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Effectiveness of a Question Prompt List Intervention for Older Patients Considering Major Surgery
A Multisite Randomized Clinical Trial

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Invited Commentary page 13

Supplemental content

IMPORTANCE Poor preoperative communication can have serious consequences, including unwanted treatment and postoperative conflict.

OBJECTIVE To compare the effectiveness of a question prompt list (QPL) intervention vs usual care on patient engagement and well-being among older patients considering major surgery.

DESIGN, SETTING, AND PARTICIPANTS This randomized clinical trial used a stepped-wedge design to randomly assign patients to a QPL intervention (n = 223) or usual care (n = 223) based on the timing of their visit with 1 of 40 surgeons at 5 US study sites. Patients were 60 years or older with at least 1 comorbidity and an oncologic or vascular (cardiac, neurosurgical, or peripheral vascular) problem that could be treated with major surgery. Family members were also enrolled (n = 263). The study dates were June 2016 to November 2018. Data analysis was by intent-to-treat.

INTERVENTIONS A brochure of 11 questions to ask a surgeon developed by patient and family stakeholders plus an endorsement letter from the surgeon were sent to patients before their outpatient visit.

MAIN OUTCOMES AND MEASURES Primary patient engagement outcomes included the number and type of questions asked during the surgical visit and patient-reported Perceived Efficacy in Patient-Physician Interactions scale assessed after the surgical visit. Primary well-being outcomes included (1) the difference between patient's Measure Yourself Concerns and Well-being (MYCaW) scores reported after surgery and scores reported after the surgical visit and (2) treatment-associated regret at 6 to 8 weeks after surgery.

RESULTS Of 1319 patients eligible for participation, 223 were randomized to the QPL intervention and 223 to usual care. Among 446 patients, the mean (SD) age was 71.8 (7.1) years, and 249 (55.8%) were male. On intent-to-treat analysis, there was no significant difference between the QPL intervention and usual care for all patient-reported primary outcomes. The difference in MYCaW scores for family members was greater in usual care (effect estimate, 1.51; 95% CI, 0.28-2.74; $P = .008$). When the QPL intervention group was restricted to patients with clear evidence they reviewed the QPL, a nonsignificant increase in the effect size was observed for questions about options (odds ratio, 1.88; 95% CI, 0.81-4.35; $P = .16$), expectations (odds ratio, 1.59; 95% CI, 0.67-3.80; $P = .29$), and risks (odds ratio, 2.41; 95% CI, 1.04-5.59; $P = .04$) (nominal $\alpha = .01$).

CONCLUSIONS AND RELEVANCE The results of this study were null related to primary patient engagement and well-being outcomes. Changing patient-physician communication may be difficult without addressing clinician communication directly.

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Each year, more than 500 000 older Americans have major surgery to treat a serious oncologic or vascular problem.[1,2] Although surgery can prolong life and reduce symptoms, there are significant trade-offs associated with major surgery in patients 65 years and older; older patients are more likely to require intensive care, have lengthy hospitalizations, or transfer to extended care facilities after surgery.[3,4] Therefore, decisions to proceed with surgery can start patients along a care trajectory inconsistent with their personal preferences and overall health goals. Moreover, even patients who avoid complications can feel blindsided when the expected outcomes of surgery are overwhelming[5,6] or they fail to return to normal. Poor preoperative communication can have serious consequences, including unwanted treatment[7,8] and conflict between surgeons and patients about postoperative care.[9-11]

Using observational data and input from patients and families, our group found current communication practices do little to engage patients in discussions about what surgery might mean for them or set expectations for life after surgery.[5,12] Surgeons rely on informed consent to help patients make decisions, yet this process focuses on risks and benefits and fails to describe how patients might experience expected downstream outcomes like a major change in functional status or new care needs. Surgeons routinely encourage patients to ask questions, yet patients often respond with technical or logistic concerns (eg, "Will you use stitches or staples?" and "Can my wife sleep in my room?").[13] These questions do not help patients deliberate about whether to have surgery or prepare for the experience of surgery.

To address these problems, we worked with stakeholders to develop a question prompt list (QPL) brochure targeting informational needs of patients considering major surgery.[14] It includes 11 questions that prompt patients and their family members to query their surgeon about treatment options, expected recovery, and management of serious complications (eFigure 1 in Supplement 1). The QPL intervention includes the brochure plus a letter of endorsement from the surgeon sent to the patient before the outpatient appointment. The objective of this study was to compare the effectiveness of the QPL vs usual care on patient and family engagement, psychological well-being, and posttreatment regret among older patients.

Key Points

Question Is a patient-mediated question prompt list intervention effective in improving patient engagement during preoperative visits and subsequent well-being?

Findings In this randomized clinical trial of 40 surgeons and 446 patients, there was no difference in primary outcomes related to patient engagement or well-being. There was a significant difference in the change in rating of concerns reported by family members between 6 weeks after surgery and just after the surgical visit that was greater in usual care.

Meaning This interventional study highlights the challenges of evaluating and changing patient-physician communication.

Methods

This study was approved by the institutional review boards at University of Wisconsin-Madison; University of California, San Francisco; Rutgers New Jersey Medical School, Newark; Brigham and Women's Hospital, Boston, Massachusetts; and Oregon Health and Science University, Portland. The trial protocol is available in Supplement 2. This study followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines. We used a stepped-wedge design to randomly assign patients to a study arm based on the timing of their surgical consultation; all 40 study-enrolled surgeons were randomly assigned (within site) a time to cross over to QPL intervention, whereby the QPL was mailed to all patients coming to discuss surgical treatment[15] (eTable 1 in Supplement 1). This study design allowed all surgeons access to the QPL intervention and avoided contamination between study participants based on changes in the surgeon's practice because of QPL implementation.

Study Participants

We invited surgeons who routinely perform high-risk oncologic (colorectal, hepatobiliary, urologic, gynecologic, neurosurgical, or head and neck) or vascular (cardiac, neurosurgical, or peripheral vascular) operations and regularly see older patients with comorbid conditions in the outpatient setting. We stratified willing participants by institution and specialty, then randomly selected surgeons who expressed interest within specialty to assure at least 3 surgeons per specialty were included studywide.

We screened enrolled surgeons' clinics for patients 60 years or older with at least 1 comorbidity and an oncologic or vascular problem potentially treatable with 1 of 227 high-risk operations.[16] Family members were also enrolled (n = 263). The study dates were June 2016 to November 2018. We confirmed with the surgeon or clinic staff that the patient's illness could be treated with surgery and the patient was physically and cognitively fit for study participation. We approached eligible patients and 1 accompanying family member (or "like family" friend) just before their clinic appointment and obtained written informed consent. Family member participation was not required. We excluded patients who did not have access for follow-up, who could not speak English or Spanish with fluency required for decision-making, or whose appointment had been scheduled within 5 days of the clinic visit.

Randomization and QPL Intervention

We aimed to enroll 2 to 3 patients per surgeon over each 4-month period (wave). All surgeons were initially assigned to usual care. On completion of each wave, an independent statistician randomly selected 1 to 2 surgeons per site to cross over into the QPL intervention group. Research staff then sent the QPL to all patients coming to discuss surgical treatment regardless of study eligibility. Patients described in the health record as Spanish speakers were sent the QPL in English and Spanish. By the sixth wave, all surgeons were in the QPL intervention group. For 32 surgeons, we sent the QPL to all new

patients, with enrollment at the first visit. Some surgeons noted their practice was to have a decision-making conversation during a second visit and the QPL might not be appropriate for all new patients. For these 8 surgeons, all patients were recruited and enrolled at the second visit, and the QPL was mailed to patients scheduled for a second visit.

One month before crossover, surgeons and clinic staff were given information about QPL intervention procedures. We imposed a 2-week data collection hiatus to ensure no contamination of the usual care group, and that patients in the QPL intervention group had opportunity to receive the QPL intervention. To establish adequate enrollment, we implemented rules estimating the ideal timing for crossover, ensuring at least 70% enrollment before moving to the subsequent wave (eFigure 2 in Supplement 1).

Surgeons were not blinded to QPL intervention status, although they were not informed about study outcomes. Patients and family members were blinded to the objective of testing the QPL. Study staff were not blinded during data collection but were asked to adhere to a strict script during survey administration. Coders (M.L.S., A.B., J.L.T., C.J.Z., A.K., N.D.B., D.A.F., and A.E.S.) were blinded and provided an even mix of QPL intervention and usual care data throughout coding.

Data Collection

We audiorecorded the entire visit between attending surgeon and patient and all others present. Study staff telephoned participants 24 to 48 hours later to conduct surveys with patients and family members separately. Race/ethnicity was self-reported by participants at this time per Patient-Centered Outcomes Research Institute (PCORI) standards. Staff called patients 1 to 2 weeks after the patient's surgery and 6 to 8 weeks later (eFigure 3 in Supplement 1). For patients whose treatment decision was nonsurgical, staff surveyed participants 6 to 8 weeks after enrollment and 12 to 14 weeks after enrollment. For patients without an explicit treatment decision at the time of the clinic visit, we collected data in relation to the eventual treatment plan (eg, 2 and 6 weeks after [subsequently scheduled] surgery). To minimize missing data, we also contacted participants via mail and email. We reviewed electronic medical records to determine the patient's treatment plan and procedures performed. On study completion, we solicited surgeons for feedback about the QPL.

Outcomes

We compared the effectiveness of the QPL intervention vs usual care in the 2 domains of patient engagement and well-being. For patient engagement, our primary outcomes were the number of questions asked by patients and family during the recorded visit related to treatment options, expectations, and risks and advance care planning, as well as the 5-item Perceived Efficacy in Patient-Physician Interactions (PEPPI-5) scale assessed after the clinic visit. Secondary patient engagement outcomes included the 5-domain Observing Patient Involvement in Decision Making (OPTION5) scale score, an observer-measured assessment of shared decision-making, and the Health Care Climate Questionnaire (HCCQ) assessed after the clinic visit. For patient well-being, we used the Measure Yourself Concerns and Well-being (MYCaW) instrument (possible score range 0-6; higher scores indicate more concern), which allows patients to identify and rate their most pressing concern. Our primary outcomes related to well-being were (1) the difference between patient's MYCaW scores reported 2 and 6 weeks after surgery (or 6 to 8 weeks and at 12 to 14 weeks after enrollment) and scores reported at 24 to 48 hours after meeting with a surgeon and (2) treatment-associated regret at 6 to 8 weeks after surgery or 12 to 14 weeks after enrollment. We specifically asked the following question: "Looking back, is there anything about your treatment that you would do differently?" Secondary well-being outcomes included Patient-Reported Outcomes Measurement Information System (PROMIS) measures and the Psychosocial Illness Impact (PII) measure at 2 weeks and 6 to 8 weeks after surgery.

Statistical Analysis

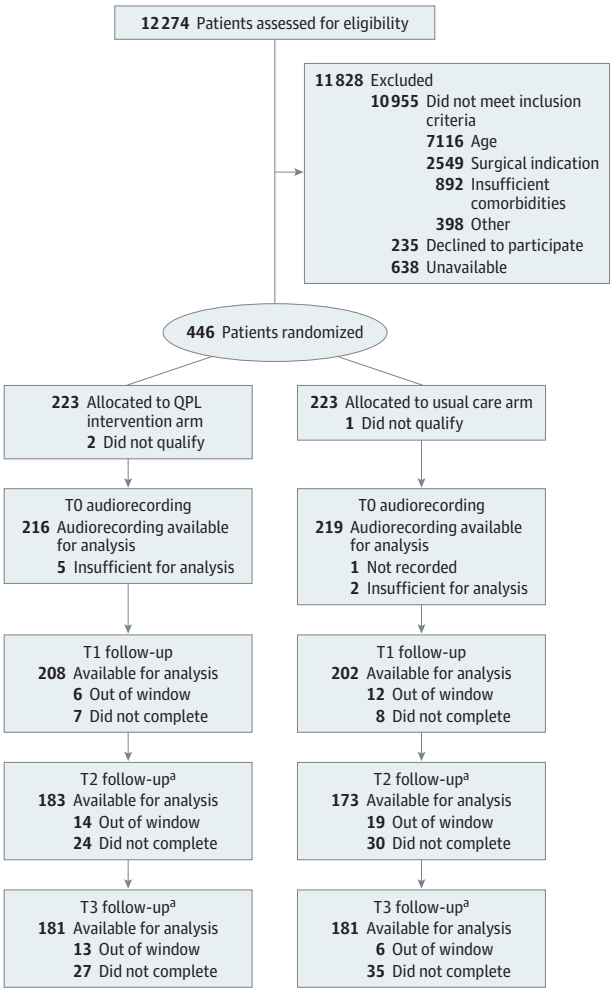
Audiorecordings were transcribed with all identifying information removed. All data coding was completed before unblinding. To code the number and types of questions asked, we developed and tested a coding scheme building on others' prior methodological work.[17] The codebook is available online.[18] We used a random set of 30 transcripts to test the intraclass correlation between coders, which ranged from 0.76 to 0.92; therefore, the remaining audiorecordings were coded by 1 of 6 coders. For OPTION5 scoring, we could not achieve reasonable intraclass correlation, so 2 coders coded each transcript, and the research team adjudicated discrepancies. Three coders met regularly to achieve consensus on categories of MYCaW scores and regrets described by participants.

We registered our complete statistical analysis plan at ClinicalTrials.gov before unblinding and updated our power calculations to harmonize with the final analysis plan and realized recruitment, which had a slight reduction in patient sample size (from 240 per group to 223 per group). We used a nominal α of .01 for multiple outcomes related to patient engagement and $\alpha = .025$ for outcomes related to well-being and regret. We estimated 91% power to detect a difference in the options, expectations, and risks question categories and 83% power to detect a difference in the advance care planning category.

We performed intent-to-treat analysis with 2-sided tests for significance. For categorical responses, we used generalized linear mixed models with a treatment dummy variable, surgeon random effect, and site by time dummy variables to control for site-specific secular trends in accord with the stepped-wedge design. Numbers of questions by type were considered ordinal categories (0, 1, or ≥2) except for advance care planning (0 or ≥1) and regret, with any expression of regret by patient or family as positive for regret (yes or no). We used linear mixed models for continuous variables. All analyses were performed with R statistical software, version 3.5.2 (R Foundation for Statistical Computing).

We conducted 2 restricted analyses. We first removed 59 participants from the cohort because major oncologic or vascular surgery was not discussed during the recorded visit. We further restricted the cohort based on the observed penetrance of the QPL intervention when (1) there was unequivocal report

Figure 1. CONSORT Diagram for Patients Enrolled in the Study



CONSORT indicates Consolidated Standards of Reporting Trials; QPL, question prompt list; T0, time of enrollment and surgical visit; T1, survey administration 24 to 48 hours after meeting with the surgeon; T2, 1 to 2 weeks after surgery or 6 weeks after enrollment; and T3, 6 to 8 weeks after surgery or 12 to 14 weeks after enrollment.

[a] Data available for the difference in Measure Yourself Concerns and Well-being (MYCaW) scores, T2 minus T1 and T3 minus T1, are less than the number available for analysis because 72 patients and 39 family members in the QPL intervention group and 48 patients and 28 family members in the usual care group noted they had no concerns to rate at T1.

from patient or family that they received the QPL before the visit, (2) clear evidence that the QPL was used during the recorded conversation, and (3) research staff observed study participants holding the QPL in clinic (n = 93).

Results

We mailed QPLs to 6176 patients of 40 surgeons over 26 months. Of 1319 patients eligible for participation, 223 were randomized to QPL intervention and 223 to usual care (**Figure 1**). Among 446 patients, the mean (SD) age was 71.8 (7.1) years, and 249 (55.8%) were male. Demographic characteristics did not differ between treatment groups. Because of the stepped-wedge design, the distribution of study group assignment was uneven across some specialties (**Table 1**).

Table 1. Patient Characteristics[a]

Variable	No. (%) QPL Intervention (n = 221)	No. (%) Usual Care (n = 222)
Age, mean (SD), y	71.0 (6.7)	72.6 (7.4)
Male sex	118 (53.4)	130 (58.6)
Self-reported race/ethnicity		
White	178 (80.5)	189 (85.1)
Black or African American	20 (9.0)	17 (7.7)
Asian	10 (4.5)	4 (1.8)
Other	15 (6.8)	18 (8.1)
No response	6 (2.7)	3 (1.4)
Hispanic, Latino, or Spanish origin	20 (9.0)	15 (6.8)
Educational attainment		
Some high school or less	23 (10.4)	20 (9.0)
High school diploma or GED	46 (20.8)	57 (25.7)
Vocational degree or some college	55 (24.9)	55 (24.8)
College degree	50 (22.6)	48 (21.6)
Graduate school degree or higher	38 (17.2)	33 (14.9)
How often need help reading material from physician or pharmacy?		
Never/rarely	168 (76.0)	180 (81.1)
Often/always	45 (20.4)	34 (15.3)
Language spoken		
English	211 (95.0)	215 (96.8)
Spanish	10 (4.5)	7 (3.2)
Insurance		
Medicare and Medicare plus supplemental	143 (64.7)	154 (69.4)
Any Medicaid	21 (9.5)	16 (7.2)
Private insurance	56 (25.3)	49 (22.1)
Family member present at initial visit	163 (73.8)	173 (77.9)
Family member enrolled	120 (54.3)	142 (64.0)
Surgical indication		
Cardiac	17 (7.7)	22 (9.9)
Colorectal	28 (12.7)	36 (16.2)
Hepatobiliary	40 (18.1)	41 (18.5)
Neurosurgical	17 (7.7)	7 (3.2)
Peripheral vascular	5 (2.3)	30 (13.5)
Thoracic	44 (19.9)	19 (8.6)
Urologic	36 (16.3)	36 (16.2)
Gynecologic-oncology	21 (9.5)	12 (5.4)
Head and neck	13 (5.9)	19 (8.6)
Charlson Comorbidity Index, mean (SD)	5 (2)	5 (2)
Patients who decided not to have surgery[b]	32 (14.5)	25 (11.3)
Patients who had surgery during the study period[b]	135 (61.1)	139 (62.6)
Patients who had major postoperative complications[b]	21 (9.5)	24 (10.8)

Abbreviations: GED, general equivalency diploma; QPL, question prompt list.

[a] *P* values between arms are all greater than .06 except for age (*P* = .02) and surgical indication (*P* < .001). Data are missing on educational attainment for 18 patients, for health literacy (How often need help reading material from physician or pharmacy?) for 16 patients, and on insurance for 4 patients.

[b] Denotes a postrandomization variable.

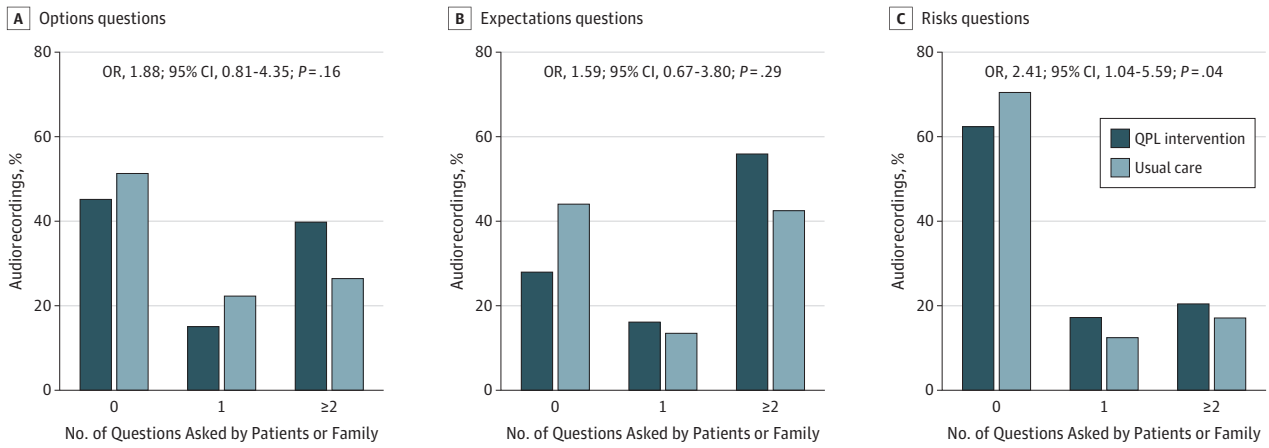
Table 2. Patient Engagement Outcomes Related to Patient Engagement and Well-being[a]

Variable	QPL Intervention	Usual Care	Adjusted OR (95% CI)	Adjusted Effect Estimate (95% CI)	*P* Value
Questions asked at 1 consultation with patient and family, unadjusted question count	(n = 186)	(n = 193)			
Options ≥2	60	51	1.19 (0.62 to 2.28)		.61
Expectations ≥2	90	82	1.10 (0.61 to 1.99)		.75
Risks ≥2	33	33	1.82 (0.97 to 3.42)		.06
Advance care planning total	3	0	NA		.10
Verbatim QPL questions total	13	0	NA		NA
Visit length, mean, min	22.7	24.7		−1.18 (−4.49 to 2.14)	.46
OPTION5 scale score, mean	36.5	32.9		6.01 (0.00 to 12.03)	.046
Patient T1, mean (SD), scale score	(n = 179)	(n = 175)			
PEPPI-5	21.8 (3.4)	21.5 (3.4)		−0.36 (−1.37 to 0.65)	.46
HCCQ	6.42 (0.80)	6.51 (0.63)		−0.24 (−0.44 to −0.04)	.02
Family T1, mean (SD), scale score	(n = 91)	(n = 108)			
PEPPI-5	22.0 (2.5)	21.4 (3.2)		0.67 (−0.54 to 1.88)	.24
HCCQ	6.62 (0.50)	6.55 (0.51)		0.04 (−0.15 to 0.25)	.63

Abbreviations: HCCQ, Health Care Climate Questionnaire (range 0-7; higher scores indicate more patient-reported support for autonomy); NA, not applicable; OPTION5, 5-domain Observing Patient Involvement Scale (range 0-100; higher scores indicate more shared decision-making); OR, odds ratio; PEPPI-5, 5-item Perceived Efficacy in Patient-Physician Interactions, (range 0-25; higher scores indicate greater perceived efficacy in communication); QPL, question prompt list; T1, survey administration 24 to 48 hours after meeting with the surgeon.

[a] For the cohort of patients who had a discussion about major oncologic or vascular (cardiac, neurosurgical, or peripheral vascular) surgery with a study-enrolled surgeon.

Figure 2. Numbers of Options, Expectations, and Risks Questions Asked by Patients and Family Members During Conversations With Study-Enrolled Surgeons



The question prompt list (QPL) intervention cohort is restricted to 93 patients who had a discussion about major oncologic or vascular (cardiac, neurosurgical, or peripheral vascular) surgery and who had clear evidence they had reviewed the QPL. OR indicates odds ratio.

Patient Engagement

On intent-to-treat analysis, there was no significant difference between QPL intervention and usual care for primary outcomes (eTable 2 in Supplement 1). Patient HCCQ scores were higher in usual care (effect estimate, −0.25; 95% CI, −0.45 to −0.06; *P* = .009), but ceiling effects render this difference meaningless. When we restricted our analysis to patients who had a discussion about major oncologic or vascular surgery, we found no significant differences between QPL intervention and usual care related to question asking about options (odds ratio [OR], 1.19; 95% CI, 0.62-2.28; *P* = .61), expectations (OR, 1.10; 95% CI, 0.61-1.99; *P* = .75), and risks (OR, 1.82; 95% CI, 0.97-3.42; *P* = .06). There were only 3 patient or family-initiated questions about advance care planning, all in the QPL intervention group. We observed 13 verbatim questions from the QPL in the QPL intervention group and zero in the usual care group (**Table 2**). When we restricted the QPL intervention group to patients with clear evidence they had reviewed the QPL, we observed an increase in our effect size for questions about options (OR, 1.88; 95% CI, 0.81-4.35; *P* = .16), expectations (OR, 1.59; 95% CI, 0.67-3.80; *P* = .29), and risks (OR, 2.41; 95% CI, 1.04-5.59; *P* = .04), but this did not reach significance (nominal α = .01) (**Figure 2**). The PEPPI-5 scale scores were high and did not differ between groups. Observer-measured shared decision-making (OPTION5 scoring) was higher in the QPL intervention group (effect estimate, 6.01; 95% CI, 0.00-12.03; *P* = .046) (Table 2 and **Figure 3**).

Well-being

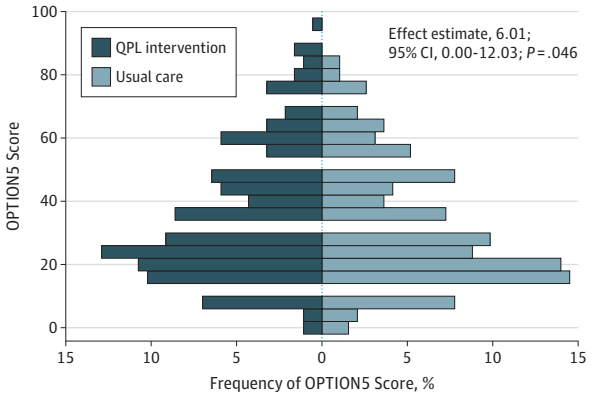
On intent-to-treat analysis, we found no significant difference between QPL intervention and usual care for primary patient well-being outcomes. One secondary outcome was

significant, namely, the difference in MYCaW rating for family members measured at 6 weeks after treatment and just after meeting with a surgeon. This was greater in usual care (effect estimate, 1.51; 95% CI, 0.28-2.74; P = .008). These results were unchanged when we restricted the cohort (eTable 3 in Supplement 1). Numerically, there was more treatment-associated regret in the QPL intervention group (OR, 1.74; 95% CI, 0.70-4.32; P = .25). On exploration, most regrets reported by patients or family were related to not seeking care earlier. Only 17 regrets were related to preoperative question asking; these were evenly split between groups. PROMIS measures were slightly worse in the QPL intervention group; for example, on average, anxiety scores were 1.3 (95% CI, 0.2-2.4) points higher for patients in the QPL intervention group. These effects were less than the minimally important difference of 2.5 points[19] (eFigure 4 in Supplement 1).

Surgeon Reflections

Surgeons strongly supported using the QPL in clinic. There were 2 of 6176 episodes when surgeons noted the QPL was inappropriate. Surgeons reported the QPL empowered patients to ask questions (eg, "I've heard several comments saying that, you know, 'This pamphlet actually helped me constructing all the questions.'"). Thirty of 35 surgeons interviewed desired continued QPL use after study completion.

Figure 3. Observing Patient Involvement in Decision Making (OPTION5) Scores for Conversations About Major Surgery Between Surgeons and Patients With an Oncologic or Vascular Problem



QPL indicates question prompt list.

Discussion

Compared with usual care, the QPL intervention did not have a significant effect on patient engagement or well-being. However, a significant difference in the change in rating for MYCaW scores was observed for family members between 6 weeks after surgery and just after meeting with a surgeon, which was greater in the usual care group.

We note several explanations for the lack of QPL intervention effect on patient engagement outcomes. First, we had estimated QPL intervention penetrance near 80% given the common practice of mailing information to patients before clinic visits. However, there is a difference between mailing information and having information reviewed and used by those who receive it. We are confident the QPL was mailed to patients in the QPL intervention arm, but in this pragmatic study we did not take additional measures to ensure materials were reviewed by participants. We suspect the penetrance of the QPL intervention was closer to 40% to 50%, leaving us underpowered to perceive significant effects. Second, while this patient-mediated intervention to change communication is easy to implement relative to interventions that require physician training,[20-22] surgeon speech consumes much of the preoperative visit.[23] Therefore, it is not surprising the effects of a patient-mediated QPL intervention are small, perhaps too small to perceive in a study of this size. Third, in contrast to other studies,[24-26] participants consistently rated their surgeons at the highest end of the scale on assessments of patient engagement. It is unknown whether these ceiling effects reflect something unique about surgeons willing to participate in our study or if these measures can truly discriminate between patient satisfaction and perceived support for decision-making.

Although our primary outcomes related to well-being and regret were not significantly different, we saw a greater difference in family-reported MYCaW scores between 6 weeks after surgery and just after the surgical visit for participants in usual care. However, participants were asked to identify their most pressing concern and then rate it, so it is difficult to know how to interpret this finding given the wide variability of reported concerns. We posit this effect is largely because of family members in usual care rating the magnitude of their concerns higher after meeting with a surgeon, resulting in more change over time as those concerns resolved (eFigure 5 in Supplement 1). Additional analysis is needed to fully characterize the qualitative nature of these results; still, it appears the QPL may have had a small effect on mitigating family concerns after meeting with a surgeon. There was a small and significant difference in postsurgical PII scores, which were worse for patients in the QPL intervention group. However this small difference was not clinically significant.[19] When we adjusted for surgeon specialty, this effect attenuated and was nonsignificant for some measures.

Are these results enough to consider routine use of the QPL? The QPL is easy to implement, does not change visit length, and is low risk and low cost, particularly for clinics currently mailing previsit information to new patients. Furthermore, surgeons in our study, many of whom had 100 or more patients receive the QPL, believed the QPL intervention supported patients and desired continued use after study completion. While surgeons scored high relative to nonsurgeons in shared decision-making (OPTION5),[27,28] we observed improvement in OPTION5 scores with prolonged exposure to the QPL. We suspect the QPL changes the content of communication between surgeons and patients and note questions about options, postoperative expectations, and risks might seem obvious but are not often asked. Although surgeons can address these domains without prompting, because the patient-physician relationship is transactional, patients who are

actively engaged in back-and-forth communication are more likely to succeed in collaborative decision-making.[29] Moreover, in this cohort of older patients with multiple comorbidities facing major surgery, it is remarkable that questions were virtually nonexistent about care they would want if serious complications occurred (ie, advance care planning). Additional strategies to explore patient preferences in this high-risk group are needed.

Limitations

This study has limitations consistent with other studies[30-33] of communication interventions that failed to demonstrate efficacy of primary outcomes. Unlike physiologic outcomes, which are measured precisely with continuous variables, there are a range of outcomes and care trajectories related to communication for which the signal and noise are difficult to discriminate. Although we believe we chose the best measures to evaluate patient engagement, we used rigid definitions and categorical variables to avoid miscounting, which may have limited our ability to capture an effect. There were also unanticipated enrollment challenges because some eligible patients found study participation overwhelming. This was exacerbated by the stepped-wedge design when the need to move the study forward conflicted with filling the cohort. Finally, we developed strict entry criteria; however, on post hoc review we found 59 enrolled patients who did not actually discuss major oncologic or vascular surgery.

Conclusions

For older patients with comorbid illness considering major surgery, the QPL did not improve patient engagement or well-being. These findings raise questions about the ability to evaluate and change patient-physician communication without addressing clinician communication directly.

ARTICLE INFORMATION

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Author Contributions: Dr Schwarze had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
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Invited Commentary

Interventions to Improve Informed Consent
Perhaps Surgeons Should Speak Less and Listen More

Peter Angelos, MD, PhD

High-quality informed consent is central to the ethical practice of surgery. In this issue of *JAMA Surgery*, Schwarze and colleagues[1] report on a novel attempt to increase patient engagement and well-being by sending older surgical patients a question prompt list (QPL) before their visit with a surgeon. For older patients undergoing high-risk operations, the authors have appropriately pointed out that the surgical procedure is often the start of a lengthy hospitalization and subsequent substantial changes in their ability to live independently or return to preoperative health status. They sought to improve the informed consent process for this group of vulnerable patients by working with surgeons to develop an informational brochure with a list of 11 questions to prompt patients and family members to ask their surgeons about treatment options, expectations for recovery, and management of potential serious complications.

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The QPL was designed to improve the patient's active participation in informed consent discussions. However, Schwarze and colleagues[1] showed that the QPL did not enhance patient engagement or outcomes. However, if we explore the results further, several additional conclusions can be drawn. Surgeons overwhelmingly supported the use of a QPL, even without evidence of measurable benefit for patients, suggesting that surgeons appreciate the value in encouraging more patient interaction in the consent process. The authors found that surgeon speech consumed much of the preoperative visit; therefore, patients actually had little time to ask questions. An important lesson for surgeons is that saying less and soliciting more questions may improve patient engagement in the informed consent process.