BMJ Open

Navigating High Risk Surgery: A Multi-Site Cluster-Randomized Trial of a Question Prompt List Intervention to Empower Older Adults to Ask Questions that Inform Treatment Decisions

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-014002
Article Type:	Protocol
Date Submitted by the Author:	23-Aug-2016
Complete List of Authors:	Taylor, Lauren; University of Wisconsin Madison, Surgery Rathouz, Paul; University of Wisconsin Madison, Biostatistics Berlin, Ana; Rutgers New Jersey Medical School, Surgery Brasel, Karen; Oregon Health and Science University, Surgery Mosenthal, Anne; Rutgers New Jersey Medical School, Surgery Finlayson , Emily; University of California San Francisco, Surgery Cooper, Zara; Brigham and Women's Hospital Steffens, Nicole; Denver Health and Hospital Authority, Denver Public Health Jacobson , Nora; University of Wisconsin Madison Institute for Clinical and Translational Research Buffington, Anne; University of Wisconsin Madison, Surgery Tucholka, Jennifer; University of Wisconsin Madison, Surgery Zhao , Qianqian; University of Wisconsin Madison, Biostatistics Schwarze, Margaret; University of Wisconsin Madison, Surgery; University of Wisconsin Madison, Medical History and Bioethics
Primary Subject Heading:	Surgery
Secondary Subject Heading:	Patient-centred medicine, Research methods
Keywords:	Adult surgery < SURGERY, GERIATRIC MEDICINE, Adult oncology < ONCOLOGY

Navigating High Risk Surgery: A Multi-Site Cluster-Randomized Trial of a Question Prompt List Intervention to Empower Older Adults to Ask Questions that Inform Treatment Decisions

Authors:

1. Lauren J Taylor, MD; Department of Surgery, University of Wisconsin. Madison, Wisconsin, USA. Ltaylor2@uwhealth.org
2. Paul J Rathouz, PhD; Department of Biostatistics & Medical Informatics, University of Wisconsin. Madison, Wisconsin, USA. Rathouz@biostat.wisc.edu
3. Ana Berlin, MD, MPH; Department of Surgery, Rutgers New Jersey Medical School. Newark, New Jersey, USA. ana.berlin@njms.rutgers.edu
4. Karen J Brasel, MD, MPH; Department of Surgery, Oregon Health and Science University. Portland, Oregon, USA. Brasel@ohsu.edu
5. Anne C Mosenthal, MD; Department of Surgery, Rutgers New Jersey Medical School. Newark, New Jersey, USA. mosentac@njms.rutgers.edu
6. Emily Finlayson, MD, MS; Department of Surgery, University of California, San Francisco, California, USA. Emily.finlayson@ucsf.edu
7. Zara Cooper, MD, MSc; Department of Surgery, Brigham and Women's Hospital. Boston, Massachusetts, USA. Zcooper@partners.org
8. Nicole M Steffens, MPH; Denver Public Health, Denver Health and Hospital Authority. Denver, Colorado, USA. Nicole.steffens@gmail.com
9. Nora Jacobson, PhD; University of Wisconsin Institute for Clinical and Translational Research. Madison, Wisconsin, USA. najacobson@wisc.edu
10. Anne Buffington, MPH; Department of Surgery, University of Wisconsin. Madison, Wisconsin, USA. buffington@surgery.wisc.edu
11. Jennifer L Tucholka, BS; Department of Surgery, University of Wisconsin. Madison, Wisconsin, USA. tucholka@surgery.wisc.edu
12. Qianqian Zhao, MS; Department of Biostatistics & Medical Informatics, University of Wisconsin. Madison, Wisconsin, USA. qizhao@biostat.wisc.edu
13. Margaret L Schwarze, MD, MPP; Department of Surgery, Department of Medical History and Bioethics, University of Wisconsin. Madison, Wisconsin, USA. schwarze@surgery.wisc.edu

Corresponding Author:
Margaret L. Schwarze, MD, MPP
G5/315 CSC
600 Highland Ave
Madison, WI 53792
Phone: 608-265-4420
Fax: 608-265-1148
Email: schwarze@surgery.wisc.edu

Word count: 4,898
Tables: 3
Figures: 3
References: 64

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 multi-site cluster-randomized trial of a patient-driven question prompt list intervention aimed to improve preoperative decision making and inform postoperative expectations.

Methods and analysis

This Patient-Centered Outcomes Research Institute (PCORI) funded trial will be conducted at five academic medical centers in the United States. Study participants include surgeons who routinely perform vascular or oncologic surgery, their patients and families. Patients age 65 or older who see a study-enrolled surgeon to discuss a vascular or oncologic problem that could be treated with high-risk surgery will be enrolled at their clinic visit. Together with stakeholders, we designed a question prompt list 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 question prompt list 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: patient engagement in decision-making, psychological wellbeing and post-treatment regret for patients and families, and inter 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: ClinicalTrials.gov NCT02623335; registration first received November 24, 2015

Keywords: communication, question prompt list, geriatric surgery, shared decision making

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 United States 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 hospitalizations,[6, 7] and potential suffering at the end of life.[8, 9] Furthermore, fifty percent of Medicare beneficiaries 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 hospitalizations.[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 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"[16] ch.3 p.38 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 multi-site cluster-randomized trial of an intervention to improve preoperative communication between surgeons and older adults considering major vascular or oncologic 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 analyzed over 90 preoperative conversations between surgeons and patients considering high risk

cardiovascular, oncologic, 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” model[25] 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 the 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 physiologic 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.

We also drew from our previous work using physician surveys[26-29] and qualitative interviews with surgeons[30] 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.[26, 30] While this implicit contract is understood by surgeons, it is not recognized 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[31, 32] 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

Question prompt lists 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.[33-35] 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.[36] For patients considering surgery[37] and those with life-limiting illness,[38] QPLs effectively increase the number of questions about prognosis and facilitate better alignment between treatment expectations and likely outcomes. These interventions also produce behavior change in physicians, including surgeons,[37] so that patients receive more information about treatment alternatives and attention to personal preferences. [39]

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.[40] Our research group gathered over 300 questions from publically 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.[40]

Theoretical framework underlying the QPL intervention

Based on the theories of self-determination[41] and relational autonomy[42, 43] described by Elwyn,[44] 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,[45] activated patients will receive more patient-centered care and take part in more collaborative decision making, even within the same provider. By supporting patients' need for autonomy and relatedness, interventions to help patients gain knowledge about treatment options – such as a QPL – offer a strategy to promote patients' self-perceived capacity to engage in treatment decisions.[46]

Randomized 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 in decision making for high risk surgery, (2) psychological wellbeing 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 hypothesize 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 and family member psychological wellbeing
- 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 multi-site prospective cluster-randomized trial using a stepped-wedge design[47] to compare the effectiveness of the surgical QPL intervention to usual care for older patients

considering high risk vascular and oncologic procedures. We are conducting the study in the outpatient surgical clinics at five high-volume academic medical centers across the United States: University of Wisconsin Hospital and Clinics (Madison, WI); University of California San Francisco (San Francisco, CA); Brigham and Women's Hospital (Boston, MA); Rutgers New Jersey Medical School/The University Hospital (Newark, NJ); and Oregon Health Sciences University Hospital and Clinics (Portland, OR). We selected these five sites to represent distinct geographic regions and demographic groups in order to capture diverse experiences with surgical decision making.

Participating surgeons from these five centers routinely perform high-risk oncologic or vascular surgery. Patients and family members are invited to participate as dyads. However, patients may participate alone while family members can only enroll with a corresponding patient. We will enroll 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 zero, all patients will receive usual care. With each subsequent wave, eight of the forty 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 pre-defined time points. In addition, we will perform qualitative interviews with a subset of participants who experienced serious postoperative complications.

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

Number of surgeons in the intervention group at each site (# of surgeons added per wave)						
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 # of patients per site*	**72**	**84**	**96**	**108**	**120**	**480**

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

Participants

Attending surgeons at participating sites who routinely perform high risk vascular (peripheral, neurologic, or cardiovascular) or oncologic operations on older patients will be invited to participate. Eligible patients are age 65 and older with one or more chronic health condition who have an outpatient consultation with a study-enrolled surgeon to discuss a new surgical problem. The surgical problem must be vascular or oncologic in nature and could be treated with one of the 227 ICD-9 coded procedures our research group previously defined as high risk.[48] 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 or Spanish-speaking, have self-reported 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 surgery, for example an aneurysm that does not meet size guidelines

for operative repair, will be excluded based on chart review or pre-visit determination by the surgeon.

Recruitment

At each study site, all eligible surgeons will receive an invitation via email by the site principal investigator. Surgeons who do not opt out will be chosen based first 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 enroll 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 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 enroll 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 hospitalization, prolonged length of stay in intensive care, prolonged mechanical ventilation,

myocardial infarction, major cerebral vascular accident, new onset dialysis or death.[12, 36] 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 becomes 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]

Randomization 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. Upon study commencement, we established a step-wise randomization using a computer-generated randomization schedule to determine crossover for each surgeon within each site. Surgeon cross-over will occur in one direction only and each within-site change will happen once every four 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.

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. Study staff will not be blinded during data collection. In an attempt

to insulate study staff from group assignment during data collection, they will adhere to a study script and will not specifically question participants about the receipt of the QPL intervention.

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 postoperative outcomes; and 3) experience less postoperative conflict about treatment of serious complications. Once a surgeon has crossed over into the intervention arm, his or her patients with a new vascular or oncologic 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 systemically 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 A) treatment decisions are typically made during the first clinical encounter, or B) 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. Administration of two subsequent questionnaires will be linked to the treatment plan and administered via phone or email 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)

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.

Qualitative interviews

For patients who suffer serious postoperative complications, a trained interviewer from each center 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

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 colleagues[33] 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 (OPTION)[49, 50] used for the recorded conversation, and the Health Care Climate Questionnaire (HCCQ)[51] 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)

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

Construct	Specific Measure	Source	Timing
Patient engagement			
Engagement in decision making	○ **Number and type of questions using a pre-defined coding scheme** ○ OPTION	Audio recording	Clinic visit
Self-efficacy in patient physician interactions	○ **PEPPI-5** (perceived efficacy) ○ HCCQ (autonomy support)	Patient and family member	1st questionnaire
Psychological wellbeing and treatment received			
Concerns and wellbeing	○ **MyCaW** (self-identified concerns and wellbeing)	Patient and family member	1st – 2nd 1st – 3rd questionnaires
Post-treatment regret	○ **"Looking back, is there anything about your treatment that you would do differently?"**	Patient and family member	3rd questionnaire
Psychological wellbeing (patient)	○ PROMIS ○ Psychosocial Illness Impact-Neg 4a ○ Psychosocial Illness Impact-Pos 4a ○ Anxiety 4a	Patient	2nd and 3rd questionnaires

Psychological wellbeing (family)	○ PROMIS ○ SF Global Health ○ Anxiety 4a	Family member	2nd and 3rd questionnaires
Treatment received	○ Total number of operations scheduled after visit with surgeon ○ Total number of operations scheduled and performed	Chart review	Clinic visit 3rd questionnaire

Psychological wellbeing

We selected psychological wellbeing 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 wellbeing 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 wellbeing. 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 re-score their initial concerns and wellbeing at the two subsequent time points corresponding to the second and third questionnaires; the difference in scores describes improvement or deterioration in their wellbeing. 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.[52] We will also analyze 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.[53] 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 SF Global Health. Because studies of other interventions that support shared decision making show that in some situations informed patients elect more conservative treatment,[54] 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.

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 any information in the mail to prepare you to ask questions during your appointment with the surgeon?" (yes/no/uncertain)	Patient	1st questionnaire
Variables mediating psychological wellbeing			
Surgical complications	National Surgical Quality Improvement Project (NSQIP) definition (yes/no)	Chart review	3rd questionnaire
Advance directive	New advance directive completed	Chart review	3rd

	or prior advance directive documented in patient chart (yes/no)		questionnaire
DNR	New DNR order placed or existing DNR order documented in patient chart (yes/no)	Chart review	3rd questionnaire
Covariates			
Comorbid illness	Charlson comorbidity score	Chart review	Clinic visit
Indication for surgery	Patient's presenting problem	Chart review	Clinic visit
MD sub-specialty	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	1st questionnaire
MD demographics	Languages spoken, age, gender, race/ethnicity	Surgeon	Clinic visit

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."[55] 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 wellbeing. 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 generalized linear mixed-effects models[56, 57] with a treatment dummy variable, surgeon random effect and site-by-time dummy variables to control for site-specific secular trends. We will adjust for covariates to increase the statistical precision of our treatment effect estimation. We will use linear mixed-effect models for continuous responses such as self-efficacy (PEPPI-5), and wellbeing (MYCaW), logistic random-effects models for binary responses and log-linear random-effect models for count-dependent variables.

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 wellbeing. We will use the generalized linear mixed modeling framework used in primary analyses for these outcomes.

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. Through secondary analysis we will also test the impact of the QPL intervention on psychological wellbeing endpoints by way of surgical complications. To accomplish this, we will compare the indirect effect to 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 cofactors: indication for surgery, patient comorbid illness, and insurance status. Therefore, we will test the effect of treatment separately in each subpopulation.

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. If data are missing on predictor variables of interest, values will be imputed using multiple imputation techniques (i.e. chained equations imputations).[58, 59] If drop-out 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 post-visit) to impute responses from the final two questionnaires, to maximize statistical efficiency and minimize bias.

Sample Size 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 though we will enroll up to 480 family members if all patients have a family member interested in participating. The total number of all possible participants (surgeons, patients and family members) is 1000.

For each 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 each aim. 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 (versus within) surgeons, we assumed a worst-case scenario between-surgeon variance of 30%. Extending the information-based method of computing power for a basic stepped-wedge design [47] to the case of our multi-site stepped-wedge design, we computed power of 82% to detect small-to-medium and 93% to detect medium effect sizes of Cohen's D[60]=0.425 and D=0.5, respectively. Assuming PEPPI-5 within treatment arm SD=4.3,[61] 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.[38] Assuming over-dispersion of 2 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 wellbeing scale, Jolliffe et al[62] 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 a MYCaW difference as small as 0.5*1.26=0.63, comparable to the difference over time in Jolliffe et al.[62] For regret, we assume the upper bound risk of the presence of regret is 0.3,[52] 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).

Qualitative analysis

We will use directed content analysis[63] to compare interpersonal and intrapersonal conflict between study arms as it relates to the phenomenon of surgical buy-in.[26, 30, 64] 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.[26] We will use this understanding of surgical buy-in to code and analyze 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 (IRB) 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 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 the patient's 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 generalizable 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 behavior 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 (NSQIP) 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.

ACKNOWLEDGEMENTS: The authors would like to thank Betty Kaiser, PhD, RN and Gay Thomas, MA of the Wisconsin Network for Research Support for guidance in creating and planning the Patient and Family Advisory Council. They would also like to acknowledge the patients and family stakeholders who provided invaluable feedback throughout the development of the QPL intervention and development of study materials.

CONTRIBUTORS: MLS is the principal investigator for this study. She developed the original study design and protocol together with PR, who provided study design and biostatistical support, and the site principal investigators ZC, AB (Newark), AM, EF, and KB. NJ provided guidance in study design specific to the qualitative components. QZ provided biostatistics support. AB (Madison) is the study coordinator and has the primary responsibility of coordinating development of all study materials. LT drafted this manuscript and along with JT helped with development of study materials. JT and NS synthesized input from patient and family stakeholders and contributed to study design. All authors reviewed and approved this manuscript.

FUNDING: Research reported in this work was funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (CDR-1502-27462). Dr. Schwarze was also supported by 1) Training Award KL2TR000428 from the Clinical and Translational Science Award program, in part by grant UL1TR000427 to UW ICTR from NIH/NCATS; 2) through the University of Wisconsin-Madison School of Medicine and Public Health's Wisconsin Partnership Program, WPP-ICTR grant #3086; and 3) the Greenwall Foundation Kornfeld grant. Dr. Taylor is supported by a Training Award T32CA090217 from the NIH. Dr. Berlin is supported by the New Jersey Medical School Hispanic Center of Excellence, Health Resources and Services Administration through Grant D34HP26020. This content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH or the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee.

COMPETING INTERESTS: None.

ETHICS APPROVAL: The trial protocol and all study forms and material have been approved by the University of Wisconsin Institutional Review Board as well as the Institutional Review Boards at each participating site.

FIGURE LEGENDS:

Figure 1: Patient and family stakeholder-proposed QPL targets and resulting goals

Figure 2: Theoretical framework behind the QPL intervention and the study design

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

REFERENCES:

1. Goodney PP, Stukel TA, Lucas FL, et al. Hospital volume, length of stay, and readmission rates in high-risk surgery. *Ann Surg* 2003;238(2):161-7. doi:10.1097/01.SLA.0000081094.66659.c3
2. Finks JF, Osborne NH, Birkmeyer JD. Trends in hospital volume and operative mortality for high-risk surgery. *N Engl J Med* 2011;364(22):2128-37. doi:10.1056/NEJMsa1010705
3. Fuchs VR. Health care for the elderly: how much? Who will pay for it? *Health Aff (Millwood)* 1999;18(1):11-21. doi:10.1377/hlthaff.18.1.11
4. Kaufman SR. Making longevity in an aging society: linking Medicare policy and the new ethical field. *Perspect Biol Med* 2010;53(3):407-24. doi:10.1353/pbm.0.0164
5. Finlayson E, Zhao S, Boscardin WJ, et al. Functional status after colon cancer surgery in elderly nursing home residents. *J Am Geriatr Soc* 2012;60(5):967-73. doi:10.1111/j.1532-5415.2012.03915.x
6. Fry DE, Pine M, Pine G. Medicare post-discharge deaths and readmissions following elective surgery. *Am J Surg* 2013;207(3):326-30. doi:10.1016/j.amjsurg.2013.09.007
7. Rosen AK, Chen Q, Shin MH, et al. Medical and Surgical Readmissions in the Veterans Health Administration: What Proportion are Related to the Index Hospitalization? *Med Care* 2013;52(3):243-9. doi:10.1097/MLR.0000000000000081
8. Scarborough JE, Pappas TN, Bennett KM, et al. Failure-to-pursue rescue: explaining excess mortality in elderly emergency general surgical patients with preexisting "do-not-resuscitate" orders. *Ann Surg* 2012;256(3):453-61. doi:10.1097/SLA.0b013e31826578fb
9. Paul Olson TJ, Pinkerton C, Brasel KJ, et al. Palliative Surgery for Malignant Bowel Obstruction From Carcinomatosis: A Systematic Review. *JAMA Surg* 2014;149(4):383-92. doi:10.1001/jamasurg.2013.4059
10. Schneider KM, O'Donnell BE, Dean D. Prevalence of multiple chronic conditions in the United States' Medicare population. *Health Qual Life Outcomes* 2009;7:82. doi:10.1186/1477-7525-7-82
11. Finlayson EV, Birkmeyer JD. Operative mortality with elective surgery in older adults. *Eff Clin Pract* 2001;4(4):172-7.
12. Khuri SF, Henderson WG, DePalma RG, et al. Determinants of long-term survival after major surgery and the adverse effect of postoperative complications. *Ann Surg* 2005;242(3):326-41. doi:10.1097/01.sla.0000179621.33268.83
13. Kwok AC, Semel ME, Lipsitz SR, et al. The intensity and variation of surgical care at the end of life: a retrospective cohort study. *Lancet* 2011;378(9800):1408-13. doi:10.1016/S0140-6736(11)61268-3
14. Finlayson E, Fan Z, Birkmeyer JD. Outcomes in octogenarians undergoing high-risk cancer operation: a national study. *J Am Coll Surg* 2007;205(6):729-34. doi:10.1016/j.jamcollsurg.2007.06.307

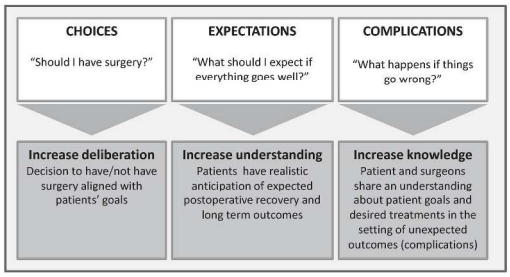
15. Doherty C, Saunders MN. Elective surgical patients' narratives of hospitalization: The co-construction of safety. *Soc Sci Med* 2013;98:29-36. doi:10.1016/j.socscimed.2013.08.014
16. Institute of Medicine. *Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life*. Washington, DC: The National Academies Press, 2014.
17. Braddock C, 3rd, Hudak PL, Feldman JJ, et al. "Surgery is certainly one good option": quality and time-efficiency of informed decision-making in surgery. *J Bone Joint Surg Am* 2008;90(9):1830-8. doi:10.2106/jbjs.g.00840
18. Kruser JM, Pecanac KE, Brasel KJ, et al. "And I Think That We Can Fix It": Mental Models Used in High-risk Surgical Decision Making. *Ann Surg* 2015;261(4):678-84. doi:10.1097/sla.0000000000000714
19. Fagerlin A, Sepucha KR, Couper MP, et al. Patients' knowledge about 9 common health conditions: the DECISIONS survey. *Med Decis Making* 2010;30(5 Suppl):35s-52s. doi:10.1177/0272989x10378700
20. King JS, Moulton BW. Rethinking informed consent: the case for shared medical decision-making. *Am J Law Med* 2006;32(4):429-501.
21. Pecanac KE, Kehler JM, Brasel KJ, et al. It's Big Surgery: Preoperative Expressions of Risk, Responsibility, and Commitment to Treatment After High-Risk Operations. *Ann Surg* 2014;259(3):458-63. doi:10.1097/SLA.0000000000000314
22. Russ AJ, Kaufman SR. Family perceptions of prognosis, silence, and the "suddenness" of death. *Cult Med Psychiatry* 2005;29(1):103-23. doi:10.1007/s11013-005-4625-6
23. Kaufman SR. *And a time to die: how American hospitals shape the end of life*. New York, NY: A Lisa Drew Book/Scribner, 2005.
24. Nabozny MJ, Kruser JM, Steffens NM, et al. Patient Reported Limitations to Surgical Buy-in: A Qualitative Study of Patients Facing High-Risk Surgery. *Ann Surg* 2016; [Epub ahead of print]. doi:10.1097/SLA.0000000000001645
25. Lynn J, DeGrazia D. An outcomes model of medical decision making. *Theor Med* 1991;12(4):325-43. doi:10.1007/BF00489892
26. Schwarze ML, Redmann AJ, Alexander GC, et al. Surgeons expect patients to buy-in to postoperative life support preoperatively: results of a national survey. *Crit Care Med* 2013;41(1):1-8. doi:10.1097/CCM.0b013e31826a4650
27. Paul Olson TJ, Brasel KJ, Redmann AJ, et al. Surgeon-reported conflict with intensivists about postoperative goals of care. *JAMA Surg* 2013;148(1):29-35. doi:10.1001/jamasurgery.2013.403
28. Redmann AJ, Brasel KJ, Alexander CG, et al. Use of advance directives for high-risk operations: a national survey of surgeons. *Ann Surg* 2012;255(3):418-23. doi:10.1097/SLA.0b013e31823b6782
29. Schwarze ML, Redmann AJ, Brasel KJ, et al. The role of surgeon error in withdrawal of postoperative life support. *Ann Surg* 2012;256(1):10-5. doi:10.1097/SLA.0b013e3182580de5
30. Schwarze ML, Bradley CT, Brasel KJ. Surgical "buy-in": the contractual relationship between surgeons and patients that influences decisions regarding life-supporting therapy. *Crit Care Med* 2010;38(3):843-8. doi:10.1097/CCM.0b013e3181cc466b

31. Danjoux Meth N, Lawless B, Hawryluck L. Conflicts in the ICU: perspectives of administrators and clinicians. *Intensive Care Med* 2009;35(12):2068-77. doi:10.1007/s00134-009-1639-5
32. Cassell J, Buchman TG, Streat S, et al. Surgeons, intensivists, and the covenant of care: administrative models and values affecting care at the end of life--Updated. *Crit Care Med* 2003;31(5):1551-7. doi:10.1097/00003246-200305000-00039
33. Walczak A, Butow PN, Clayton JM, et al. Discussing prognosis and end-of-life care in the final year of life: a randomised controlled trial of a nurse-led communication support programme for patients and caregivers. *BMJ Open* 2014;4(6):e005745. doi:10.1136/bmjopen-2014-005745
34. Kinnersley P, Edwards A, Hood K, et al. Interventions before consultations for helping patients address their information needs. *Cochrane Database Syst Rev* 2007(3):Cd004565. doi:10.1002/14651858.CD004565.pub2
35. Brandes K, Linn AJ, Butow PN, et al. The characteristics and effectiveness of Question Prompt List interventions in oncology: a systematic review of the literature. *Psychooncology* 2014;24(3):245-52. doi:10.1002/pon.3637
36. Brown R, Butow PN, Boyer MJ, et al. Promoting patient participation in the cancer consultation: evaluation of a prompt sheet and coaching in question-asking. *Br J Cancer* 1999;80(1-2):242-8. doi:10.1038/sj.bjc.6690346
37. Smets EM, van Heijl M, van Wijngaarden AK, et al. Addressing patients' information needs: a first evaluation of a question prompt sheet in the pretreatment consultation for patients with esophageal cancer. *Dis Esophagus* 2012;25(6):512-9. doi:10.1111/j.1442-2050.2011.01274.x
38. Clayton JM, Butow PN, Tattersall MH, et al. Randomized controlled trial of a prompt list to help advanced cancer patients and their caregivers to ask questions about prognosis and end-of-life care. *J Clin Oncol* 2007;25(6):715-23. doi:10.1200/jco.2006.06.7827
39. Shepherd HL, Barratt A, Trevena LJ, et al. Three questions that patients can ask to improve the quality of information physicians give about treatment options: a cross-over trial. *Patient Educ Couns* 2011;84(3):379-85. doi:10.1016/j.pec.2011.07.022
40. Steffens NM, Tucholka JL, Nabozny MJ, et al. Engaging Patients, Health Care Professionals, and Community Members to Improve Preoperative Decision Making for Older Adults Facing High-Risk Surgery. *JAMA Surg* 2016; [Epub ahead of print]. doi:10.1001/jamasurg.2016.1308
41. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *Am Psychol* 2000;55(1):68-78. doi:10.1037/0003-066X.55.1.68
42. Entwistle VA, Carter SM, Cribb A, et al. Supporting patient autonomy: the importance of clinician-patient relationships. *J Gen Intern Med* 2010;25(7):741-5. doi:10.1007/s11606-010-1292-2
43. Mackenzie C. Relational Autonomy, Normative Authority and Perfectionism. *Journal of Social Philosophy* 2008;39(4):512-33. doi:10.1111/j.1467-9833.2008.00440.x
44. Elwyn G, Frosch D, Thomson R, et al. Shared decision making: a model for clinical practice. *J Gen Intern Med* 2012;27(10):1361-7. doi:10.1007/s11606-012-2077-6

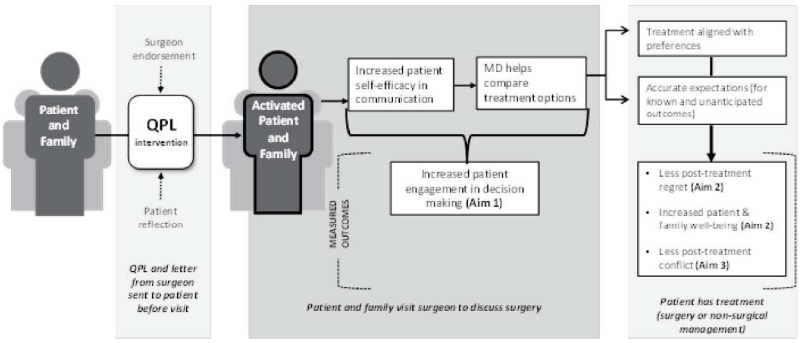
45. Greene J, Hibbard JH, Sacks R, et al. When Seeing The Same Physician, Highly Activated Patients Have Better Care Experiences Than Less Activated Patients. *Health Affairs* 2013;32(7):1299-305. doi:10.1377/hlthaff.2012.1409
46. Joseph-Williams N, Elwyn G, Edwards A. Knowledge is not power for patients: a systematic review and thematic synthesis of patient-reported barriers and facilitators to shared decision making. *Patient Educ Couns* 2014;94(3):291-309. doi:10.1016/j.pec.2013.10.031
47. Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. *Contemp Clin Trials* 2007;28(2):182-91. doi:10.1016/j.cct.2006.05.007
48. Schwarze ML, Barnato AE, Rathouz PJ, et al. Development of a List of High-Risk Operations for Patients 65 Years and Older. *JAMA Surg* 2015;150(4):325-31. doi:10.1001/jamasurg.2014.1819
49. Elwyn G, Tsulukidze M, Edwards A, et al. Using a 'talk' model of shared decision making to propose an observation-based measure: Observer OPTION 5 Item. *Patient Educ Couns* 2013;93(2):265-71. doi:10.1016/j.pec.2013.08.005
50. Couet N, Desroches S, Robitaille H, et al. Assessments of the extent to which health-care providers involve patients in decision making: a systematic review of studies using the OPTION instrument. *Health Expect* 2015;18(4):542-61. doi:10.1111/hex.12054
51. Williams GC, Grow VM, Freedman ZR, et al. Motivational predictors of weight loss and weight-loss maintenance. *J Pers Soc Psychol* 1996;70(1):115-26. doi:10.1037/0022-3514.70.1.115
52. Fernandes-Taylor S, Bloom JR. Post-treatment regret among young breast cancer survivors. *Psychooncology* 2011;20(5):506-16. doi:10.1002/pon.1749
53. Cella D, Riley W, Stone A, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. *J Clin Epidemiol* 2010;63(11):1179-94. doi:10.1016/j.jclinepi.2010.04.011
54. Stacey D, Bennett CL, Barry MJ, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2011(10):CD001431. doi:10.1002/14651858.CD001431.pub3
55. Spradley JP. *The Ethnographic Interview*. New York: Holt, Rinehart and Winston, 1979.
56. Laird NM, Ware JH. Random-effects models for longitudinal data. *Biometrics* 1982;38(4):963-74. doi:10.2307/2529876
57. Stroup WW. *Generalized linear mixed models. modern concepts, methods and applications Stroup, Stroup*. Boca Raton, Fla.: CRC Press, 2012.
58. White IR, Royston P, Wood AM. Multiple imputation using chained equations: Issues and guidance for practice. *Stat Med* 2011;30(4):377-99. doi:10.1002/sim.4067
59. Schafer JL. *Analysis of incomplete multivariate data*. London; New York: Chapman & Hall, 1997.
60. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*: L. Erlbaum Associates, 1988.
61. ten Klooster PM, Oostveen JC, Zandbelt LC, et al. Further validation of the 5-item Perceived Efficacy in Patient-Physician Interactions (PEPPI-5) scale in patients with osteoarthritis. *Patient Educ Couns* 2012;87(1):125-30. doi:10.1016/j.pec.2011.07.017
62. Jolliffe R, Seers H, Jackson S, et al. The responsiveness, content validity, and convergent validity of the Measure Yourself Concerns and Wellbeing (MYCaW) patient-reported

outcome measure. *Integr Cancer Ther* 2015;14(1):26-34. doi:10.1177/1534735414555809

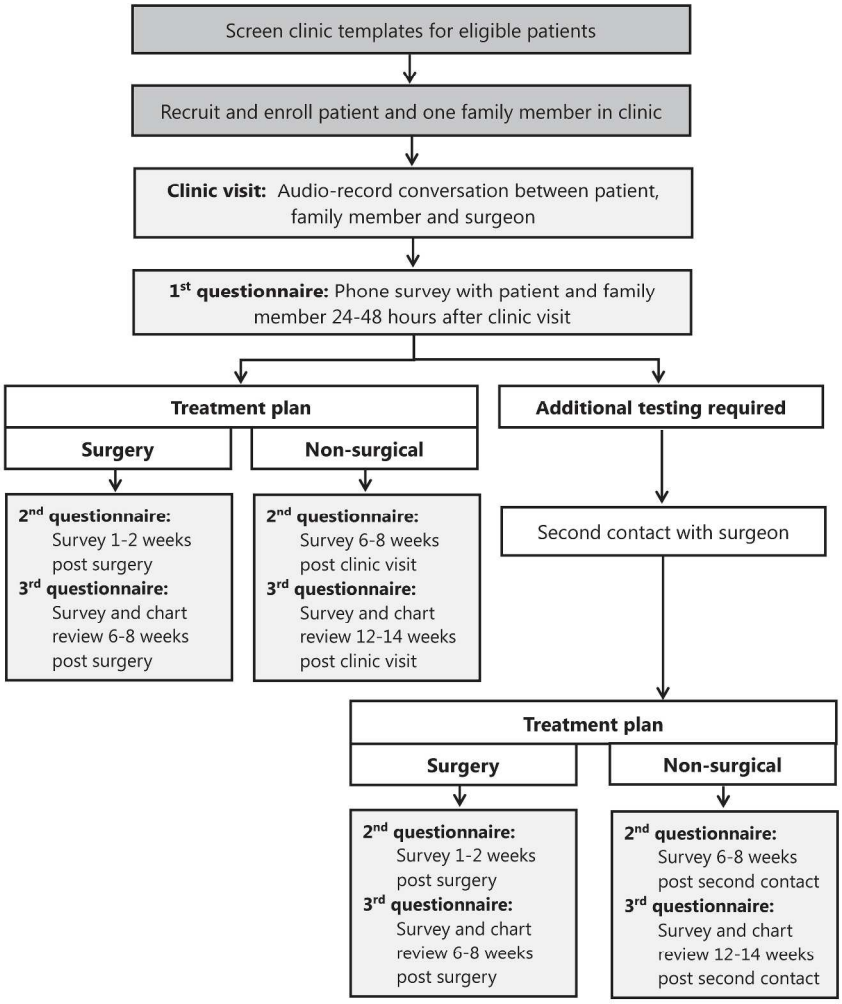
63. Hsieh H-F, Shannon SE. Three Approaches to Qualitative Content Analysis. *Qual Health Res* 2005;15(9):1277-88. doi:10.1177/1049732305276687
64. Robinson TN, Wu DS, Sauaia A, et al. Slower Walking Speed Forecasts Increased Postoperative Morbidity and 1-Year Mortality across Surgical Specialties. *Ann Surg* 2013;258(4):582-90. doi:10.1097/SLA.0b013e3182a4e96c



Patient and family stakeholder-proposed QPL targets and resulting goals
Figure 1
279x361mm (300 x 300 DPI)



Theoretical framework behind the QPL intervention and the study design
Figure 2
279x361mm (300 x 300 DPI)



Screening, recruitment, enrollment and data collection points for patients in the control and intervention arms at each site

Figure 3

279x361mm (300 x 300 DPI)

BMJ Open

Navigating High Risk Surgery: Protocol for A Multi-Site Stepped-Wedge Cluster-Randomized Trial of a Question Prompt List Intervention to Empower Older Adults to Ask Questions that Inform Treatment Decisions

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-014002.R1
Article Type:	Protocol
Date Submitted by the Author:	10-Jan-2017
Complete List of Authors:	Taylor, Lauren; University of Wisconsin Madison, Surgery Rathouz, Paul; University of Wisconsin Madison, Biostatistics Berlin, Ana; Rutgers New Jersey Medical School, Surgery Brasel, Karen; Oregon Health and Science University, Surgery Mosenthal, Anne; Rutgers New Jersey Medical School, Surgery Finlayson , Emily; University of California San Francisco, Surgery Cooper, Zara; Brigham and Women's Hospital Steffens, Nicole; Denver Health and Hospital Authority, Denver Public Health Jacobson , Nora; University of Wisconsin Madison Institute for Clinical and Translational Research Buffington, Anne; University of Wisconsin Madison, Surgery Tucholka, Jennifer; University of Wisconsin Madison, Surgery Zhao , Qianqian; University of Wisconsin Madison, Biostatistics Schwarze, Margaret; University of Wisconsin Madison, Surgery; University of Wisconsin Madison, Medical History and Bioethics
Primary Subject Heading:	Surgery
Secondary Subject Heading:	Patient-centred medicine, Research methods
Keywords:	Adult surgery < SURGERY, GERIATRIC MEDICINE, Adult oncology < ONCOLOGY

Navigating High Risk Surgery: Protocol for a Multi-Site Stepped-Wedge Cluster-Randomized Trial of a Question Prompt List Intervention to Empower Older Adults to Ask Questions that Inform Treatment Decisions

Authors:

1. Lauren J Taylor, MD; Department of Surgery, University of Wisconsin. Madison, Wisconsin, USA. Ltaylor2@uwhealth.org
2. Paul J Rathouz, PhD; Department of Biostatistics & Medical Informatics, University of Wisconsin. Madison, Wisconsin, USA. Rathouz@biostat.wisc.edu
3. Ana Berlin, MD, MPH; Department of Surgery, Rutgers New Jersey Medical School. Newark, New Jersey, USA. ana.berlin@njms.rutgers.edu
4. Karen J Brasel, MD, MPH; Department of Surgery, Oregon Health and Science University. Portland, Oregon, USA. Brasel@ohsu.edu
5. Anne C Mosenthal, MD; Department of Surgery, Rutgers New Jersey Medical School. Newark, New Jersey, USA. mosentac@njms.rutgers.edu
6. Emily Finlayson, MD, MS; Department of Surgery, University of California, San Francisco, California, USA. Emily.finlayson@ucsf.edu
7. Zara Cooper, MD, MSc; Department of Surgery, Brigham and Women's Hospital. Boston, Massachusetts, USA. Zcooper@partners.org
8. Nicole M Steffens, MPH; Denver Public Health, Denver Health and Hospital Authority. Denver, Colorado, USA. Nicole.steffens@gmail.com
9. Nora Jacobson, PhD; University of Wisconsin Institute for Clinical and Translational Research. Madison, Wisconsin, USA. najacobson@wisc.edu
10. Anne Buffington, MPH; Department of Surgery, University of Wisconsin. Madison, Wisconsin, USA. buffington@surgery.wisc.edu
11. Jennifer L Tucholka, BS; Department of Surgery, University of Wisconsin. Madison, Wisconsin, USA. tucholka@surgery.wisc.edu
12. Qianqian Zhao, MS; Department of Biostatistics & Medical Informatics, University of Wisconsin. Madison, Wisconsin, USA. qizhao@biostat.wisc.edu
13. Margaret L Schwarze, MD, MPP; Department of Surgery, Department of Medical History and Bioethics, University of Wisconsin. Madison, Wisconsin, USA. schwarze@surgery.wisc.edu

Corresponding Author:
Margaret L. Schwarze, MD, MPP
G5/315 CSC
600 Highland Ave
Madison, WI 53792
Phone: 608-265-4420
Fax: 608-265-1148
Email: schwarze@surgery.wisc.edu

Word count: 5,411
Tables: 3
Figures: 3
References: 70

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 multi-site cluster-randomized trial that uses a stepped-wedge design to test a patient-driven question prompt list intervention aimed to improve preoperative decision making and inform postoperative expectations.

Methods and analysis

This Patient-Centered Outcomes Research Institute (PCORI) funded trial will be conducted at five academic medical centers in the United States. Study participants include surgeons who routinely perform vascular or oncologic surgery, their patients and families. We aim to enroll 40 surgeons and 480 patients over 24 months. Patients age 65 or older who see a study-enrolled surgeon to discuss a vascular or oncologic problem that could be treated with high-risk surgery will be enrolled at their clinic visit. Together with stakeholders, we developed a question prompt list 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 question prompt list 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 wellbeing and post-treatment regret for patients and families, and inter 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: ClinicalTrials.gov NCT02623335; registration first received November 24, 2015

Keywords: communication, question prompt list, geriatric surgery, shared decision making

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 United States 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 hospitalizations,[6, 7] and potential suffering at the end of life.[8, 9] Furthermore, fifty percent 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 hospitalizations.[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 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"[16] ch.3 p.38 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 multi-site cluster-randomized trial of an intervention to improve preoperative communication between surgeons and older adults considering major vascular or oncologic 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 analyzed over 90 preoperative conversations between surgeons and patients considering high risk

cardiovascular, oncologic, 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” model[25] 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 physiologic 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 emphasize in-hospital risks and technical aspects of the procedure rather than long-term functional outcomes.[26, 27]

We also drew from our previous work using physician surveys[28-31] and qualitative interviews with surgeons[32] 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 recognized 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

Question prompt lists 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 surgery[39] 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 behavior 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-determination[43] and relational autonomy[44, 45] described by Elwyn,[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-centered 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]

Randomized 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, (2) psychological wellbeing 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 hypothesize 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 and family member psychological wellbeing
- 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 multi-site prospective cluster-randomized trial using a stepped-wedge design[49] to compare the effectiveness of the surgical QPL intervention to usual care for older patients considering high risk vascular and oncologic procedures. We are conducting the study in the outpatient surgical clinics at five high-volume academic medical centers across the United States: University of Wisconsin Hospital and Clinics (Madison, WI); University of California San Francisco (San Francisco, CA); Brigham and Women's Hospital (Boston, MA); Rutgers New Jersey Medical School/The University Hospital (Newark, NJ); and Oregon Health Sciences University Hospital and Clinics (Portland, OR). We selected these five sites to represent distinct geographic regions and demographic groups in order to capture diverse experiences with surgical decision making.

Participating surgeons from these five centers routinely perform high-risk oncologic or vascular surgery. Patients and family members are invited to participate as dyads. However, patients may participate alone while family members can only enroll with a corresponding patient. We will enroll 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 zero, all patients will receive usual care. With each subsequent wave, eight of the forty 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 pre-defined time points. In

addition, we will perform qualitative interviews with a subset of participants who experienced serious postoperative complications.

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

Number of surgeons in the intervention group at each site (# of surgeons added per wave)						
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 # of patients per site*	**72**	**84**	**96**	**108**	**120**	**480**

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

Participants

Attending surgeons at participating sites who routinely perform high risk vascular (peripheral, neurologic, or cardiovascular) or oncologic 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 oncologic 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 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 surgery, for example an aneurysm that does not meet size guidelines for operative repair, will be excluded based on chart review or pre-visit determination by the surgeon.

Recruitment

At each study site, all eligible surgeons will receive an invitation via email by the site principal investigator. Surgeons who do not opt out will be chosen based first 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 enroll 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 enroll 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 hospitalization (more than 8 days postoperatively), prolonged length of stay in intensive care (greater than 3 days), prolonged mechanical ventilation, myocardial 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 becomes 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]

Randomization 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. Upon study commencement, a Master's level statistician established a step-wise randomization using a computer-generated randomization 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 cross-over will occur in one direction only, and each within-site change will happen once every four 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 enrollment 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 inquire about receipt of the QPL (with all patients regardless of group assignment) one day after enrollment 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 postoperative 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 oncologic 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 systemically 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 A) treatment decisions are typically made during the first clinical encounter, or B) 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 email 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 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 center 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 colleagues[35] 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 (OPTION)[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)

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	○ **Number and type of questions using a pre-defined coding scheme** ○ OPTION	Audio recording	Clinic visit
Self-efficacy in patient physician interactions	○ **PEPPI-5** (perceived efficacy) ○ HCCQ (autonomy support)	Patient and family member	1st questionnaire
Aim 2: Psychological wellbeing and treatment received			
Concerns and wellbeing	○ **MyCaW** (self-identified concerns and wellbeing)	Patient and family member	1st – 2nd 1st – 3rd questionnaires
Post-treatment regret	○ **"Looking back, is there anything about your treatment that you would do differently?"**	Patient and family member	3rd questionnaire
Psychological wellbeing (patient)	○ PROMIS ○ Psychosocial Illness Impact-Neg 4a ○ Psychosocial Illness Impact-Pos 4a ○ Anxiety 4a	Patient	2nd and 3rd questionnaires
Psychological wellbeing (family)	○ PROMIS ○ SF Global Health	Family member	2nd and 3rd questionnaires

	○ Anxiety 4a		
Treatment received	○ Total number of operations scheduled after visit with surgeon ○ Total number of operations scheduled and performed	Chart review	Clinic visit 3rd questionnaire

Aim 2: Psychological wellbeing

We selected psychological wellbeing 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 wellbeing 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 wellbeing. 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 re-score their initial concerns and wellbeing at the two subsequent time points corresponding to the second and third questionnaires; the difference in scores describes improvement or deterioration in their wellbeing. 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 analyze 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 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.

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	1st questionnaire
Variables mediating psychological wellbeing			
Surgical complications	National Surgical Quality Improvement Project (NSQIP) definition (yes/no)	Chart review	3rd questionnaire
Advance directive	New advance directive completed or prior advance directive	Chart review	3rd questionnaire

	documented in patient chart (yes/no)		
DNR	New DNR order placed or existing DNR order documented in patient chart (yes/no)	Chart review	3rd questionnaire
Covariates			
Comorbid illness	Charlson comorbidity score	Chart review	Clinic visit
Indication for surgery	Patient's presenting problem	Chart review	Clinic visit
MD* sub-specialty	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	1st questionnaire
MD demographics	Languages spoken, age, gender, race/ethnicity	Surgeon	Clinic visit

*Medical Doctor (MD)

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 wellbeing. 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 generalized 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 wellbeing (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 pre-specified 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 wellbeing. We will use the generalized linear mixed modeling framework used in primary analyses for these outcomes. All models will be estimated and tested using PROC MIXED or PROC NLMIX in SAS version 9.3 (SAS Institute, Cary, NC).

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 to 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 (i.e. chained equations imputations).[61, 62] If drop-out 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 post-visit) to impute responses from the final two questionnaires, to maximize statistical efficiency and minimize 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 though we will enroll up to 480 family members if all patients have a family member interested in

participating. Assuming all enrolled patients enroll 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 α=0.05; under a Bonferroni correction, tests will be conducted with nominal α=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 (versus 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 (i.e. ICC = 0.05 to 0.30). Extending the information-based method of computing power for a basic stepped-wedge design [49] to the case of our multi-site stepped-wedge design, we custom-programmed power calculations using R version 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[63]=0.425 and D=0.5, respectively. Assuming PEPPI-5 within treatment arm SD=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 over-dispersion of 2 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 wellbeing 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 a MYCaW difference as small as 0.5*1.26=0.63, comparable to 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 analysis[67] 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 analyze 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 (IRB) 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 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 generalizable 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 behavior 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 (NSQIP) 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 pragmatic[69] and cluster randomized[70] trials. Study results will be released to participating surgeons, patients, families and the general medical community.

ACKNOWLEDGEMENTS: The authors would like to thank Betty Kaiser, PhD, RN and Gay Thomas, MA of the Wisconsin Network for Research Support for guidance in creating and planning the Patient and Family Advisory Council. They would also like to acknowledge the patients and family stakeholders who provided invaluable feedback throughout the development of the QPL intervention and development of study materials.

CONTRIBUTORS: MLS is the principal investigator for this study. She developed the original study design and protocol together with PR, who provided study design and biostatistical support, and the site principal investigators ZC, AB (Newark), AM, EF, and KB. NJ provided guidance in study design specific to the qualitative components. QZ provided biostatistics support. AB (Madison) is the study coordinator and has the primary responsibility of coordinating development of all study materials. LT drafted this manuscript and along with JT helped with development of study materials. JT and NS synthesized input from patient and family stakeholders and contributed to study design. All authors reviewed and approved this manuscript.

FUNDING: Research reported in this work was funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (CDR-1502-27462). Dr. Schwarze was also supported by 1) Training Award KL2TR000428 from the Clinical and Translational Science Award program, in part by grant UL1TR000427 to UW ICTR from NIH/NCATS; 2) through the University of Wisconsin-Madison School of Medicine and Public Health's Wisconsin Partnership Program, WPP-ICTR grant #3086; and 3) the Greenwall Foundation Kornfeld grant. Dr. Taylor is supported by a Training Award T32CA090217 from the NIH. Dr. Berlin is supported by the New Jersey Medical School Hispanic Center of Excellence, Health Resources and Services Administration through Grant D34HP26020. This content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH or the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee.

COMPETING INTERESTS: None.

ETHICS APPROVAL: The trial protocol and all study forms and material have been approved by the University of Wisconsin Institutional Review Board as well as the Institutional Review Boards at each participating site.

FIGURE LEGENDS:

Figure 1: Patient and family stakeholder-proposed QPL targets and resulting goals

Figure 2: Theoretical framework behind the QPL intervention and the study design

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

REFERENCES:

1. Goodney PP, Stukel TA, Lucas FL, et al. Hospital volume, length of stay, and readmission rates in high-risk surgery. *Ann Surg* 2003;238(2):161-7. doi:10.1097/01.SLA.0000081094.66659.c3
2. Finks JF, Osborne NH, Birkmeyer JD. Trends in hospital volume and operative mortality for high-risk surgery. *N Engl J Med* 2011;364(22):2128-37. doi:10.1056/NEJMsa1010705
3. Fuchs VR. Health care for the elderly: how much? Who will pay for it? *Health Aff (Millwood)* 1999;18(1):11-21. doi:10.1377/hlthaff.18.1.11
4. Kaufman SR. Making longevity in an aging society: linking Medicare policy and the new ethical field. *Perspect Biol Med* 2010;53(3):407-24. doi:10.1353/pbm.0.0164
5. Finlayson E, Zhao S, Boscardin WJ, et al. Functional status after colon cancer surgery in elderly nursing home residents. *J Am Geriatr Soc* 2012;60(5):967-73. doi:10.1111/j.1532-5415.2012.03915.x
6. Fry DE, Pine M, Pine G. Medicare post-discharge deaths and readmissions following elective surgery. *Am J Surg* 2013;207(3):326-30. doi:10.1016/j.amjsurg.2013.09.007
7. Rosen AK, Chen Q, Shin MH, et al. Medical and Surgical Readmissions in the Veterans Health Administration: What Proportion are Related to the Index Hospitalization? *Med Care* 2013;52(3):243-9. doi:10.1097/MLR.0000000000000081
8. Scarborough JE, Pappas TN, Bennett KM, et al. Failure-to-pursue rescue: explaining excess mortality in elderly emergency general surgical patients with preexisting "do-not-resuscitate" orders. *Ann Surg* 2012;256(3):453-61. doi:10.1097/SLA.0b013e31826578fb
9. Paul Olson TJ, Pinkerton C, Brasel KJ, et al. Palliative Surgery for Malignant Bowel Obstruction From Carcinomatosis: A Systematic Review. *JAMA Surg* 2014;149(4):383-92. doi:10.1001/jamasurg.2013.4059
10. Schneider KM, O'Donnell BE, Dean D. Prevalence of multiple chronic conditions in the United States' Medicare population. *Health Qual Life Outcomes* 2009;7:82. doi:10.1186/1477-7525-7-82
11. Finlayson EV, Birkmeyer JD. Operative mortality with elective surgery in older adults. *Eff Clin Pract* 2001;4(4):172-7.
12. Khuri SF, Henderson WG, DePalma RG, et al. Determinants of long-term survival after major surgery and the adverse effect of postoperative complications. *Ann Surg* 2005;242(3):326-41. doi:10.1097/01.sla.0000179621.33268.83
13. Kwok AC, Semel ME, Lipsitz SR, et al. The intensity and variation of surgical care at the end of life: a retrospective cohort study. *Lancet* 2011;378(9800):1408-13. doi:10.1016/S0140-6736(11)61268-3
14. Finlayson E, Fan Z, Birkmeyer JD. Outcomes in octogenarians undergoing high-risk cancer operation: a national study. *J Am Coll Surg* 2007;205(6):729-34. doi:10.1016/j.jamcollsurg.2007.06.307

15. Doherty C, Saunders MN. Elective surgical patients' narratives of hospitalization: The co-construction of safety. *Soc Sci Med* 2013;98:29-36. doi:10.1016/j.socscimed.2013.08.014
16. Institute of Medicine. *Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life*. Washington, DC: The National Academies Press, 2014.
17. Braddock C, 3rd, Hudak PL, Feldman JJ, et al. "Surgery is certainly one good option": quality and time-efficiency of informed decision-making in surgery. *J Bone Joint Surg Am* 2008;90(9):1830-8. doi:10.2106/jbjs.g.00840
18. Kruser JM, Pecanac KE, Brasel KJ, et al. "And I Think That We Can Fix It": Mental Models Used in High-risk Surgical Decision Making. *Ann Surg* 2015;261(4):678-84. doi:10.1097/sla.0000000000000714
19. Fagerlin A, Sepucha KR, Couper MP, et al. Patients' knowledge about 9 common health conditions: the DECISIONS survey. *Med Decis Making* 2010;30(5 Suppl):35s-52s. doi:10.1177/0272989x10378700
20. King JS, Moulton BW. Rethinking informed consent: the case for shared medical decision-making. *Am J Law Med* 2006;32(4):429-501.
21. Pecanac KE, Kehler JM, Brasel KJ, et al. It's Big Surgery: Preoperative Expressions of Risk, Responsibility, and Commitment to Treatment After High-Risk Operations. *Ann Surg* 2014;259(3):458-63. doi:10.1097/SLA.0000000000000314
22. Russ AJ, Kaufman SR. Family perceptions of prognosis, silence, and the "suddenness" of death. *Cult Med Psychiatry* 2005;29(1):103-23. doi:10.1007/s11013-005-4625-6
23. Kaufman SR. *And a time to die: how American hospitals shape the end of life*. New York, NY: A Lisa Drew Book/Scribner, 2005. 100.
24. Nabozny MJ, Kruser JM, Steffens NM, et al. Patient Reported Limitations to Surgical Buy-in: A Qualitative Study of Patients Facing High-Risk Surgery. *Ann Surg* 2016; [Epub ahead of print]. doi:10.1097/SLA.0000000000001645
25. Lynn J, DeGrazia D. An outcomes model of medical decision making. *Theor Med* 1991;12(4):325-43. doi:10.1007/BF00489892
26. Blazeby JM, Macefield R, Blencowe NS, et al. Core information set for oesophageal cancer surgery. *Br J Surg* 2015;102(8):936-43. doi:10.1002/bjs.9840
27. McNair AG, MacKichan F, Donovan JL, et al. What surgeons tell patients and what patients want to know before major cancer surgery: a qualitative study. *BMC Cancer* 2016;16:258. doi:10.1186/s12885-016-2292-3
28. Schwarze ML, Redmann AJ, Alexander GC, et al. Surgeons expect patients to buy-in to postoperative life support preoperatively: results of a national survey. *Crit Care Med* 2013;41(1):1-8. doi:10.1097/CCM.0b013e31826a4650
29. Paul Olson TJ, Brasel KJ, Redmann AJ, et al. Surgeon-reported conflict with intensivists about postoperative goals of care. *JAMA Surg* 2013;148(1):29-35. doi:10.1001/jamasurgery.2013.403
30. Redmann AJ, Brasel KJ, Alexander CG, et al. Use of advance directives for high-risk operations: a national survey of surgeons. *Ann Surg* 2012;255(3):418-23. doi:10.1097/SLA.0b013e31823b6782
31. Schwarze ML, Redmann AJ, Brasel KJ, et al. The role of surgeon error in withdrawal of postoperative life support. *Ann Surg* 2012;256(1):10-5. doi:10.1097/SLA.0b013e3182580de5

32. Schwarze ML, Bradley CT, Brasel KJ. Surgical "buy-in": the contractual relationship between surgeons and patients that influences decisions regarding life-supporting therapy. *Crit Care Med* 2010;38(3):843-8. doi:10.1097/CCM.0b013e3181cc466b
33. Danjoux Meth N, Lawless B, Hawryluck L. Conflicts in the ICU: perspectives of administrators and clinicians. *Intensive Care Med* 2009;35(12):2068-77. doi:10.1007/s00134-009-1639-5
34. Cassell J, Buchman TG, Streat S, et al. Surgeons, intensivists, and the covenant of care: administrative models and values affecting care at the end of life--Updated. *Crit Care Med* 2003;31(5):1551-7. doi:10.1097/00003246-200305000-00039
35. Walczak A, Butow PN, Clayton JM, et al. Discussing prognosis and end-of-life care in the final year of life: a randomised controlled trial of a nurse-led communication support programme for patients and caregivers. *BMJ Open* 2014;4(6):e005745. doi:10.1136/bmjopen-2014-005745
36. Kinnersley P, Edwards A, Hood K, et al. Interventions before consultations for helping patients address their information needs. *Cochrane Database Syst Rev* 2007(3):Cd004565. doi:10.1002/14651858.CD004565.pub2
37. Brandes K, Linn AJ, Butow PN, et al. The characteristics and effectiveness of Question Prompt List interventions in oncology: a systematic review of the literature. *Psychooncology* 2014;24(3):245-52. doi:10.1002/pon.3637
38. Brown R, Butow PN, Boyer MJ, et al. Promoting patient participation in the cancer consultation: evaluation of a prompt sheet and coaching in question-asking. *Br J Cancer* 1999;80(1-2):242-8. doi:10.1038/sj.bjc.6690346
39. Smets EM, van Heijl M, van Wijngaarden AK, et al. Addressing patients' information needs: a first evaluation of a question prompt sheet in the pretreatment consultation for patients with esophageal cancer. *Dis Esophagus* 2012;25(6):512-9. doi:10.1111/j.1442-2050.2011.01274.x
40. Clayton JM, Butow PN, Tattersall MH, et al. Randomized controlled trial of a prompt list to help advanced cancer patients and their caregivers to ask questions about prognosis and end-of-life care. *J Clin Oncol* 2007;25(6):715-23. doi:10.1200/jco.2006.06.7827
41. Shepherd HL, Barratt A, Trevena LJ, et al. Three questions that patients can ask to improve the quality of information physicians give about treatment options: a cross-over trial. *Patient Educ Couns* 2011;84(3):379-85. doi:10.1016/j.pec.2011.07.022
42. Steffens NM, Tucholka JL, Nabozny MJ, et al. Engaging Patients, Health Care Professionals, and Community Members to Improve Preoperative Decision Making for Older Adults Facing High-Risk Surgery. *JAMA Surg* 2016; [Epub ahead of print]. doi:10.1001/jamasurg.2016.1308
43. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *Am Psychol* 2000;55(1):68-78. doi:10.1037/0003-066X.55.1.68
44. Entwistle VA, Carter SM, Cribb A, et al. Supporting patient autonomy: the importance of clinician-patient relationships. *J Gen Intern Med* 2010;25(7):741-5. doi:10.1007/s11606-010-1292-2
45. Mackenzie C. Relational Autonomy, Normative Authority and Perfectionism. *Journal of Social Philosophy* 2008;39(4):512-33. doi:10.1111/j.1467-9833.2008.00440.x

46. Elwyn G, Frosch D, Thomson R, et al. Shared decision making: a model for clinical practice. *J Gen Intern Med* 2012;27(10):1361-7. doi:10.1007/s11606-012-2077-6
47. Greene J, Hibbard JH, Sacks R, et al. When Seeing The Same Physician, Highly Activated Patients Have Better Care Experiences Than Less Activated Patients. *Health Affairs* 2013;32(7):1299-305. doi:10.1377/hlthaff.2012.1409
48. Joseph-Williams N, Elwyn G, Edwards A. Knowledge is not power for patients: a systematic review and thematic synthesis of patient-reported barriers and facilitators to shared decision making. *Patient Educ Couns* 2014;94(3):291-309. doi:10.1016/j.pec.2013.10.031
49. Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. *Contemp Clin Trials* 2007;28(2):182-91. doi:10.1016/j.cct.2006.05.007
50. Schwarze ML, Barnato AE, Rathouz PJ, et al. Development of a List of High-Risk Operations for Patients 65 Years and Older. *JAMA Surg* 2015;150(4):325-31. doi:10.1001/jamasurg.2014.1819
51. Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42(2):377-81. doi:10.1016/j.jbi.2008.08.010
52. Elwyn G, Tsulukidze M, Edwards A, et al. Using a 'talk' model of shared decision making to propose an observation-based measure: Observer OPTION 5 Item. *Patient Educ Couns* 2013;93(2):265-71. doi:10.1016/j.pec.2013.08.005
53. Couet N, Desroches S, Robitaille H, et al. Assessments of the extent to which health-care providers involve patients in decision making: a systematic review of studies using the OPTION instrument. *Health Expect* 2015;18(4):542-61. doi:10.1111/hex.12054
54. Williams GC, Grow VM, Freedman ZR, et al. Motivational predictors of weight loss and weight-loss maintenance. *J Pers Soc Psychol* 1996;70(1):115-26. doi:10.1037/0022-3514.70.1.115
55. Fernandes-Taylor S, Bloom JR. Post-treatment regret among young breast cancer survivors. *Psychooncology* 2011;20(5):506-16. doi:10.1002/pon.1749
56. Cella D, Riley W, Stone A, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. *J Clin Epidemiol* 2010;63(11):1179-94. doi:10.1016/j.jclinepi.2010.04.011
57. Stacey D, Bennett CL, Barry MJ, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2011(10):CD001431. doi:10.1002/14651858.CD001431.pub3
58. Spradley JP. *The Ethnographic Interview*. New York: Holt, Rinehart and Winston, 1979.
59. Laird NM, Ware JH. Random-effects models for longitudinal data. *Biometrics* 1982;38(4):963-74. doi:10.2307/2529876
60. Stroup WW. *Generalized linear mixed models. modern concepts, methods and applications Stroup, Stroup*. Boca Raton, Fla.: CRC Press, 2012.
61. White IR, Royston P, Wood AM. Multiple imputation using chained equations: Issues and guidance for practice. *Stat Med* 2011;30(4):377-99. doi:10.1002/sim.4067
62. Schafer JL. *Analysis of incomplete multivariate data*. London; New York: Chapman & Hall, 1997.
63. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*: L. Erlbaum Associates, 1988.

64. ten Klooster PM, Oostveen JC, Zandbelt LC, et al. Further validation of the 5-item Perceived Efficacy in Patient-Physician Interactions (PEPPI-5) scale in patients with osteoarthritis. *Patient Educ Couns* 2012;87(1):125-30. doi:10.1016/j.pec.2011.07.017
65. Jolliffe R, Seers H, Jackson S, et al. The responsiveness, content validity, and convergent validity of the Measure Yourself Concerns and Wellbeing (MYCaW) patient-reported outcome measure. *Integr Cancer Ther* 2015;14(1):26-34. doi:10.1177/1534735414555809
66. McCullagh P, Nelder JA. *Generalized Linear Models, Second Edition*. Boca Raton, FL: Chapman & Hall/CRC, 1989. 151-154.
67. Hsieh H-F, Shannon SE. Three Approaches to Qualitative Content Analysis. *Qual Health Res* 2005;15(9):1277-88. doi:10.1177/1049732305276687
68. Robinson TN, Wu DS, Sauaia A, et al. Slower Walking Speed Forecasts Increased Postoperative Morbidity and 1-Year Mortality across Surgical Specialties. *Ann Surg* 2013;258(4):582-90. doi:10.1097/SLA.0b013e3182a4e96c
69. Zwarenstein M, Treweek S, Gagnier JJ, et al. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. *BMJ* 2008;337:a2390. doi:10.1136/bmj.a2390
70. Campbell MK, Piaggio G, Elbourne DR, et al. Consort 2010 statement: extension to cluster randomised trials. *BMJ* 2012;345:e5661. doi:10.1136/bmj.e5661

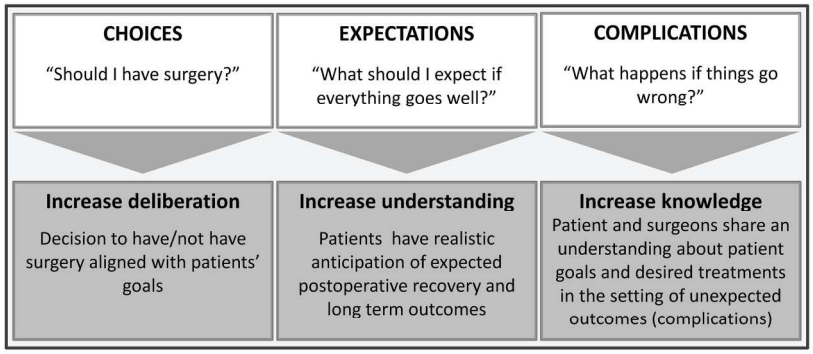


Figure 1: Patient and family stakeholder-proposed QPL targets and resulting goals
Figure 1
190x142mm (300 x 300 DPI)

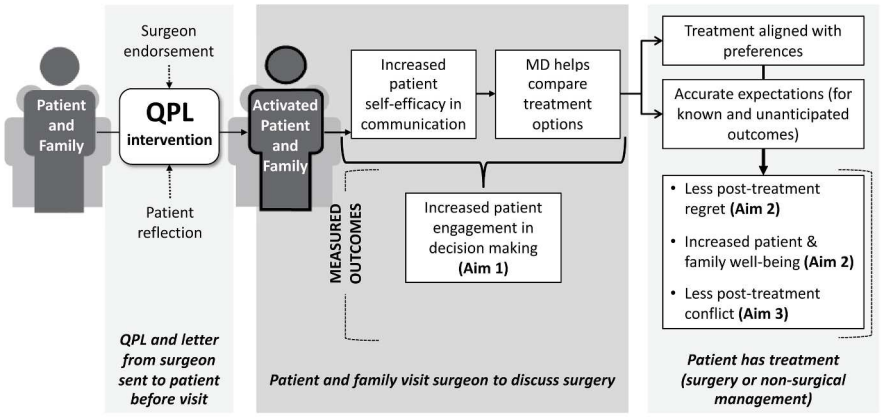
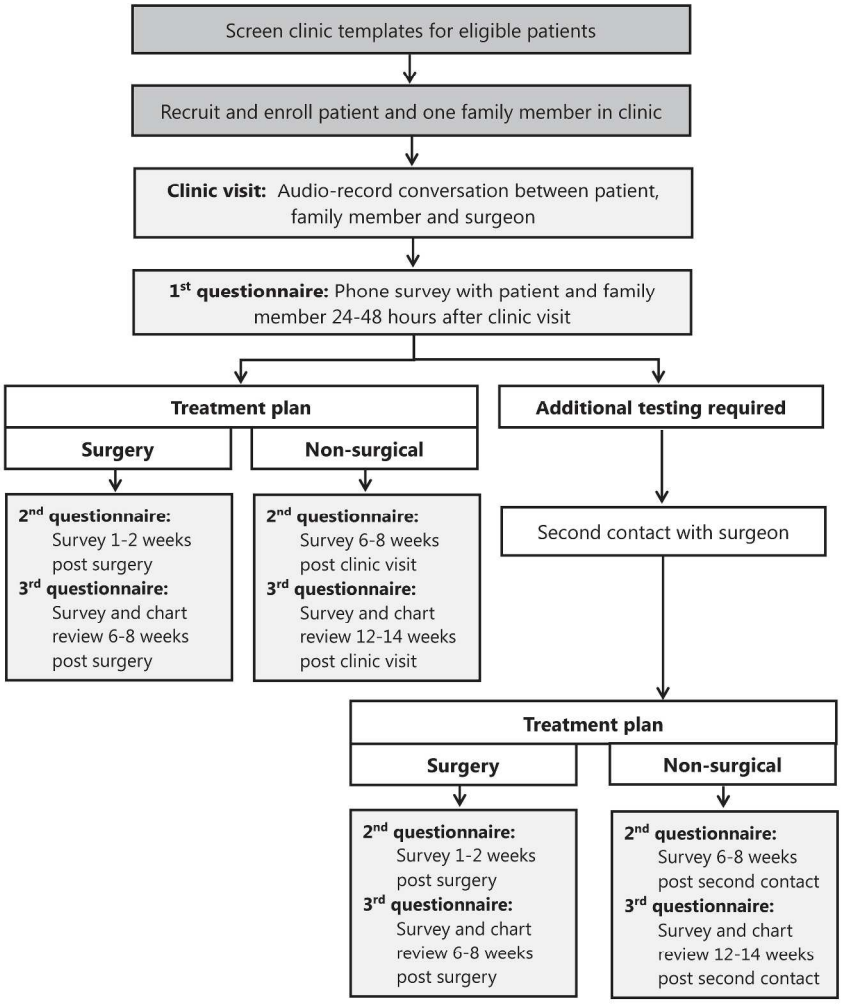


Figure 2: Theoretical framework behind the QPL intervention and the study design
Figure 2
253x190mm (300 x 300 DPI)



Screening, recruitment, enrollment and data collection points for patients in the control and intervention arms at each site
Figure 3
279x361mm (300 x 300 DPI)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	_____1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	____3_____
	2b	All items from the World Health Organization Trial Registration Data Set	__1,3, 10, 11, 16, 21_____
Protocol version	3	Date and version identifier	_manuscript written based on study protocol from 7/5/2016_
Funding	4	Sources and types of financial, material, and other support	_____28_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_____1_____
	5b	Name and contact information for the trial sponsor	__28_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	__28_____

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	__details of data management team not included in manuscript, available in full protocol_____
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	__4-9_____
	6b	Explanation for choice of comparators	_6,7_____
Objectives	7	Specific objectives or hypotheses	___9_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	__10_____
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	__10_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	___11_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	__15_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	__n/a minimal risk
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	__13, 14_____

	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_12_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	_17-21_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	__15-16____
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	__23-24_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	__12-13_____
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	___13_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	__13_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	_13-14_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	__14_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	__13-14_____

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	_17-21_____
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	_12, 22_____
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	__15,16,23 and available in full protocol from the study investigators___
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	__21-22_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	__21-22_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	___21_____

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	__23,24, 26; further details on composition of DMC available in full protocol.__
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	__no interim analysis____

Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	___25_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	__25_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	___25_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	__26-27_____
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	__12_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	__n/a_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	___25_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	___28_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	__not included in manuscript, available in full protocol_____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	___n/a_____

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	__26_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	__28_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	___n/a_____ _
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	__not included in manuscript, available in full protocol_____ ___
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	__n/a_____ _

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.