgeon commits to operating and the patient commits to endure potentially burdensome postoperative care.²⁸ We will use this understanding of surgical buy-in to code and analyse preoperative clinic visits and postoperative interview transcripts with the goal of understanding how the contractual relationship that surgeons perceive is experienced by patients. We will explore how postoperative complications were discussed during the initial patient–surgeon interaction with and without the QPL and whether this interaction has impact on subsequent treatment decisions, interpersonal and intrapersonal conflict.

ETHICS AND DISSEMINATION

Ethical review

All participants will provide written informed consent and may withdraw from the study at any time without affecting the medical care they receive from the clinical team. For surgeons, study participation will not affect their professional standing. Institutional review board approval has been granted at each of the five sites, and a Certificate of Confidentiality has been granted in order to offer enrolled surgeons protection from legal demands, such as subpoenas and court orders for study data. Identifying information on recorded transcripts will be redacted prior to analysis, and all audio recordings and hard copies of data will be destroyed after analysis is complete and manuscripts are submitted. The aims of the study meet the criteria for minimal risk. We will follow accepted adverse event monitoring procedures including regular review by the Data Monitoring Committee.

Relevance and dissemination

The design of the QPL intervention addresses important gaps in preoperative communication between surgeons and older adults facing a decision about high-risk surgery. The results of this study will inform our understanding of how interventions to confront interactional barriers between doctors and patients affect patients' capacity to participate and share in decision making. The engagement of a variety of stakeholders and incorporation of deeply held concerns of patients and families into the development of the QPL are strengths that create potential

for significant impact. Furthermore, should we find the intervention superior to usual care, it is inexpensive and easily scalable to facilitate widespread dissemination in all outpatient clinics where high-risk surgery is considered. We anticipate these results will be generalisable to other surgical settings as well as encounters for patients who have been referred specifically for discussion of other types of treatment, for example in medical or radiation oncology clinics.

Efficacy, however, is contingent upon a letter of endorsement from the surgeon that accompanies the QPL brochure. Furthermore, durable changes in surgeon behaviour as a result of questions and attitudes the QPL engenders in their patients may contribute to the effectiveness of the intervention over time. As such, our dissemination strategies will be targeted primarily at surgeons. We have support of leadership at the American College of Surgeons (ACS) and anticipate dissemination through various ACS portals, including the National Surgical Quality Improvement Program and the Coalition for Quality in Geriatric Surgery, as well as distribution of the intervention and description of the implementation processes on the ACS website. In addition, based on feedback from our patient and family advisors who felt dissemination of results to patients and families is critically important, we will provide study updates and distribute study results via a study website. We plan to present study results at the annual ACS Clinical Congress and local chapter meetings. We plan to publish the main trial outcomes in a peer-reviewed journal. We will follow the CONSORT reporting standards for pragmatic⁶⁹ and cluster-randomised⁷⁰ trials. Study results will be released to participating surgeons, patients, families and the general medical community.

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Contributors MLS is the principal investigator for this study. She developed the original study design and protocol together with PJR, who provided study design and biostatistical support, and the site principal investigators ZC, AnaB, ACM, EF and KJB. NJ provided guidance in study design specific to the qualitative

components. QZ provided biostatistics support. AnneB is the study coordinator and has the primary responsibility of coordinating development of all study materials. LJT drafted this manuscript and along with JLT helped with development of study materials. JLT and NMS synthesised input from patient and family stakeholders and contributed to study design. All authors reviewed and approved this manuscript.

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