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Utilizing Advance Care Planning Videos to Empower Perioperative Patients and Families: A Study Protocol of a Randomized Controlled Trial

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Title: Utilizing Advance Care Planning Videos to Empower Perioperative Patients and Families: A Study Protocol of a Randomized Controlled Trial

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ABSTRACT

Introduction: Despite positive health outcomes associated with advance care planning (ACP), little research has investigated the impact of ACP in surgical populations. Our goal is to evaluate how an ACP intervention video impacts the patient-centeredness of the patient-surgeon conversation during the presurgical consent visit. We hypothesize that patients who view the intervention will engage in more patient-centered communication with their surgeons compared to patients who view a control video.
Methods and analysis: Randomized controlled superiority trial of an ACP video with two study arms: intervention ACP video and control video; and four visits: baseline, presurgical consent, postoperative one week, and postoperative one month. Surgeons, patients, Principal Investigator, and analysts are blinded to the randomization assignment.

Setting: Single, academic, inner city, tertiary care hospital. Data collection began July 16, 2015 and continues to March 2017.

Participants: Patients recruited from nine surgical oncology clinicas who are undergoing major cancer surgery.

Interventions: In the intervention arm, patients view a patient preparedness video developed through extensive consultation with patients, surgeons, and other stakeholders. Patients randomized to the control arm viewed an informational video about the hospital surgical program.

Main Outcomes and Measures: Primary Outcome: Patient-centeredness of patient-surgeon conversations during the presurgical consent visit as measured through the Roter Interaction Analysis System (RIAS). Secondary outcomes: patient Hospital Anxiety and Depression Scale score; patient goals of care; patient, companion, and surgeon satisfaction; video helpfulness; medical decision maker designation; and the frequency patients watch the video. Intent-to-treat analysis will be used to assess the impact of video assignment upon outcomes. Sensitivity analyses will assess whether there are differential effects contingent upon patient or surgeon characteristics.
Ethics and Dissemination: This study has been approved by the Johns Hopkins School of Medicine Institutional Review Board and is registered on clinicaltrials.gov (NCT02489799, First received: July 1, 2015).

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Data Sharing and Competing Interest Statement

This is a study protocol and thus does not contain or reflect any primary data.

We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests.

Strengths and Limitations of this study:

Strengths:

- The intervention being tested, as well as the trial outcomes, were developed and selected through extensive stakeholder – patient, family member, surgeon, palliative care clinician – engagement.
- There is limited existing research of advance care planning and palliative care in surgical populations.
- The study will enable a detailed examination of the patient experience surrounding major cancer surgery as well as an indepth analysis of how surgeons and patients preoperatively discuss surgical risk.
- The study intervention is a video and thus, if effective, it can be easily disseminated.

Limitations

- The video was initially conceptualized for a pancreatic cancer population, though its content was broadened to address all major surgery; the final video address surgery, but not specifically pancreatic cancer or cancer surgery.
- The selected outcomes and timeframe of the study (one month following surgery) may be too short to fully capture the effect of the intervention.
- Surgeon and surgery level factors could influence study outcomes. For example, perhaps certain types of surgery are more likely to be associated with perioperative patient depression scores.
- The study cannot control for the potential effect of a patient's medical and surgical course on study outcomes.

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INTRODUCTION

In 2010, there were approximately 51 million surgeries performed in the United States.[1] Although most surgeries will be performed successfully, patient morbidity and mortality persist,[2-5] and some surgeries require postoperative life-sustaining treatments in an intensive care unit.[6] While patients may be stratified for perioperative complications, it is difficult to impossible to predict which patients will die or suffer a major perioperative complication.[3,5,7]

Advance care planning (ACP) is a process by which individuals contemplate future health states, clarify and discuss their goals, and express goals-informed wishes for those health states—particularly if illness may render that person unable to make decisions for him or herself in the future.[8] Evidence supports that ACP discussions may decrease health care utilization, while increasing patient satisfaction, use of hospice and palliative care, and compliance with a patient's end-of-life wishes.[9-13] For family members, ACP may also decrease anxiety, depression, and stress, while increasing satisfaction with the quality of care.[9,14,15] ACP is appropriate throughout multiple stages of illness and has not been associated with harm in previous studies.[16] Finally, the landmark 2014 Institute of Medicine report *Dying in America* advocates for increased ACP to explore patient wishes before they become acutely ill.[17]

As patients undergoing major surgery are at risk of perioperative morbidity and mortality, it is likely beneficial for them to initiate ACP prior to surgery. A recent systematic review of palliative care interventions for surgical populations[18] highlighted five studies that explored ACP interventions in surgical populations.[19-23] These interventions involved further training or activation of surgical providers (i.e., surgeons, anesthesiologists, and/or nurses) to have an ACP conversation with the patient prior to surgery and/or involvement of a palliative care specialist specifically to discuss ACP with the patient prior to surgery. These interventions found improved concordance and decreased decisional conflict between patients and surrogates about goals of care,[19,20,22] improved documentation regarding power of attorney,[21] and were deemed helpful by study participants;[20] none of these trials documented harms to patients or family members.

Verbal communication is the predominant modality for ACP between patients and providers[24] and was the communication modality used in the above ACP interventions in surgical populations.[19-23] Yet, there are multiple barriers to optimal verbal communication in the patient-doctor relationship. Most importantly, verbal communication about ACP is inherently inconsistent and subjective, as standardizing these conversations is challenging to impossible.[25-29] Conversations may also inaccurately convey the burden and outcomes of medical interventions, particularly when the patient has no previous knowledge or experience of aggressive medical treatments (i.e., intubation, artificial ventilation, artificial nutrition) and/or settings (i.e., an intensive care unit).[30] While ACP innately requires verbal communication between patients and providers, such communication can be facilitated or enhanced through educational tools, such as a video. Video ACP tools have inherently stable content and thus may be a more objective, simple to understand, and realistic modality through which to educate and activate patients about ACP.[31,32] Thirteen randomized controlled trials in varying populations support that video-based ACP tools can empower patients and families to have ACP-related discussions,[33-45] though none of these studies were completed in surgical populations.

This investigation builds on the paucity of research concerning video ACP tools in surgical populations.[18] Towards this goal, a randomized, controlled clinical trial was initiated (clinicaltrials.gov Identifier NCT02489799). The objective of this study is to evaluate an ACP video developed for patients and families pursuing aggressive surgical treatment for cancer. Patients will be randomized to (1) an intervention arm that views the ACP intervention video or (2) a control arm that views a control video.

OBJECTIVE

Our primary aim is to evaluate whether the ACP intervention video impacts the patient-centeredness of the patient-surgeon conversation during the audiorecorded presurgical consent visit. As

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this trial is funded by the Patient-Centered Outcomes Research Institute (PCORI), the primary aim was selected based on two years of intense engagement with patients and family members, as well as other key stakeholders including surgeons, anesthesiologists, surgical nurses, surgical intensive care unit nurses, palliative care clinicians, and health services researchers. We hypothesize that patients who view the intervention video will engage in more patient-centered communication with their surgeons, as compared to patients who view the control video (Hypothesis 1).

Our secondary aims explore how the ACP intervention video may impact other related outcomes, such as patient anxiety and depression, helpfulness of the video (from patient and companion perspectives), the patient's stated goals of care, satisfaction with the presurgical consent visit (from patient, companion, and surgeon perspectives, and from consensus perspectives), whether the patient designates a medical decision maker and discusses his/her wishes with this designated person, and the frequency with which patients watch the video outside of the site of recruitment. We will measure the patient's level of anxiety and depression during two separate presurgical visits, as well as one week after surgery, and one month after surgery. We hypothesize that patients who view the intervention video will be less anxious and depressed across all visits, as compared to patients who view the control video (Hypothesis 2). We hypothesize that patients will find the intervention video more helpful than the control video (Hypothesis 3). We also hypothesize that that patients will watch the intervention video more often than the control video (Hypothesis 4).

METHODS AND ANALYSIS

STUDY DESIGN

The study is a 2-arm, randomized superiority trial of an ACP video developed for patients undergoing major surgery for advanced cancer at a single, academic, inner city, tertiary care hospital. The study began data collection on July 16, 2015 (**Figure 1**).

Institutional Review Board Determination

The Johns Hopkins Medicine and the Sidney Kimmel Comprehensive Cancer Center Institutional Review Boards reviewed and approved the study protocol.

Study Sample Population

Our study sample includes patients undergoing major cancer surgery with one of nine surgeons participating in this study. These nine surgeons were chosen as they had sufficient cancer patient populations and were willing to be in the trial. All surgeons were comfortable with the ACP video and were shown both intervention and control videos prior to when data collection from their clinics commenced. In preparation for the study, surgeons described variations in their practice regarding presurgical visits and agreed on a single format to uniformly use for study patients; this format is comprised of at least two visits with the surgeon prior to the actual surgery.

Eligibility Criteria

Eligible patients must be undergoing major surgery such that, due to the surgery itself and/or the patient's underlying medical conditions, the surgeon plans to postoperatively admit the patient to the surgical intensive care unit (SICU). Major surgery is defined as "surgery involving a risk to the life of the patient; specifically: an operation upon an organ within the cranium, chest, abdomen, or pelvic cavity."[46] Study patients must also be scheduled for non-emergent surgery such that they have at least a day to review the video prior to signing surgical consent. Potential study patients must also meet the following inclusion criteria: plan to undergo surgery with one of the study surgeons, able to give informed consent, and able to speak English. Patients will be excluded if they are younger than 18 years old or have visual or hearing impairments such that they are unable to view and/or hear the study videos.

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Many patients are accompanied to the surgeon's clinic by a family member or friend (i.e. a "companion"). There is no screening of companions for eligibility to participate. If eligible patients have a companion present during the audiorecording, these individuals are orally consented prior to the recording. Companions under the age of 18 cannot participate in the audiorecording unless consented by parent/guardian. The oncologic surgeons (n=9) and any of their clinic staff or trainees also provide written consent to be audiorecorded.

Recruitment

Patients are recruited out of the nine surgical oncology clinics. Study staff wait in the clinics, and, if surgeons deem patients potentially eligible, study staff meet with patients to determine full eligibility, consent patients for the study, and conduct the baseline visit activities.

Patients are provided with a $25 gift card upon completion of the four visits of the study.

Due to the nature of major surgery, the study team anticipates some patient drop out due to emotional distress, time constraints, surgery cancellation, or patient death.

Randomization

With each study patient as a unit of randomization, we randomize immediately following enrollment so that the study patient receives either the intervention or control video (**Figure 2**). Patients are stratified by surgeon through a computer algorithm written in R,[47] which performed a block randomization with a block size of six. We are adopting a stratified approach to randomization as we hypothesize that individual differences in surgeon demeanor will also impact the patient-centeredness of the surgeon-patient communication. The surgeons, patients, companions, Principal Investigator, coders, and data analysts are blinded to the randomization assignment; however, the recruitment staff cannot be blinded as they show the video and provide a video link to study patients.

Study Arms

Patients are randomly assigned to one of two arms: intervention video or control video. Patients are randomized on site by study staff upon completion of patient consent. Both videos are six minutes in duration.

Intervention

Over the past two years, the study team developed a video-based ACP tool for patients pursuing aggressive surgical treatments. The video design process involved extensive engagement with patients and families and key stakeholders such as surgeons, palliative care clinicians, ACP experts, and surgical nurses, and included interviews, focus groups, stakeholder summits, and a de-identified cross-sectional survey regarding potential video content (further manuscripts in process).[48-51] The video features patients, companions, and medical professionals (two surgeons, one anesthesiologist, one SICU nurse) discussing both the course of a typical surgical day – pre-operative area, operating room, and SICU – as well as the importance of preoperative ACP – identifying a medical decision maker, discussing one's wishes with that decision maker, and communicating those wishes to the surgical team prior to the surgery.

Control

The control video is an informational video about the Johns Hopkins surgery program, which was created by the Marketing Department. The video catalogues the history and evolution of surgery at Johns Hopkins Medicine. The video highlights scientific developments and ongoing innovations in patient safety.

Primary Outcome - Roter Interaction Analysis System (RIAS)

The primary outcome is the surgeon-patient conversation as analyzed using the Roter Interaction Analysis System (RIAS). RIAS a quantitative coding system for medical dialogue, which has demonstrated reliability and predictive validity for patient satisfaction, utilization, and adherence.[52] The coding unit of analysis is a complete thought that varies in length from a single word to a sentence. The RIAS coder is blinded to the randomization assignment of the patient and is unaware of the study

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hypotheses. RIAS coding has a reliability of > 0.85 in most studies.[52] This study will have one coder for all recordings.

RIAS will also be used to calculate a patient-centeredness summary score, which has been used in past studies with predictive and concurrent validity for a variety of patient and physician outcomes.[53] The patient-centeredness summary score is a ratio of statements that reflect the psychosocial and socio-emotional elements of exchange about the lived illness experience of patients relative to statements that reflect a more biomedical and disease focused perspective. This score reflects the encounter as a whole, rather than an individual's dialogue. A value greater than one indicates a more patient-centered encounter; whereas, a value less than one indicates a more biomedical encounter.

Patient trajectory and secondary outcomes

The study includes four visits with each study patient: baseline visit (V1, non-recorded), presurgical consent visit (V2, recorded), postoperative one week visit (V3, non-recorded), and postoperative one month visit (V4, non-recorded; **Figure 3**).

Baseline Visit (V1)

Once consented for the study, patients complete self-administered measures including sociodemographic measures and a question concerning whether the patient has assigned a medical decision maker and how recently he/she has had a conversation with that medical decision maker about care preferences. Patients also complete the Hospital Anxiety and Depression Scale (HADS)[54] and the Iowa Criteria Goals of Care survey.[55]

Patients are randomized to either the intervention or control video. Patients then immediately view the video they were assigned in the presence of the study staff. The study staff also provide the patient a web link to the video so that they may show the video to others in their family and/or to view the video again at a later time or place.

Presurgical Consent Visit (V2)

Upon patient arrival in the clinic waiting room prior to their visit with the surgeon, study staff greet the patient, offer to show the patient the video again, and orally consent any companions who may be accompanying the patient. Once the patient is escorted back to an exam room, study staff place two recorders at different places in the room to capture the conversation during this visit. This audiorecording is used for the primary outcome RIAS analysis. For this study protocol, surgeons have agreed that the V2 goal is to discuss the risks and benefits of the upcoming surgery and for the patient to sign surgical consent. Immediately following this conversation, both the surgeon and the patient and/or companion complete the following questionnaires:

Satisfaction Measures

After the visit, the surgeon, patient, and companion each complete a short self-administered satisfaction questionnaire about the visit. The study team has adapted measures developed and used by Roter and colleagues in previous studies to address patient satisfaction with interpersonal and informational aspects of medical visits.[56-59] The patient satisfaction questionnaire includes six items; an eight item version used in a past study had a Cronbach's alpha of 0.89.[60] The clinician satisfaction questionnaire includes six items; an eight-item version used in a past study had a Cronbach's alpha of 0.83.[61] The companion satisfaction questionnaire includes eight items and has not been used in a past study, though it is directly based on the patient satisfaction questionnaire. The internal reliability of these questionnaires will be estimated with Cronbach's alpha.

Helpfulness Survey

Patients also complete a measure regarding their perceptions of the helpfulness of the video. Volandes et al. used this measure in their previous studies but do not report on the psychometric

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properties of the tool.[31,33,39-41,43] This measure asks whether the patient was comfortable watching the video, whether the patient perceived the video to be helpful in preparing him/her for surgery, and whether the patient would recommend the video to other patients.

Other V2 Measures

Patients also complete HADS and the Iowa Criteria Goals of Care measure. Companions complete self-administered questions about the nature of their relationship with the patient, as well as a self-administered survey about the helpfulness of the video.

Postsurgical One Week Visit (V3)

Approximately one week after the patients' surgery, a study staff meets with patients while they are still in the hospital, but after they have been transferred from the ICU to another unit. Patients complete the HADS and Iowa Criteria Goals of Care surveys.

Postsurgical One Month Visit (V4)

Approximately one month after the patients' surgery, study staff communicate with patients either in person during the patient's one month follow up with the surgeon or over the phone. The patient completes the HADS and Iowa Criteria Goals of Care surveys. Patients also answer one question regarding whether the patient has assigned a medical decision maker and how recently he/she has had a conversation with that medical decision maker about care preferences.

Medical Record Abstraction

Outside the scheduled study visits, the study team abstract medical record information, which is incorporated as descriptive data on each patient. Information abstracted includes the patient's primary diagnosis, surgical procedure, active medical history (e.g., hypertension, coronary artery disease), hospital admission and discharge (related to the major surgery they received), and any hospital readmission data collected within one month after the surgery. A second study team member independently verifies all medical record abstraction.

DATA COLLECTION

Mode of Data Entry

Patients enter all surveys directly into REDCap[62] on study computers; patients also have the option to complete surveys on paper at any point. Paper surveys are further available in the event of technical difficulties. Patients also have the option to complete questions verbally if they prefer not to input data into the computer or onto a paper form. Surgeon and companion surveys are completed on paper. All paper forms completed are entered into REDCap by one study staff member and independently verified by a second study staff member.

For medical record abstractions, the team uses information obtained from the hospital electronic medical record systems. Information is abstracted by one study staff member and independently verified by a second study staff member.

STATISTICAL METHODS

Statistical Significance and Software

The team will set the overall level of statistical significance at $P < .05$. All statistical analyses will be performed in Stata statistical software.[63] Analysis will be rerun in R to confirm results.

Intent-to-Treat

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Our study will use an intent-to-treat approach in which all data from study patients in both intervention and control arms are used, regardless of the level of adherence to the study arms. We have also designed the study to minimize the possibility of both patient crossovers between intervention groups, as well as to reduce the chance that patients may see the video to which they are not randomized.

Evaluation of Hypotheses Overview

Descriptive statistics will be calculated to summarize patients' characteristics and other baseline variables. Comparability of the intervention arm and the control arm will be assessed with regard to pre-intervention sociodemographic and health status measures derived from Medical Record Abstraction. While randomization should account for such differences, a two-sample t test/ Mann-Whitney test will be performed to investigate the difference in two means or medians for continuous variables, and Fisher's exact test or Chi-squared test will be used to investigate the difference in proportions for binary or categorical variables. We will therefrom identify and determine possible necessary adjustment for some baseline attributes. Historically, patient gender, age, race, education and health status have been identified as important attributes and are usually adjusted for in the model. Surgeon attributes will be examined similarly.

Further statistical analyses will explore the association between intervention assignment and each of the outcomes. Based on the type of the data, summary univariate (descriptive) statistics (mean, standard deviation, median, interquartile range, max, min, count, percentage) of all outcomes stratified by intervention assignment will be provided. Descriptive time trend plots (multiple visits) stratified by intervention assignment will be presented for outcomes that are measured at multiple visits. These plots will allow for the visual comparison of change patterns before and after the intervention in the two arms. Differences in outcomes between two arms at each visit will be tested by two-sample t test/Mann-Whitney test or Fisher's exact test/Chi-squared test, based on the data types of the outcomes.

For the primary outcome and some of the secondary outcomes, the descriptive statistical analyses will be followed by regression analyses, using mixed effects generalized linear models with link functions chosen that are specific to the data types of the outcomes. The data will have a two-level structure, being defined by individual patient nested within surgeons. To address the potential unmeasured influence of surgeon-level attributes on patient-level outcomes, we will model the variable "surgeon" as a random intercept. In most cases, the parameter of interest is the coefficient of the arm indicator, to be estimated as the intervention effect. All standard errors will be computed using the robust method.

Hypothesis 1

Specifically, the primary outcome, patient-centeredness of patient-surgeon conversations during a pre-surgical consent visit as measured through the Roter Interaction Analysis System (RIAS), is a continuous variable. Therefore, mixed effects linear regression models will be used, adjusting for relevant covariates, with inclusion of a random intercept for surgeon to account for the correlation of outcome values from patients of the same surgeon.

Hypothesis 2

The secondary outcome *HADS* consists of two subscales, symptoms of anxiety and symptoms of depression. Subscale scores range from 0, indicating no distress, to 21, indicating maximum distress; a score higher than 7 indicates clinically meaningful anxiety or depression.[54] We will therefore consider these two outcomes as two binary variables indicating the absence or presence of clinically meaningful anxiety or depression. HADS will be measured at all four visits. To examine the effect of the intervention on these two outcomes, mixed effects logistic regression models will be used, adjusting for baseline scores and other relevant covariates, with inclusion of a surgeon random intercept. This model will be used to assess the difference in HADS subscale scores between the two arms at V2, V3, and then at V4. To assess the robustness of our estimates, an alternative model with the inclusion of interaction terms between arm indicator and visit indicator will be used to estimate the difference in differences from

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baseline to later visits between the two arms. This will provide us information on the changes in HADS scores across visits within each arm as well as how the change patterns differ between the two arms.

Hypothesis 3

The secondary outcome *Video Helpfulness* will be measured at V2, and will be summarized into two categories, helpful vs. not helpful. A mixed effects logistic regression, adjusting for relevant covariates, with a surgeon random intercept will be used to compare the helpfulness of the intervention video and the control video.

Hypothesis 4

The frequencies the intervention video and control video are watched by patients outside of the medical clinic (i.e., the extent to which patients choose to watch the video on their own time outside of direct interaction with the study's staff) will be presented for comparison.

Other Outcomes and Hypotheses

Goals of Care (IOWA Goals of Care) has two questions. The first asks patients to check their current medical goals relating to their surgery. The second asks patients to list and rank the top three goals. Goals of care data are to be collected at all four visits. We will stratify the data by intervention assignment, and then calculate frequencies and percentages of goals of care chosen and being ranked as top three goals at each visit to assess the changes in goals of care across visits and differences between the two arms.

Patient and Surgeon Satisfaction will be measured at the end of V2. The satisfaction score, as the sum of the scores of six questions (all in a Likert scale), ranges from 6 to 30, with a higher score indicating higher level of satisfaction. The intervention effects on patient satisfaction score and surgeon satisfaction score (surgeon's perception of patient's satisfaction level) will be examined separately by mixed effects linear regression models, adjusting for relevant covariates, with inclusion of a random intercept for surgeon. Future analyses will also explore whether discrepancy exists between patients', companions', and surgeons' perception.

Medical Decision Maker Designation will be measured at baseline and V4. It is an ordered categorical variable consisting of four possible answer options: (1) No, I don't have a medical decision maker; (2) Yes, I have a medical decision maker, but we have not talked specifically talked about this [what medical decisions they should make for me]; (3) Yes, I have a medical decision maker, and our talk about this [what medical decisions they should make for me] was over six months ago; and (4) Yes, I have a medical decision maker, and our talk this [what medical decisions they should make for me] was within the last six months. We will construct a binary variable indicating whether there is an upward change in medical decision maker designation from V1 to V4. A mixed effects logistic regression, adjusting for baseline value and other relevant covariates, with a surgeon random intercept will be used to examine the difference in change patterns between the two arms.

DATA MONITORING

Data Security

During the data collection period, only the study team has access to the REDCap site that links the IDs to study patients. The electronic dataset and recordings are stored on an encrypted computer that is password protected with a secure server. All paper copies of the consent form are stored in a locked filing cabinet.

Study Management

We use standard processes to enhance data quality and reduce bias. We strive to have consistent recruitment staff at each study site, and all staff are required to follow the protocol document when

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interacting with patients. We monitor for data completeness on our REDCap data collection site to reduce missing or incomplete data, inaccuracies, and measurement bias and execessive variability. If we find missing data, we will run exploratory analyses to determine the missing data pattern, and then run appropriate analyses to address the problem and account for it in our models.

DESIGN JUSTIFICATIONS

Sample Size Calculation

The sample size calculation was based on a measure of patient-centeredness that was generated from the Roter Interaction Analysis System (RIAS). This measure incorporates the verbal contributions of patients, surgeons, and companions. Steinwachs et al.[61] used this patient-centeredness variable as the primary outcome in a study testing the effectiveness of a 20-minute computer-based intervention to activate patients to address a quality of care with their providers.[61] The intervention group experienced visits with significantly higher levels of patient-centeredness than the control group with an effect size of 0.6 (Cohen's d).[61]

With a 0.6 effect size, the required sample size is 72 patients (36 per group) for a one-tailed test of study hypotheses (power =.8 and alpha =.05). The study team determined that only a one-tailed test was necessary given that we are testing whether the intervention improves patient-centered communication. Based on the previous study,[61] we hypothesize that we would obtain recordings for 80-90% of recruited patients, with any discrepancies likely stemming from patient attrition, technology failure, and/or scheduling miscommunication. Accounting for an 80% recordings rate, the study team will need to recruit 90 patients to obtain the desired number of 72 recordings.

Once recruitment is complete, a power analysis will be performed to determine whether a conclusive finding or pattern of findings is due to insufficient power or the intervention.

Superiority Design

We powered our study for a one-tailed test as we believe that the intervention video will have a likely impact on the outcome.

Study Organization and Institutional Assurances

A Data and Safety Monitoring Board (DSMB) will independently review preliminary results after 50% of the data has been collected to determine whether the intervention is causing undue harm to the patients or their companions. In addition, per standard processes at our institution, the study will undergo a yearly audit. The hospital legal division was involved to ensure proper procedures for developing a video for research purpose and proper use of media releases.

ETHICS AND DISSEMINATION

This study is a two-arm, randomized superiority trial comparing the effectiveness of an ACP video tool as compared to a control video at increasing the patient-centeredness of presurgical consent conversations between surgeons and patients preparing for major cancer surgery. The risk to participants is low.

The current study examines how ACP might be incorporated into surgical settings. As patients undergoing major surgery are at risk for perioperative morbidity and mortality, it is appropriate for these patients to initiate ACP prior to surgery. While the surgical consent process involves an explanation of the risks and benefits of the surgery, previous research[64] suggests that surgeons may have difficulty discussing detailed ACP wishes. Using an ACP video, this study hopes to empower patients to have more meaningful presurgical contemplation and conversation with both family members and their surgical team concerning their goals and wishes prior to major surgery.

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If effective, the ACP video could be easily disseminated among patients, family members, surgery clinics, and/or other pertinent stakeholders. Timing of when the patient watches the video in relation to their surgery and/or their visit(s) with the surgeon can be determined in future studies or per individual decision by the patient or surgeon. In planning this study, participant surgeons noted practice variations within general "standard-of-care" including that some surgeons routinely met with patients at least twice before the day of surgery, while others would meet only once. For the purpose of this study, participant surgeons agreed on the above-described standardized format of two pre-surgery visits and therefore, timing of when the patient watched the video was standardized to be immediately after the surgeon recommended that the patient be scheduled for surgery.

In keeping with the principles of patient-centered outcomes research, both the intervention video and the resulting randomized control trial to assess its impact have been designed with extensive input from patients, family members, surgeons, health researchers, and other stakeholders. This trial is also overseen by a readily available patient/family co-investigator who communicates at least monthly with the study team and reviews study progress as well as participates in data evaluation. Thus, the current investigation is patient-centered not only in outcomes, but also in facilitation and data analysis.

Potential Contributions of this Study

To the best of our knowledge, this is the first investigation to explore the impact of a video ACP tool on surgeon, patient, and family communication prior to major surgery. A strength of this study is that the intervention video and resulting randomized control trial were both developed based on input from patients, companions, surgeons, health services researchers, and other stakeholders. Ultimately, the results of this RCT may demonstrate that easy-to-disseminate videos may activate patients and improve the patient-centeredness of surgeon/patient interactions.

Limitations

Several limitations regarding the study should be noted. First, the intervention video was initially conceptualized for a pancreatic cancer surgical population, potentially creating an issue for the generalizability of the video to a wider surgical population. Although the video was initially developed for the pancreatic cancer setting, the severity of pancreatic cancer surgery is analogous to other high-mortality/high-morbidity cancer surgeries. Moreover, the video itself does not specifically discuss cancer or pancreatic cancer. Thus, the intervention video should be relevant to a range of surgical patients and their families and is being evaluated among a group of patients with diverse cancer diagnoses.

Second, the selected outcomes and timeframe of the study may not be able to fully capture the effect of the intervention as the impact of the surgery and video may persist beyond the one month time frame of the study. In order to mitigate this concern, data for multiple patient-centered outcomes is collected, many of which have been previously validated and used in surgical settings. These outcomes enable multi-faceted evaluation of the intervention. Additionally, results will be examined at several time-points, including both pre-operatively (V1, V2) and post-operatively (V3, V4). Yet, as other studies have shown benefit of ACP discussions as far as 12 months after hospitalization and patient death,[65] we might also hypothesize further benefits of the intervention to be apparent just before and after patient death, which is outside of the current trial timeframe.

Third, surgeon level factors will likely influence study outcomes. As all surgeons were privy to a general overview of the study and were provided with the opportunity to watch the intervention and control videos prior to agreeing to participate, the surgeons who ultimately decided to participate in the study may be biased in their pre-existing support for ACP. It is also possible that surgeons may have their own unconscious selection biases when referring patients to the study.

Fourth, one of the participating surgeons was featured in the intervention video. It is therefore possible that patients of this surgeon who are randomized to watch this video might surmise they are in the intervention group, which might impact their outcomes. In order to best account for these potential sources of bias, study randomization is nested within surgeon site of recruitment. Further, the analysis

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plan's designation of the surgeon as a random intercept should address the potential unmeasured influence of surgeon-level attributes on patient-level outcomes.

A final limitation of the study is that it can not control for the effect of a patient's medical course on study outcomes. Both presurgical factors such as diagnosis, as well as postsurgical factors such as surgical course or change in prognosis, might contribute to anxiety and depression, as well as to a patient's goals of care.

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AUTHORS' CONTRIBUTIONS

RAA is the study principal investigator and she directed all study activities and coordinated between team members.

Study design: RAA, SRI, TY, MW, AEV, JFPB, DLR

Analysis design: RAA, SRI, TY, NLC, DLR

Protocol generation: RAA, SRI, NLC, AMCC, TY

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Figure legends

Figure 1. Trial Timeline

Figure 2. Trial Enrollment Diagram

Figure 3. Data Collection Plan

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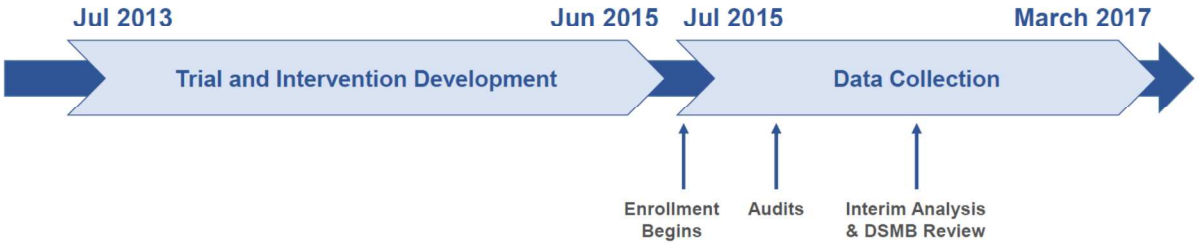

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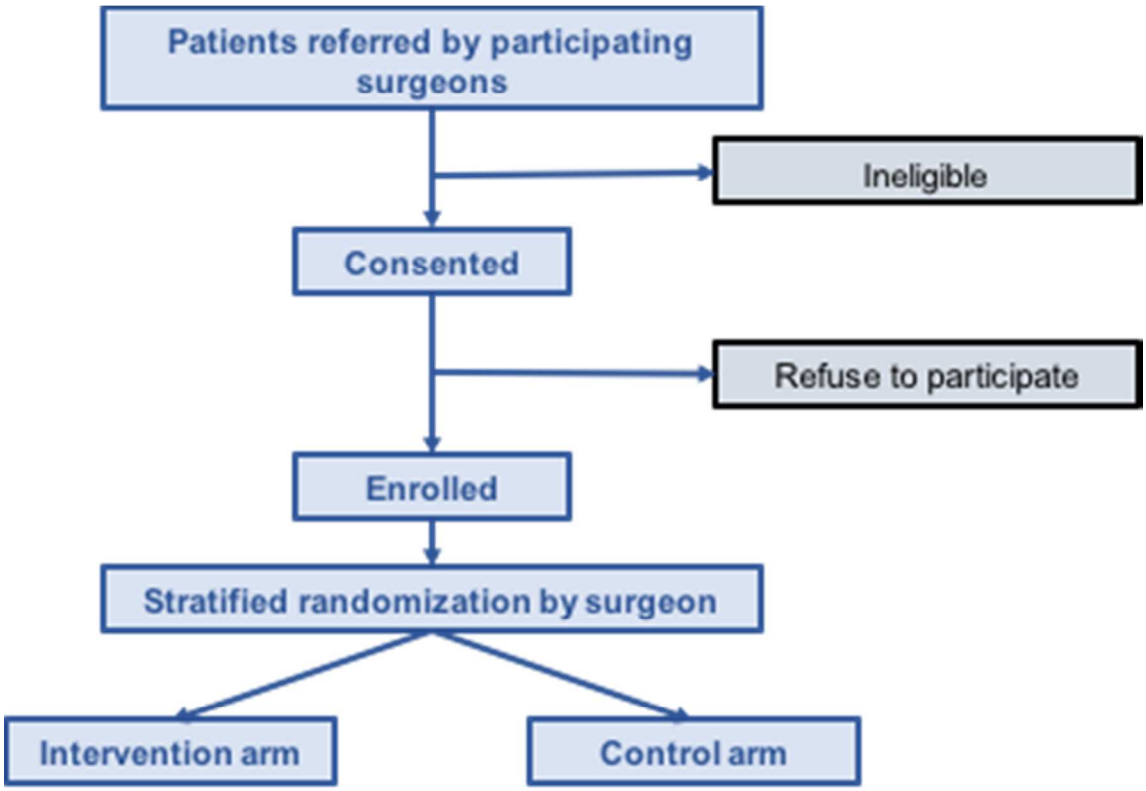

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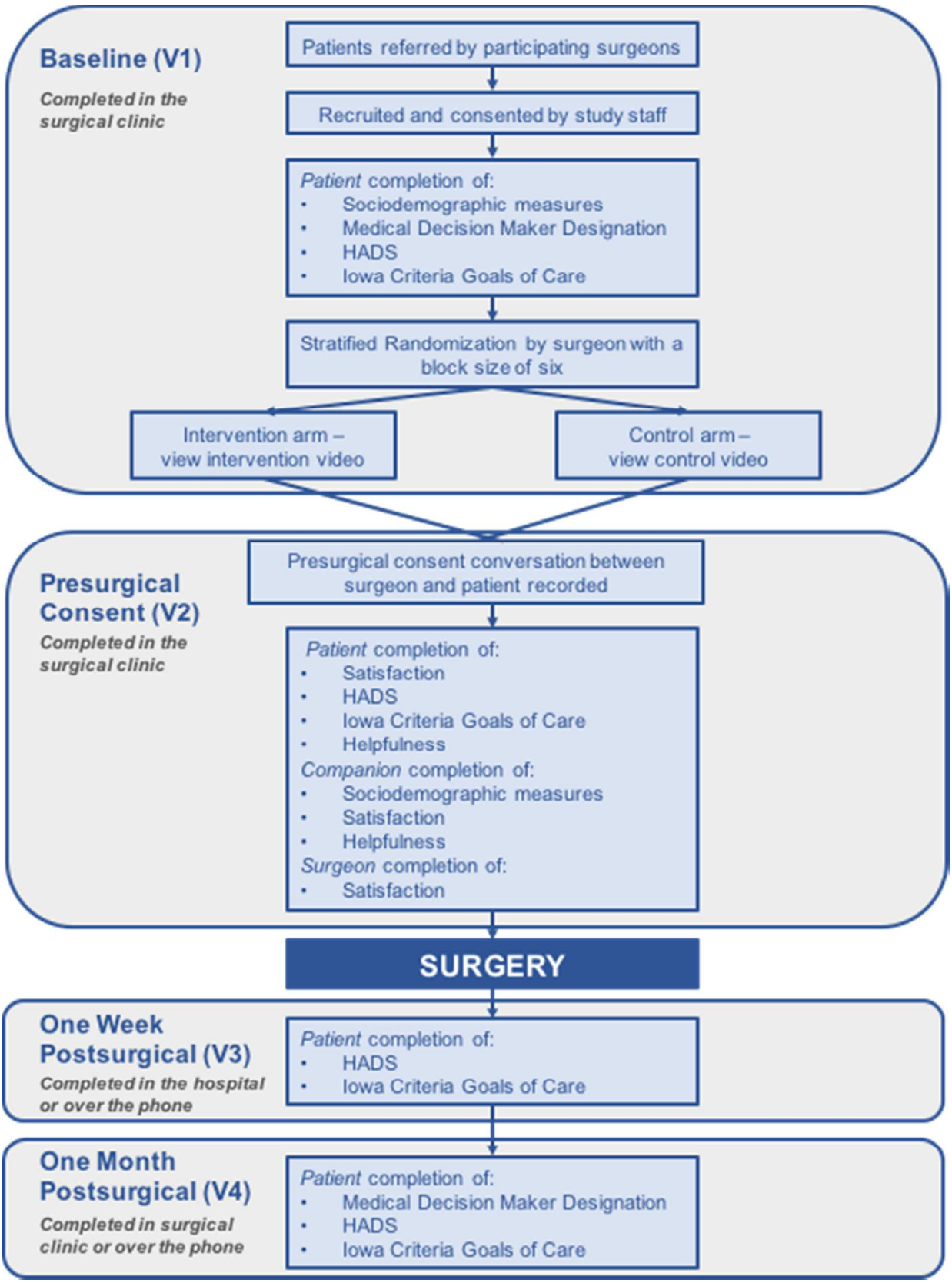
Baseline (V1)
Completed in the surgical clinic
Patients referred by participating surgeons
Recruited and consented by study staff
Patient completion of:
• Sociodemographic measures
• Medical Decision Maker Designation
• HADS
• Iowa Criteria Goals of Care
Stratified Randomization by surgeon with a block size of six
Intervention arm – view intervention video
Control arm – view control video
Presurgical Consent (V2)
Completed in the surgical clinic
Presurgical consent conversation between surgeon and patient recorded
Patient completion of:
• Satisfaction
• HADS
• Iowa Criteria Goals of Care
• Helpfulness
Companion completion of:
• Sociodemographic measures
• Satisfaction
• Helpfulness
Surgeon completion of:
• Satisfaction
SURGERY
One Week Postsurgical (V3)
Completed in the hospital or over the phone
Patient completion of:
• HADS
• Iowa Criteria Goals of Care
One Month Postsurgical (V4)
Completed in surgical clinic or over the phone
Patient completion of:
• Medical Decision Maker Designation
• HADS
• Iowa Criteria Goals of Care

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Utilizing Advance Care Planning Videos to Empower Perioperative Cancer Patients and Families: A Study Protocol of a Randomized Controlled Trial

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Title: Utilizing Advance Care Planning Videos to Empower Perioperative Cancer Patients and Families: A Study Protocol of a Randomized Controlled Trial

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ABSTRACT

Introduction: Despite positive health outcomes associated with advance care planning (ACP), little research has investigated the impact of ACP in surgical populations. Our goal is to evaluate how an ACP intervention video impacts the patient-centeredness of the patient-surgeon conversation during the presurgical consent visit. We hypothesize that patients who view the intervention will engage in more patient-centered communication with their surgeons compared to patients who view a control video.
Methods and analysis: Randomized controlled superiority trial of an ACP video with two study arms: intervention ACP video and control video; and four visits: baseline, presurgical consent, postoperative one week, and postoperative one month. Surgeons, patients, Principal Investigator, and analysts are blinded to the randomization assignment.

Setting: Single, academic, inner city, tertiary care hospital. Data collection began July 16, 2015 and continues to March 2017.

Participants: Patients recruited from nine surgical oncology clinicas who are undergoing major cancer surgery.

Interventions: In the intervention arm, patients view a patient preparedness video developed through extensive consultation with patients, surgeons, and other stakeholders. Patients randomized to the control arm viewed an informational video about the hospital surgical program.

Main Outcomes and Measures: Primary Outcome: Patient-centeredness of patient-surgeon conversations during the presurgical consent visit as measured through the Roter Interaction Analysis System (RIAS). Secondary outcomes: patient Hospital Anxiety and Depression Scale score; patient goals of care; patient, companion, and surgeon satisfaction; video helpfulness; medical decision maker designation; and the frequency patients watch the video. Intent-to-treat analysis will be used to assess the impact of video assignment upon outcomes. Sensitivity analyses will assess whether there are differential effects contingent upon patient or surgeon characteristics.
Ethics and Dissemination: This study has been approved by the Johns Hopkins School of Medicine Institutional Review Board and is registered on clinicaltrials.gov (NCT02489799, First received: July 1, 2015).

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Trial Registration: clinicaltrials.gov Identifier NCT02489799

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Data Sharing and Competing Interest Statement

This is a study protocol and thus does not contain or reflect any primary data.

We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests.

Strengths and Limitations of this study:

Strengths:

- The intervention being tested, as well as the trial outcomes, were developed and selected through extensive stakeholder – patient, family member, surgeon, palliative care clinician – engagement.
- There is limited existing research of advance care planning and palliative care in surgical populations.
- The study will enable a detailed examination of the patient experience surrounding major cancer surgery as well as an indepth analysis of how surgeons and patients preoperatively discuss surgical risk.
- The study intervention is a video and thus, if effective, it can be easily disseminated.

Limitations

- The video was initially conceptualized for a pancreatic cancer population, though its content was broadened to address all major surgery; the final video addresses surgery, but not specifically pancreatic cancer or cancer surgery.
- The selected outcomes and timeframe of the study (one month following surgery) may be too short to fully capture the effect of the intervention.
- Surgeon and surgery level factors could influence study outcomes. For example, perhaps certain types of surgery are more likely to be associated with perioperative patient depression scores.
- The study cannot control for the potential effect of a patient's medical and surgical course on study outcomes.

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INTRODUCTION

In 2010, there were approximately 51 million surgeries performed in the United States.[1] Although most surgeries will be performed successfully, patient morbidity and mortality persist,[2-5] and some surgeries require postoperative life-sustaining treatments in an intensive care unit.[6] While patients may be stratified for perioperative complications, it is difficult to impossible to predict which patients will die or suffer a major perioperative complication.[3,5,7]

Advance care planning (ACP) is a process by which individuals contemplate future health states, clarify and discuss their goals, and express goals-informed wishes for those health states—if illness may render that person unable to make decisions for him or herself in the future.[8] Evidence supports that ACP discussions may decrease health care utilization, while increasing patient satisfaction, use of hospice and palliative care, and compliance with a patient's end-of-life wishes.[9-13] For family members, ACP may also decrease anxiety, depression, and stress, while increasing satisfaction with the quality of care.[9,14,15] ACP is appropriate throughout multiple stages of illness and has not been associated with harm in previous studies.[16] Finally, the landmark 2014 Institute of Medicine report *Dying in America* advocates for increased ACP to explore patient wishes before they become acutely ill.[17]

As patients with advanced cancer undergoing major surgery often experience conditions that may increase their risk for both complications during surgery and post-operative outcomes (e.g., functional decline, frailty, comorbidities, and polypharmacy),[18-22] it is likely beneficial for them to initiate ACP prior to surgery. A recent systematic review of palliative care interventions for surgical populations[23] highlighted five studies that explored ACP interventions in surgical populations.[24-28] These interventions involved further training or activation of surgical providers (i.e., surgeons, anesthesiologists, and/or nurses) to have an ACP conversation with the patient prior to surgery and/or involvement of a palliative care specialist specifically to discuss ACP with the patient prior to surgery. These interventions found improved concordance and decreased decisional conflict between patients and surrogates about goals of care,[24,25,27] improved documentation regarding power of attorney,[26] and were deemed helpful by study participants;[25] none of these trials documented harms to patients or family members.

Verbal communication is the predominant modality for ACP between patients and providers[29] and was the communication modality used in the above ACP interventions in surgical populations.[19-23] Yet, there are multiple barriers to optimal verbal communication in the patient-doctor relationship. Most importantly, verbal communication about ACP is inherently inconsistent and subjective, as standardizing these conversations is challenging to impossible.[30-34] Conversations may also inaccurately convey the burden and outcomes of medical interventions, particularly when the patient has no previous knowledge or experience of aggressive medical treatments (i.e., intubation, artificial ventilation, artificial nutrition) and/or settings (i.e., an intensive care unit).[35] While ACP innately requires verbal communication between patients and providers, such communication can be facilitated or enhanced through educational tools, such as a video. Video ACP tools have inherently stable content and thus may be a more objective, simple to understand, and realistic modality through which to educate and activate patients about ACP.[36,37] Thirteen randomized controlled trials in varying populations support that video-based ACP tools can empower patients and families to have ACP-related discussions,[38-50] though none of these studies were completed in surgical populations.

This investigation builds on the paucity of research concerning video ACP tools in surgical populations.[23] Towards this goal, a randomized, controlled clinical trial was initiated (clinicaltrials.gov Identifier NCT02489799).

OBJECTIVE

The objective of this study is to evaluate whether, compared to a control video, an ACP video developed for patients and families pursuing aggressive surgical treatment for cancer impacts the patient centeredness of the patient-surgeon conversation during the audiorecorded presurgical consent visit. The trial is funded by the Patient Centered Outcomes Research Institute, which supports comparative

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effectiveness research to help patients and other stakeholders make informed medical decisions.[51] In light of this funding, the primary aim was selected based on two years of intense engagement with patients and family members, as well as other key stakeholders including surgeons, anesthesiologists, surgical nurses, surgical intensive care unit nurses, palliative care clinicians, and health services researchers. We hypothesize that patients who view the intervention video will engage in more patient-centered communication with their surgeons, as compared to patients who view the control video (Hypothesis 1).

Our secondary aims explore multiple other patient and companion outcomes. Of note, accompanying family members or friends (i.e., "companions") are often present during the audiorecording of the presurgical visit. Our secondary outcomes include: how the ACP intervention video may impact mood-related outcomes, such as patient anxiety and depression; helpfulness of the video (from patient and companion perspectives); the patient's stated goals of care; satisfaction with the presurgical consent visit (from patient, companion, and surgeon perspectives, and from consensus perspectives); whether the patient designates a medical decision maker and discusses his/her wishes with this designated person; and the frequency with which patients watch the video outside of the site of recruitment. We will measure the patient's level of anxiety and depression during two separate presurgical visits, as well as one week after surgery, and one month after surgery. We hypothesize that patients who view the intervention video will be less anxious and depressed across all visits, as compared to patients who view the control video (Hypothesis 2). We hypothesize that patients will find the intervention video more helpful than the control video (Hypothesis 3). We also hypothesize that that patients will watch the intervention video more often than the control video (Hypothesis 4).

METHODS AND ANALYSIS

STUDY DESIGN

The study is a 2-arm, randomized superiority trial of an ACP video developed for patients undergoing major surgery for advanced cancer at a single, academic, inner city, tertiary care hospital. The study began data collection on July 16, 2015 (**Figure 1**).

Institutional Review Board Determination

The Johns Hopkins Medicine and the Sidney Kimmel Comprehensive Cancer Center Institutional Review Boards (IRB) reviewed and approved the study protocol. All changes in study protocol, as needed, are to be submitted and reviewed by the IRB.

Study Sample Population

Our study sample includes patients undergoing major cancer surgery with one of nine surgeons participating in this study. These nine surgeons were chosen as they had sufficient cancer patient populations and were willing to be in the trial. All surgeons were comfortable with the ACP video and were shown both intervention and control videos prior to when data collection from their clinics commenced. In preparation for the study, surgeons described variations in their practice regarding presurgical visits and agreed on a single format to uniformly use for study patients; this format is comprised of at least two visits with the surgeon prior to the actual surgery. Based on sample size calculations, explained in the Design Justification section below, we aimed to recruit 90 patients for the study.

Eligibility Criteria

Eligible patients must be undergoing major surgery such that, due to the surgery itself and/or the patient's underlying medical conditions, the surgeon plans to postoperatively admit the patient to the surgical intensive care unit (SICU). Major surgery is defined as "surgery involving a risk to the life of the patient; specifically: an operation upon an organ within the cranium, chest, abdomen, or pelvic cavity."[52] Study patients must also be scheduled for non-emergent surgery such that they have at least a day to

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review the video prior to signing surgical consent. Potential study patients must also meet the following inclusion criteria: plan to undergo surgery with one of the study surgeons, able to give informed consent, and able to speak English. Patients will be excluded if they are younger than 18 years old or have visual or hearing impairments such that they are unable to view and/or hear the study videos.

Many patients are accompanied to the surgeon's clinic by a family member or friend (i.e. a "companion"). There is no screening of companions for eligibility to participate. If eligible patients have a companion present during the audiorecording, these individuals are orally consented prior to the recording. Companions under the age of 18 cannot participate in the audiorecording unless consented by parent/guardian. The oncologic surgeons (n=9) and any of their clinic staff or trainees also provide written consent to be audiorecorded.

Recruitment

Patients are recruited out of the nine surgical oncology clinics. Study staff wait in the clinics, and, if surgeons deem patients potentially eligible, study staff meet with patients to determine full eligibility, consent patients for the study, and conduct the baseline visit activities.

Patients are provided with a $25 gift card upon completion of the four visits of the study.

Due to the nature of major surgery, the study team anticipates some patient drop out due to emotional distress, time constraints, surgery cancellation, or patient death.

Randomization

With each study patient as a unit of randomization, we randomize immediately following enrollment so that the study patient receives either the intervention or control video (**Figure 2**). Patients are stratified by surgeon through a computer algorithm written in R,[53] which performed a block randomization with a block size of six. We are adopting a stratified approach to randomization as we hypothesize that individual differences in surgeon demeanor will also impact the patient-centeredness of the surgeon-patient communication. We do not anticipate surgeons to recruit an equal number of patients given differences in practice type and volume; however, each surgeon was encouraged to recruit at least three patients to allow for clustering by surgeon in our analysis. The surgeons, patients, companions, Principal Investigator, coders, and data analysts are blinded to the randomization assignment; however, the recruitment staff cannot be blinded as they show the video and provide a video link to study patients.

Study Arms

Patients are randomly assigned to one of two arms: intervention video or control video. Patients are randomized on site by study staff upon completion of patient consent. Both videos are six minutes in duration.

Intervention

Over the past two years, the study team developed a video-based ACP tool for patients pursuing aggressive surgical treatments. The video design process involved extensive engagement with patients and families and key stakeholders such as surgeons, palliative care clinicians, ACP experts, and surgical nurses, and included interviews, focus groups, stakeholder summits, and a de-identified cross-sectional survey regarding potential video content (further manuscripts in process).[54-57] The video features patients, companions, and medical professionals (two surgeons, one anesthesiologist, one SICU nurse) discussing both the course of a typical surgical day – pre-operative area, operating room, and SICU – as well as the importance of preoperative ACP – identifying a medical decision maker, discussing one's wishes with that decision maker, and communicating those wishes to the surgical team prior to the surgery.

Control

The control video is an informational video about the Johns Hopkins surgery program, which was created by the Marketing Department. The video catalogues the history and evolution of surgery at Johns Hopkins Medicine. The video highlights scientific developments and ongoing innovations in patient safety.

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Primary Outcome - Roter Interaction Analysis System (RIAS)

The primary outcome is the surgeon-patient conversation as analyzed using the Roter Interaction Analysis System (RIAS). RIAS a quantitative coding system for medical dialogue, which has demonstrated reliability and predictive validity for patient satisfaction, utilization, and adherence.[58] The coding unit of analysis is a complete thought that varies in length from a single word to a sentence. The RIAS coder is blinded to the randomization assignment of the patient and is unaware of the study hypotheses. RIAS coding has a reliability of > 0.85 in most studies.[58] This study will have one coder for all recordings.

RIAS will also be used to calculate a patient-centeredness summary score, which has been used in past studies with predictive and concurrent validity for a variety of patient and physician outcomes.[59] The patient-centeredness summary score is a ratio of statements that reflect the psychosocial and socio-emotional elements of exchange about the lived illness experience of patients relative to statements that reflect a more biomedical and disease focused perspective. This score reflects the encounter as a whole, rather than an individual's dialogue. A value greater than one indicates a more patient-centered encounter; whereas, a value less than one indicates a more biomedical encounter.

Patient trajectory and secondary outcomes

The study includes four visits with each study patient: baseline visit (V1, non-recorded), presurgical consent visit (V2, recorded), postoperative one week visit (V3, non-recorded), and postoperative one month visit (V4, non-recorded; **Figure 3**).

Baseline Visit (V1)

Once consented for the study, patients complete self-administered measures including sociodemographic measures and a question concerning whether the patient has assigned a medical decision maker and how recently he/she has had a conversation with that medical decision maker about care preferences. Patients also complete the Hospital Anxiety and Depression Scale (HADS)[60] and the Iowa Criteria Goals of Care survey.[61]

Patients are randomized to either the intervention or control video. Patients then immediately view the video they were assigned in the presence of the study staff. Surgeon stakeholders involved in the design of the study recommended this timing for the video viewing. The study staff also provide the patient a web link to the video so that they may show the video to others in their family and/or to view the video again at a later time or place.

Presurgical Consent Visit (V2)

Upon patient arrival in the clinic waiting room prior to their visit with the surgeon, study staff greet the patient, offer to show the patient the video again, and orally consent any companions who may be accompanying the patient. Once the patient is escorted back to an exam room, study staff place two recorders at different places in the room to capture the conversation during this visit. This audiorecording is used for the primary outcome RIAS analysis. For this study protocol, surgeons have agreed that the V2 goal is to discuss the risks and benefits of the upcoming surgery and for the patient to sign surgical consent. Immediately following this conversation, both the surgeon and the patient and/or companion complete the following questionnaires:

Satisfaction Measures

After the visit, the surgeon, patient, and companion each complete a short self-administered satisfaction questionnaire about the visit. The study team has adapted measures developed and used by Roter and colleagues in previous studies to address patient satisfaction with interpersonal and informational aspects of medical visits.[62-65] The patient satisfaction questionnaire includes six items; an eight item version used in a past study had a Cronbach's alpha of 0.89.[66] The clinician satisfaction questionnaire includes six items; an eight-item version used in a past study had a Cronbach's alpha of

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0.83.[67] The companion satisfaction questionnaire includes eight items and has not been used in a past study, though it is directly based on the patient satisfaction questionnaire. The internal reliability of these questionnaires will be estimated with Cronbach's alpha.

Helpfulness Survey

Patients also complete a measure regarding their perceptions of the helpfulness of the video. Volandes et al. used this measure in their previous studies but do not report on the psychometric properties of the tool.[36,38,44-46,48] This measure asks whether the patient was comfortable watching the video, whether the patient perceived the video to be helpful in preparing him/her for surgery, and whether the patient would recommend the video to other patients.

Other V2 Measures

Patients also complete HADS and the Iowa Criteria Goals of Care measure. Companions complete self-administered questions about the nature of their relationship with the patient, as well as a self-administered survey about the helpfulness of the video.

Postsurgical One Week Visit (V3)

Approximately one week after the patients' surgery, a study staff meets with patients while they are still in the hospital, but after they have been transferred from the ICU to another unit. Patients complete the HADS and Iowa Criteria Goals of Care surveys.

Postsurgical One Month Visit (V4)

Approximately one month after the patients' surgery, study staff communicate with patients either in person during the patient's one month follow up with the surgeon or over the phone. The patient completes the HADS and Iowa Criteria Goals of Care surveys. Patients also answer one question regarding whether the patient has assigned a medical decision maker and how recently he/she has had a conversation with that medical decision maker about care preferences.

Medical Record Abstraction

Outside the scheduled study visits, the study team abstract medical record information, which is incorporated as descriptive data on each patient. Information abstracted includes the patient's primary diagnosis, surgical procedure, active medical history (e.g., hypertension, coronary artery disease), hospital admission and discharge (related to the major surgery they received), and any hospital readmission data collected within one month after the surgery. A second study team member independently verifies all medical record abstraction.

DATA COLLECTION

Mode of Data Entry

Study data were collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at Johns Hopkins Medical Institutions.[68] REDCap is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. Patients enter all surveys directly into REDCap[68] on study computers; patients also have the option to complete surveys on paper at any point. Paper surveys are further available in the event of technical difficulties. Patients also have the option to complete questions verbally if they prefer not to input data into the computer or onto a paper form. Surgeon and companion surveys are completed on paper. All paper forms completed are entered into REDCap by one study staff member and independently verified by a second study staff member.

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For medical record abstractions, the team uses information obtained from the hospital electronic medical record systems. Information is abstracted by one study staff member and independently verified by a second study staff member.

STATISTICAL METHODS

Statistical Significance and Software

The team will set the overall level of statistical significance at $P < .05$. All statistical analyses will be performed in Stata statistical software.[69] Analysis will be rerun in R statistical software to confirm results.[53]

Intent-to-Treat

Our study will use an intent-to-treat approach in which all data from study patients in both intervention and control arms are used, regardless of the level of adherence to the study arms. We have also designed the study to minimize the possibility of both patient crossovers between intervention groups, as well as to reduce the chance that patients may see the video to which they are not randomized.

Evaluation of Hypotheses Overview

Descriptive statistics will be calculated to summarize patients' characteristics and other baseline variables. Comparability of the intervention arm and the control arm will be assessed with regard to pre-intervention sociodemographic and health status measures derived from Medical Record Abstraction. While randomization should account for such differences, a two-sample t test/ Mann-Whitney test will be performed to investigate the difference in two means or medians for continuous variables, and Fisher's exact test or Chi-squared test will be used to investigate the difference in proportions for binary or categorical variables. We will therefrom identify and determine possible necessary adjustment for some baseline attributes. Historically, patient gender, age, race, education and health status have been identified as important attributes and are usually adjusted for in the model. Surgeon attributes will be examined similarly.

Further statistical analyses will explore the association between intervention assignment and each of the outcomes. Based on the type of the data, summary univariate (descriptive) statistics (mean, standard deviation, median, interquartile range, max, min, count, percentage) of all outcomes stratified by intervention assignment will be provided. Descriptive time trend plots (multiple visits) stratified by intervention assignment will be presented for outcomes that are measured at multiple visits. These plots will allow for the visual comparison of change patterns before and after the intervention in the two arms. Differences in outcomes between two arms at each visit will be tested by two-sample t test/Mann-Whitney test or Fisher's exact test/Chi-squared test, based on the data types of the outcomes.

For the primary outcome and some of the secondary outcomes, the descriptive statistical analyses will be followed by regression analyses, using mixed effects generalized linear models with link functions chosen that are specific to the data types of the outcomes. The data will have a two-level structure, being defined by individual patient nested within surgeons. To address the potential unmeasured influence of surgeon-level attributes on patient-level outcomes, we will model the variable "surgeon" as a random intercept. In most cases, the parameter of interest is the coefficient of the arm indicator, to be estimated as the intervention effect. All standard errors will be computed using the robust method.

Hypothesis 1

Specifically, the primary outcome, patient-centeredness of patient-surgeon conversations during a pre-surgical consent visit as measured through the Roter Interaction Analysis System (RIAS), is a continuous variable. Therefore, mixed effects linear regression models will be used, adjusting for relevant covariates, with inclusion of a random intercept for surgeon to account for the correlation of outcome values from patients of the same surgeon.

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Hypothesis 2

The secondary outcome *HADS* consists of two subscales, symptoms of anxiety and symptoms of depression. Subscale scores range from 0, indicating no distress, to 21, indicating maximum distress; a score higher than 7 indicates clinically meaningful anxiety or depression.[60] We will therefore consider these two outcomes as two binary variables indicating the absence or presence of clinically meaningful anxiety or depression. HADS will be measured at all four visits. To examine the effect of the intervention on these two outcomes, mixed effects logistic regression models will be used, adjusting for baseline scores and other relevant covariates, with inclusion of a surgeon random intercept. This model will be used to assess the difference in HADS subscale scores between the two arms at V2, V3, and then at V4. To assess the robustness of our estimates, an alternative model with the inclusion of interaction terms between arm indicator and visit indicator will be used to estimate the difference in differences from baseline to later visits between the two arms. This will provide us information on the changes in HADS scores across visits within each arm as well as how the change patterns differ between the two arms.

Hypothesis 3

The secondary outcome *Video Helpfulness* will be measured at V2, and will be summarized into two categories, helpful vs. not helpful. A mixed effects logistic regression, adjusting for relevant covariates, with a surgeon random intercept will be used to compare the helpfulness of the intervention video and the control video.

Hypothesis 4

The frequencies the intervention video and control video are watched by patients outside of the medical clinic (i.e., the extent to which patients choose to watch the video on their own time outside of direct interaction with the study's staff) will be presented for comparison.

Other Outcomes and Hypotheses

Goals of Care (IOWA Goals of Care) has two questions. The first asks patients to check their current medical goals relating to their surgery. The second asks patients to list and rank the top three goals. Goals of care data are to be collected at all four visits. We will stratify the data by intervention assignment, and then calculate frequencies and percentages of goals of care chosen and being ranked as top three goals at each visit to assess the changes in goals of care across visits and differences between the two arms.

Patient and Surgeon Satisfaction will be measured at the end of V2. The satisfaction score, as the sum of the scores of six questions (all in a Likert scale), ranges from 6 to 30, with a higher score indicating higher level of satisfaction. The intervention effects on patient satisfaction score and surgeon satisfaction score (surgeon's perception of patient's satisfaction level) will be examined separately by mixed effects linear regression models, adjusting for relevant covariates, with inclusion of a random intercept for surgeon. Future analyses will also explore whether discrepancy exists between patients', companions', and surgeons' perception.

Medical Decision Maker Designation will be measured at baseline and V4. It is an ordered categorical variable consisting of four possible answer options: (1) No, I don't have a medical decision maker; (2) Yes, I have a medical decision maker, but we have not talked specifically talked about this [what medical decisions they should make for me]; (3) Yes, I have a medical decision maker, and our talk about this [what medical decisions they should make for me] was over six months ago; and (4) Yes, I have a medical decision maker, and our talk this [what medical decisions they should make for me] was within the last six months. We will construct a binary variable indicating whether there is an upward change in medical decision maker designation from V1 to V4. A mixed effects logistic regression, adjusting for baseline value and other relevant covariates, with a surgeon random intercept will be used to examine the difference in change patterns between the two arms.

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DATA MONITORING

Data Security

During the data collection period, only the study team has access to the REDCap site that links the IDs to study patients. The electronic dataset and recordings are stored on an encrypted computer that is password protected with a secure server. All paper copies of the consent form are stored in a locked filing cabinet.

Study Management

We use standard processes to enhance data quality and reduce bias. We strive to have consistent recruitment staff at each study site, and all staff are required to follow the protocol document when interacting with patients. We monitor for data completeness on our REDCap data collection site to reduce missing or incomplete data, inaccuracies, and measurement bias and excessive variability. If we find missing data, we will run exploratory analyses to determine the missing data pattern, and then run appropriate analyses to address the problem and account for it in our models.

DESIGN JUSTIFICATIONS

Sample Size Calculation

The sample size calculation was based on a measure of patient-centeredness that was generated from the Roter Interaction Analysis System (RIAS). This measure incorporates the verbal contributions of patients, surgeons, and companions. Steinwachs et al.[67] used this patient-centeredness variable as the primary outcome in a study testing the effectiveness of a 20-minute computer-based intervention to activate patients to address a quality of care with their providers.[67] The intervention group experienced visits with significantly higher levels of patient-centeredness than the control group with an effect size of 0.6 (Cohen's d).[67]

With a 0.6 effect size, the required sample size is 72 patients (36 per group) for a one-tailed test of study hypotheses (power =.8 and alpha =.05). The study team determined that only a one-tailed test was necessary given that we are testing whether the intervention improves patient-centered communication. Based on the previous study,[67] we hypothesize that we would obtain recordings for 80-90% of recruited patients, with any discrepancies likely stemming from patient attrition, technology failure, and/or scheduling miscommunication. Accounting for an 80% recordings rate, the study team will need to recruit 90 patients to obtain the desired number of 72 recordings.

Once recruitment is complete, a power analysis will be performed to determine whether a conclusive finding or pattern of findings is due to insufficient power or the intervention.

Superiority Design

We powered our study for a one-tailed test as we believe that the intervention video will have a likely impact on the outcome.

Study Organization and Institutional Assurances

A Data and Safety Monitoring Board (DSMB) will independently review preliminary results after 50% of the data has been collected to determine whether the intervention is causing undue harm to the patients or their companions. In addition, per standard processes at our institution, the study will undergo a yearly audit. The hospital legal division was involved to ensure proper procedures for developing a video for research purpose and proper use of media releases.

Dissemination Plan for Results

This trial is registered and described on clinicaltrials.gov, and results will be posted on that website. Results will also be presented and discussed at relevant professional society academic meetings and through publication in scientific journals. The full data set will be available from the study principal

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investigator, per reasonable request. In accordance with ethical publication practices, authorship related to any presentations or publications will be based on individuals having contributed substantial time and/or intellectual content (i.e. study design, analysis, project conceptualization, etc.) related to the results being presented.

ETHICS AND DISSEMINATION

This study is a two-arm, randomized superiority trial comparing the effectiveness of an ACP video tool as compared to a control video at increasing the patient-centeredness of presurgical consent conversations between surgeons and patients preparing for major cancer surgery. The risk to participants is low.

The current study examines how ACP might be incorporated into surgical settings. As patients undergoing major surgery are at risk for perioperative morbidity and mortality, it is appropriate for these patients to initiate ACP prior to surgery. While the surgical consent process involves an explanation of the risks and benefits of the surgery, previous research[70] suggests that surgeons may have difficulty discussing detailed ACP wishes. Using an ACP video, this study hopes to empower patients to have more meaningful presurgical contemplation and conversation with both family members and their surgical team concerning their goals and wishes prior to major surgery.

If effective, the ACP video could be easily disseminated among patients, family members, surgery clinics, and/or other pertinent stakeholders. Timing of when the patient watches the video in relation to their surgery and/or their visit(s) with the surgeon can be determined in future studies or per individual decision by the patient or surgeon. In planning this study, participant surgeons noted practice variations within general "standard-of-care" including that some surgeons routinely met with patients at least twice before the day of surgery, while others would meet only once. For the purpose of this study, participant surgeons agreed on the above-described standardized format of two pre-surgery visits and therefore, timing of when the patient watched the video was standardized to be immediately after the surgeon recommended that the patient be scheduled for surgery.

In keeping with the principles of patient-centered outcomes research, both the intervention video and the resulting randomized control trial to assess its impact have been designed with extensive input from patients, family members, surgeons, health researchers, and other stakeholders. This trial is also overseen by a readily available patient/family co-investigator who communicates at least monthly with the study team and reviews study progress as well as participates in data evaluation. Thus, the current investigation is patient-centered not only in outcomes, but also in facilitation and data analysis.

Potential Contributions of this Study

To the best of our knowledge, this is the first investigation to explore the impact of a video ACP tool on surgeon, patient, and family communication prior to major surgery. A strength of this study is that the intervention video and resulting randomized control trial were both developed based on input from patients, companions, surgeons, health services researchers, and other stakeholders. Ultimately, the results of this RCT may demonstrate that easy-to-disseminate videos may activate patients and improve the patient-centeredness of surgeon/patient interactions.

Limitations

Several limitations regarding the study should be noted. First, the intervention video was initially conceptualized for a pancreatic cancer surgical population, potentially creating an issue for the generalizability of the video to a wider surgical population. Although the video was initially developed for the pancreatic cancer setting, the severity of pancreatic cancer surgery is analogous to other high-mortality/high-morbidity cancer surgeries. Moreover, the video itself does not specifically discuss cancer or pancreatic cancer. Thus, the intervention video should be relevant to a range of surgical patients and their families and is being evaluated among a group of patients with diverse cancer diagnoses.

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Second, the selected outcomes and timeframe of the study may not be able to fully capture the effect of the intervention as the impact of the surgery and video may persist beyond the one month time frame of the study. In order to mitigate this concern, data for multiple patient-centered outcomes is collected, many of which have been previously validated and used in surgical settings. These outcomes enable multi-faceted evaluation of the intervention. Additionally, results will be examined at several time-points, including both pre-operatively (V1, V2) and post-operatively (V3, V4). Yet, as other studies have shown benefit of ACP discussions as far as 12 months after hospitalization and patient death,[71] we might also hypothesize further benefits of the intervention to be apparent just before and after patient death, which is outside of the current trial timeframe.

Third, surgeon level factors will likely influence study outcomes. As all surgeons were privy to a general overview of the study and were provided with the opportunity to watch the intervention and control videos prior to agreeing to participate, the surgeons who ultimately decided to participate in the study may be biased in their pre-existing support for ACP. It is also possible that surgeons may have their own unconscious selection biases when referring patients to the study.

Fourth, one of the participating surgeons was featured in the intervention video. It is therefore possible that patients of this surgeon who are randomized to watch this video might surmise they are in the intervention group, which might impact their outcomes. In order to best account for these potential sources of bias, study randomization is nested within surgeon site of recruitment. Further, the analysis plan's designation of the surgeon as a random intercept should address the potential unmeasured influence of surgeon-level attributes on patient-level outcomes.

A final limitation of the study is that it can not control for the effect of a patient's medical course on study outcomes. Both presurgical factors such as diagnosis, as well as postsurgical factors such as surgical course or change in prognosis, might contribute to anxiety and depression, as well as to a patient's goals of care.

AUTHORS' CONTRIBUTIONS

RAA is the study principal investigator and she directed all study activities and coordinated between team members.

Study design: RAA, SRI, TY, MW, AEV, JFPB, DLR

Analysis design: RAA, SRI, TY, NLC, DLR

Protocol generation: RAA, SRI, NLC, AMCC, TY

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DATA SHARING: Datasets will be available on clinicaltrials.gov and/or per reasonable request to the study Principal Investigator.

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Figure legends

Figure 1. Trial Timeline

Figure 2. Trial Enrollment Diagram

Figure 3. Data Collection Plan

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Figure 1: Trial Timeline

Utilizing Advance Care Planning Videos to Empower Perioperative Cancer Patients and Families:
The Protocol for a Patient-Centered Outcomes Research Institute-funded Study

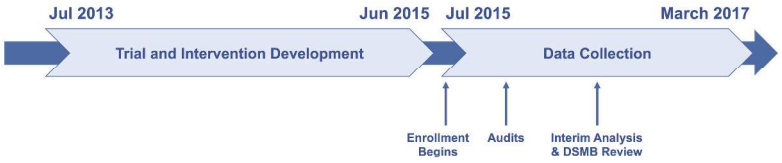

Figure 1. Trial Timeline

474x207mm (300 x 300 DPI)

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Figure 2: Trial Enrollment Diagram

Utilizing Advance Care Planning Videos to Empower Perioperative Cancer Patients and Families: The Protocol for a Patient-Centered Outcomes Research Institute-funded Study

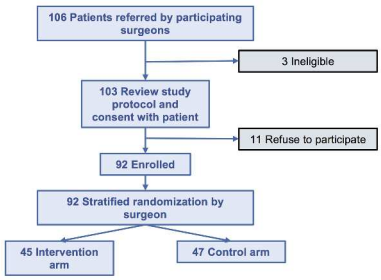

Figure 2. Trial Enrollment Diagram

353x220mm (300 x 300 DPI)

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Figure 3: Data Collection Plan

Utilizing Advance Care Planning Videos to Empower Perioperative Cancer Patients and Families: The Protocol for a Patient-Centered Outcomes Research Institute-funded Study

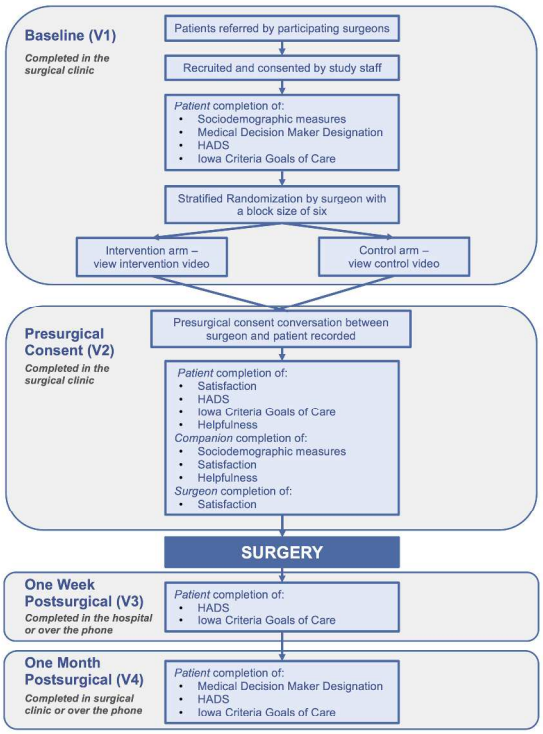

Figure 3. Data Collection Plan

339x381mm (300 x 300 DPI)

APPENDIX: Consent Forms

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A. Provider Consent Form

JOHNS HOPKINS MEDICINE

Approved June 24, 2015

Date: June 24, 2015
Principal Investigator: Rebecca Aslakson, MD PhD
Application No.: IRB00047112

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Utilizing advance care planning videos to empower perioperative cancer patients and families

(Consent for Providers)

Application No.: IRB00047112

Sponsor: Patient-Centered Outcomes Research Institute (PCORI)

Principal Investigator: Rebecca Aslakson MD PhD
Johns Hopkins Hospital
600 N. Wolfe Street
Meyer 296
Baltimore, Maryland 21287
Phone: 410-955-9080
Fax: 410-955-8978

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- If you receive routine medical treatment (including medical or laboratory tests) in the study or if you are taking part in the study at the Clinical Research Unit, information about your research study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital,

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Approved June 24, 2015

Date: June 24, 2015
Principal Investigator: Rebecca Aslakson, MD PhD
Application No.: IRB00047112

Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.

- The Johns Hopkins School of Medicine Institutional Review Board (IRB) sometimes reviews studies that are conducted at other institutions. These other institutions are solely responsible for conducting the study safely and according to the protocol that the Johns Hopkins IRB has approved. Information about how to contact the investigator at the institution that is responsible for the study is included in this form. When another institution is conducting the study, the word "we" in this consent form may include both Johns Hopkins and the participating institution.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

The purpose of this study is to test whether a video for advance care planning might help patients and family members get the most out of talking to their doctors. We want to understand how this video might change the way patients might talk to their doctors.

You have been asked to join this study because you provide medical care to patients in one of the participating surgical clinics at Johns Hopkins Hospital. All providers seeing patients in these surgical clinics will be invited to take part in this study.

How many people will be enrolled in this study?

We plan to enroll approximately 90 patient participants

3. What will happen if you join this study?

If you agree to be in this study, you will be asked to complete a 5 minute background survey before we start enrolling patients.

For approximately one year, we will be inviting patients you designate to participate in this study. These patients require a surgical procedure. If you agree to take part, you will be asked to participate whenever one of your eligible patients agrees to participate.

We will ask to audiotape the consent visit with each participant. Our research staff will take care of starting and stopping the audio recorder. The audio recorder will be in a clearly visible place in the room and you can opt-out of the recording at any time by turning off the audio recorder. After the visit is over we will ask you to complete a short survey (1-5) questions about the visit.

Our research team will transcribe the audiotape and analyze the transcript.

At the end of the study, every provider who participates will receive a composite analysis of their communication with patients in the study.

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4. What are the risks or discomforts of the study?

There is a risk of self-consciousness or embarrassment associated with having your visit audiotaped.

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Approved June 24, 2015

Date: June 24, 2015
Principal Investigator: Rebecca Aslakson, MD PhD
Application No.: IRB00047112

There is also a risk of breach of confidentiality if someone listening to the audio tape happens to recognize who you are. Our study team has built in several steps to protect your data. Once the audiotape is transcribed you will be identified only by a study ID number.

5. Are there benefits to being in the study?

There are no guaranteed benefits to taking part in this study. The results of this study may lead to improvements in doctor patient communication.

6. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not want to join you will continue to provide medical care to your patients as is standard procedure. If you do not join, your employment at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

No.

8. Will you be paid if you join this study?

No.

9. Can you leave the study early?

If you wish to leave the study you must notify a member of the study team.

10. How will your privacy be protected?

The study team will do everything they can to keep all study information private. Only code numbers, not your name, will be used on documents that list your answers to questions. The tape recording of your visit with the patient will be labeled with a study code number. Your name will be linked to this ID number in a separate file with a password. Only members of our study team will have access to this file. The file with your name will be destroyed once we have finished data collection. All study data and tape recordings will be kept in a locked file cabinet. Audiotapes will be destroyed at the end of the study. No names will be included when we type the notes of the consent visit.

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, gender and demographics about you.

Under some conditions, people in charge of making sure that the research is done properly may review your study records. This might include people from the NIH, the JHU Institutional Review Board or the Federal Office for Human Research Protections. All of these people are required to keep your identity confidential.

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JOHNS HOPKINS MEDICINE

Approved June 24, 2015

Date: June 24, 2015
Principal Investigator: Rebecca Aslakson, MD PhD
Application No.: IRB00047112

11. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Aslakson at 410-955-9080. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. Aslakson, 410-955-9080 during regular office hours.

d. What happens to Data and that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.

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JOHNS HOPKINS MEDICINE

Approved June 24, 2015

Date: June 24, 2015
Principal Investigator: Rebecca Aslakson, MD PhD
Application No.: IRB00047112

12. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time
Signature of Person Obtaining Consent	(Print Name)	Date/Time
Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required)	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

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B. Patient Consent Form

For peer review only

JOHNS HOPKINS MEDICINE

Approved September 10, 2015

Date: September 10, 2015
Principal Investigator: Rebecca Aslakson, MD PhD
Application No.: IRB00047112

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Utilizing advance care planning videos to empower perioperative patients and families

Application No.: IRB00047112

Sponsor: Patient-Centered Outcomes Research Institute (PCORI)

Principal Investigator: Rebecca Aslakson MD PhD
Johns Hopkins Hospital
600 N. Wolfe Street
Meyer 296
Baltimore, Maryland 21287
Phone: 410-955-9082 | Fax: 410-955-8978

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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Approved September 10, 2015

- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

This research is being done to see whether viewing a video before you consent to your surgery might help you or your family get the most out of talking with your surgeon. We want to understand how this video might change the way you talk to your surgeon. You are being asked to join this study because you are scheduled to undergo a surgical procedure at the Johns Hopkins Hospital. We are asking about 90 other patients like you to take part in this study.

People may join the study if they are: aged 18 and older; have study surgeons who are scheduled to have a surgical procedure; identified by study surgeons to the study team; willing to give informed consent, able to speak English; reasonably able to read a newspaper or book (without sight impairment); reasonably able to listen to radio, television (without hearing impairment).

How many people will be in this study?

We plan to enroll approximately 90 patient participants.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things. First, we will ask you some questions about yourself and ask you to fill in a survey about how you are feeling (questions about anxiety and depression-called the Hospital Anxiety and Depression Survey (HADS) and about your goals of care. This should take about 15 minutes. We will ask you to view a short video that takes about 5 minutes to view. There are two videos in this study and you will be randomized to see only one of them, similar to flipping a coin.

The video can be seen either on a DVD disc we can give to you, a web link, or you can view the video on an electronic device such as an iPad that we can temporarily provide to you when you watch the video at Johns Hopkins. We are using one of two different videos, you will view only one. You will be assigned by chance (like through a coin toss) to view one video or the other. Your surgeon will not know which video you viewed.

When you come to visit your surgeon to sign the consent form for your surgery we will ask to audiotape this visit. Everyone who comes with you to the consent for your surgery visit must be 18 years of age or older and also be willing to be audiotaped for the study in order for you to take part. The audio recorder will be in a clearly visible place in the room and you can opt-out of the recording at any time by turning off the audio recorder. After your visit with your doctor we will ask you to stay for about 30 minutes to answer some questions about what you thought about your visit and to answer some questions about yourself and to fill in a survey about how you are feeling (HADS) and about your goals of care.
After this visit is over we will type out what you and the doctors say on the tape. We will listen to the tape to see how you and the doctor talked to each other.

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About one week after your surgery we will contact you either in person if you are in the hospital or via phone to ask you to fill in a few surveys about how you are feeling (HADS and goals of care). In about

person if you are visiting your surgeon at this time or we will call you via phone. Each of these visits or calls will take about 20 minutes.

You will be in this study for about one month.

Future Follow-up and Research

We would like your permission to possibly follow-up with you on your medical course following surgery.

Please initial your choice below:
_____ Yes, you may contact me in the future to follow-up on my medical course.
_____ No, I do not want you to contact me in the future to follow-up on my medical course.

We would like your permission to contact you about other studies that you may be eligible for in the future.

Please initial your choice below:
_____ Yes, you may contact me in the future about other studies.
_____ No, I do not want you to contact me about other studies

4. What are the risks or discomforts of the study?

Video: Viewing the video or answering our questions may make you feel tired or worried. You may stop the video any time you want.
Audiotape: During the part of the study where the audiotape is on, you have the option of turning it off if you choose.
Surveys: You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

As this is a placebo-controlled study (i.e., there is a control video), there is a risk that you may not receive the video that we are testing for effectiveness. The assignment to the control branch is not anticipated to impact your continuing standard clinical care.

Your surgeon knows you are taking part of this study but does not know which video you will be watching.

In the case of an emergency, your doctor can quickly find out the branch of the study to which you are assigned.

5. Are there benefits to being in the study?

There are no direct benefits to you from taking part in this study.

The purpose of the video is to help patients and family members have a meaningful discussion with the

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6. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

The video will be provided to you free of charge. If you are given a DVD disc, you can keep it.

8. Will you be paid if you join this study?

After you complete the last study visit you will be given a $25 dollar gift card.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

10. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your

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Date: September 10, 2015
Principal Investigator: Rebecca Aslakson, MD PhD
Application No.: IRB00047112

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

11. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers at Johns Hopkins.

12. What does a conflict of interest mean to you as a participant in this study?

A researcher and Johns Hopkins have a financial or other interest in this study.

In some situations, the results of this study may lead to a financial gain for the researcher and/or Johns Hopkins. This financial interest has been reviewed in keeping with Johns Hopkins' policies. It has been approved with certain conditions, which are intended to guard against bias and to protect participants.

If you have any questions about this financial interest, please talk to Madeleine Moore at 410-614-4633. This person is a member of the study team, but does not have a financial interest related to the study. You may also call the Office of Policy Coordination (410-516-5560) for more information. The Office of Policy Coordination reviews financial interests of investigators and/or Johns Hopkins.

13. What treatment costs will be paid if you are injured in this study?

Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

- If you have health insurance: The costs for any treatment or hospital care you receive as the result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you.

- If you do not have health insurance: You will be billed for the costs of any treatment or hospital care you receive as the result of a study-related injury.

By signing this form you will not give up any rights you have to seek compensation for injury.

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14. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

Approved September 10, 2015

- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Aslakson at 410-955-9082. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. Aslakson at 410-955-9082 during regular office hours.

d. What happens to Data that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.

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Date: September 10, 2015
Principal Investigator: Rebecca Aslakson, MD PhD
Application No.: IRB00047112

15. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time
Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

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C. Oral Consent Form

JOHNS HOPKINS MEDICINE

Approved September 10, 2015

Date: September 10, 2015
Principal Investigator: Rebecca Aslakson MD PhD
Application No.: IRB00047112

ORAL CONSENT SCRIPT

Protocol Title: Utilizing advance care planning videos to empower perioperative cancer patients and families

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PURPOSE

You are invited to take part in a research study. The purpose of this study is to determine how viewing a video may impact discussion between your family member and their doctor. You are being asked to participate because you came with your family member to visit his/her doctor before surgery. This visit is being audiotaped and we are inviting you to participate in the audiotaped part of the study and to complete a short survey immediately afterwards.

PROCEDURES

During the visit with the surgeon your family member has agreed to have the visit audio-recorded. An audio-recording device will be turned on during the visit and the visit will be audio-taped. The visit is primarily between your family member and his/her doctor but you may participate in the discussion and ask questions or give answers. A written version of the audiotape will be made and persons who participated in the discussion will be given a special code and no names will be used.

RISKS/DISCOMFORTS: There is no anticipated risk for your participation. All of the discussion in the doctor visit will be kept confidential. During the visit you may feel uncomfortable knowing that the discussion is being audio-recorded. If there is something you do not want to say or something you do not want to answer you do not have to. If there is something on the short survey that you do not want to answer, you do not have to.

BENEFITS: There is no direct benefit to you from being in this study. What we learn from this study may help us understand discussions between patients and their doctor before surgery.

VOLUNTARY PARTICIPATION

You do not have to agree to be in this study. If you do not want to join the study, it will not affect your family members' care at Johns Hopkins. You may refuse to answer any questions that you do not want to answer. If you have any questions about your rights as a research participant, or if you think you have not been treated fairly, you may call the Johns Hopkins Institutional Review Board (IRB) at 410-955-3008.

HIPAA DISCLOSURE: The study team may collect information about you which would include your name, your relation to the patient, your current job status, gender, race, age and educational level.

People at Johns Hopkins who are involved in the study or who need to make sure the study is being done correctly may ask to see the information. They may need to send your information to people outside of Johns Hopkins for the same reason.

These people will use your information for the purpose of the study. We will continue to collect information about you until the end of the study unless you tell us that you have changed your mind. If you change your mind and don't want your information used for the study anymore, you can call The Johns Hopkins Institutional Review Board at 410-955-3008. Just remember, if we have already used your information for the study, the use of that information cannot be cancelled. We try to make sure that everyone who needs to see your information uses it only for the study and keeps it confidential - but, we cannot guarantee this.

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BMJ Open

Utilizing Advance Care Planning Videos to Empower Perioperative Cancer Patients and Families: A Study Protocol of a Randomized Controlled Trial

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Manuscript Submission Cover Page

Title: Utilizing Advance Care Planning Videos to Empower Perioperative Cancer Patients and Families: A Study Protocol of a Randomized Controlled Trial

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ABSTRACT

Introduction: Despite positive health outcomes associated with advance care planning (ACP), little research has investigated the impact of ACP in surgical populations. Our goal is to evaluate how an ACP intervention video impacts the patient-centeredness of the patient-surgeon conversation during the presurgical consent visit. We hypothesize that patients who view the intervention will engage in more patient-centered communication with their surgeons compared to patients who view a control video.
Methods and analysis: Randomized controlled superiority trial of an ACP video with two study arms: intervention ACP video and control video; and four visits: baseline, presurgical consent, postoperative one week, and postoperative one month. Surgeons, patients, Principal Investigator, and analysts are blinded to the randomization assignment.

Setting: Single, academic, inner city, tertiary care hospital. Data collection began July 16, 2015 and continues to March 2017.

Participants: Patients recruited from nine surgical oncology clinics who are undergoing major cancer surgery.

Interventions: In the intervention arm, patients view a patient preparedness video developed through extensive consultation with patients, surgeons, and other stakeholders. Patients randomized to the control arm viewed an informational video about the hospital surgical program.

Main Outcomes and Measures: Primary Outcome: Patient-centeredness of patient-surgeon conversations during the presurgical consent visit as measured through the Roter Interaction Analysis System (RIAS). Secondary outcomes: patient Hospital Anxiety and Depression Scale score; patient goals of care; patient, companion, and surgeon satisfaction; video helpfulness; medical decision maker designation; and the frequency patients watch the video. Intent-to-treat analysis will be used to assess the impact of video assignment upon outcomes. Sensitivity analyses will assess whether there are differential effects contingent upon patient or surgeon characteristics.
Ethics and Dissemination: This study has been approved by the Johns Hopkins School of Medicine Institutional Review Board and is registered on clinicaltrials.gov (NCT02489799, First received: July 1, 2015).

Abstract word count: 297

Trial Registration: clinicaltrials.gov Identifier NCT02489799

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Data Sharing and Competing Interest Statement

This is a study protocol and thus does not contain or reflect any primary data.

We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests.

Strengths and Limitations of this study:

Strengths:

- The intervention being tested, as well as the trial outcomes, were developed and selected through extensive stakeholder – patient, family member, surgeon, palliative care clinician – engagement.
- There is limited existing research of advance care planning and palliative care in surgical populations.
- The study will enable a detailed examination of the patient experience surrounding major cancer surgery as well as an indepth analysis of how surgeons and patients preoperatively discuss surgical risk.
- The study intervention is a video and thus, if effective, it can be easily disseminated.

Limitations

- The video was initially conceptualized for a pancreatic cancer population, though its content was broadened to address all major surgery; the final video addresses surgery, but not specifically pancreatic cancer or cancer surgery.
- The selected outcomes and timeframe of the study (one month following surgery) may be too short to fully capture the effect of the intervention.
- Surgeon and surgery level factors could influence study outcomes. For example, perhaps certain types of surgery are more likely to be associated with perioperative patient depression scores.
- The study cannot control for the potential effect of a patient's medical and surgical course on study outcomes.

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INTRODUCTION

In 2010, there were approximately 51 million surgeries performed in the United States.[1] Although most surgeries will be performed successfully, patient morbidity and mortality persist,[2-5] and some surgeries require postoperative life-sustaining treatments in an intensive care unit.[6] While patients may be stratified for perioperative complications, it is difficult to impossible to predict which patients will die or suffer a major perioperative complication.[3,5,7]

Advance care planning (ACP) is a process by which individuals contemplate future health states, clarify and discuss their goals, and express goals-informed wishes for those health states—if illness may render that person unable to make decisions for him or herself in the future.[8] Evidence supports that ACP discussions may decrease health care utilization, while increasing patient satisfaction, use of hospice and palliative care, and compliance with a patient's end-of-life wishes.[9-13] For family members, ACP may also decrease anxiety, depression, and stress, while increasing satisfaction with the quality of care.[9,14,15] ACP is appropriate throughout multiple stages of illness and has not been associated with harm in previous studies.[16] Finally, the landmark 2014 Institute of Medicine report *Dying in America* advocates for increased ACP to explore patient wishes before they become acutely ill.[17]

As patients with advanced cancer undergoing major surgery often experience conditions that may increase their risk for both complications during surgery and post-operative outcomes (e.g., functional decline, frailty, comorbidities, and polypharmacy),[18-22] it is likely beneficial for them to initiate ACP prior to surgery. A recent systematic review of palliative care interventions for surgical populations[23] highlighted five studies that explored ACP interventions in surgical populations.[24-28] These interventions involved further training or activation of surgical providers (i.e., surgeons, anesthesiologists, and/or nurses) to have an ACP conversation with the patient prior to surgery and/or involvement of a palliative care specialist specifically to discuss ACP with the patient prior to surgery. These interventions found improved concordance and decreased decisional conflict between patients and surrogates about goals of care,[24,25,27] improved documentation regarding power of attorney,[26] and were deemed helpful by study participants;[25] none of these trials documented harms to patients or family members.

Verbal communication is the predominant modality for ACP between patients and providers[29] and was the communication modality used in the above ACP interventions in surgical populations.[19-23] Yet, there are multiple barriers to optimal verbal communication in the patient-doctor relationship. Most importantly, verbal communication about ACP is inherently inconsistent and subjective, as standardizing these conversations is challenging to impossible.[30-34] Conversations may also inaccurately convey the burden and outcomes of medical interventions, particularly when the patient has no previous knowledge or experience of aggressive medical treatments (i.e., intubation, artificial ventilation, artificial nutrition) and/or settings (i.e., an intensive care unit).[35] While ACP innately requires verbal communication between patients and providers, such communication can be facilitated or enhanced through educational tools, such as a video. Video ACP tools have inherently stable content and thus may be a more objective, simple to understand, and realistic modality through which to educate and activate patients about ACP.[36,37] Thirteen randomized controlled trials in varying populations support that video-based ACP tools can empower patients and families to have ACP-related discussions,[38-50] though none of these studies were completed in surgical populations.

This investigation builds on the paucity of research concerning video ACP tools in surgical populations.[23] Towards this goal, a randomized, controlled clinical trial was initiated (clinicaltrials.gov Identifier NCT02489799).

OBJECTIVE

The objective of this study is to evaluate whether, compared to a control video, an ACP video developed for patients and families pursuing aggressive surgical treatment for cancer impacts the patient centeredness of the patient-surgeon conversation during the audiorecorded presurgical consent visit. The trial is funded by the Patient Centered Outcomes Research Institute, which supports comparative

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effectiveness research to help patients and other stakeholders make informed medical decisions.[51] In light of this funding, the primary aim was selected based on two years of intense engagement with patients and family members, as well as other key stakeholders including surgeons, anesthesiologists, surgical nurses, surgical intensive care unit nurses, palliative care clinicians, and health services researchers. We hypothesize that patients who view the intervention video will engage in more patient-centered communication with their surgeons, as compared to patients who view the control video (Hypothesis 1).

Our secondary aims explore multiple other patient and companion outcomes. Of note, accompanying family members or friends (i.e., "companions") are often present during the audiorecording of the presurgical visit. Our secondary outcomes include: how the ACP intervention video may impact mood-related outcomes, such as patient anxiety and depression; helpfulness of the video (from patient and companion perspectives); the patient's stated goals of care; satisfaction with the presurgical consent visit (from patient, companion, and surgeon perspectives, and from consensus perspectives); whether the patient designates a medical decision maker and discusses his/her wishes with this designated person; and the frequency with which patients watch the video outside of the site of recruitment. We will measure the patient's level of anxiety and depression during two separate presurgical visits, as well as one week after surgery, and one month after surgery. We hypothesize that patients who view the intervention video will be less anxious and depressed across all visits, as compared to patients who view the control video (Hypothesis 2). We hypothesize that patients will find the intervention video more helpful than the control video (Hypothesis 3). We also hypothesize that that patients will watch the intervention video more often than the control video (Hypothesis 4).

METHODS AND ANALYSIS

STUDY DESIGN

The study is a 2-arm, randomized superiority trial of an ACP video developed for patients undergoing major surgery for advanced cancer at a single, academic, inner city, tertiary care hospital. The study began data collection on July 16, 2015 (**Figure 1**).

Institutional Review Board Determination

The Johns Hopkins Medicine and the Sidney Kimmel Comprehensive Cancer Center Institutional Review Boards (IRB) reviewed and approved the study protocol. All changes in study protocol, as needed, are to be submitted and reviewed by the IRB.

Study Sample Population

Our study sample includes patients undergoing major cancer surgery with one of nine surgeons participating in this study. These nine surgeons were chosen as they had sufficient cancer patient populations and were willing to be in the trial. All surgeons were comfortable with the ACP video and were shown both intervention and control videos prior to when data collection from their clinics commenced. In preparation for the study, surgeons described variations in their practice regarding presurgical visits and agreed on a single format to uniformly use for study patients; this format is comprised of at least two visits with the surgeon prior to the actual surgery. Based on sample size calculations, explained in the Design Justification section below, we aimed to recruit 90 patients for the study.

Eligibility Criteria

Eligible patients must be undergoing major surgery such that, due to the surgery itself and/or the patient's underlying medical conditions, the surgeon plans to postoperatively admit the patient to the surgical intensive care unit (SICU). Major surgery is defined as "surgery involving a risk to the life of the patient; specifically: an operation upon an organ within the cranium, chest, abdomen, or pelvic cavity."[52] Study patients must also be scheduled for non-emergent surgery such that they have at least a day to

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review the video prior to signing surgical consent. Potential study patients must also meet the following inclusion criteria: plan to undergo surgery with one of the study surgeons, able to give informed consent, and able to speak English. Patients will be excluded if they are younger than 18 years old or have visual or hearing impairments such that they are unable to view and/or hear the study videos.

Many patients are accompanied to the surgeon's clinic by a family member or friend (i.e. a "companion"). There is no screening of companions for eligibility to participate. If eligible patients have a companion present during the audiorecording, these individuals are orally consented prior to the recording. Companions under the age of 18 cannot participate in the audiorecording unless consented by parent/guardian. The oncologic surgeons (n=9) and any of their clinic staff or trainees also provide written consent to be audiorecorded.

Recruitment

Patients are recruited out of the nine surgical oncology clinics. Study staff wait in the clinics, and, if surgeons deem patients potentially eligible, study staff meet with patients to determine full eligibility, consent patients for the study, and conduct the baseline visit activities.

Patients are provided with a $25 gift card upon completion of the four visits of the study.

Due to the nature of major surgery, the study team anticipates some patient drop out due to emotional distress, time constraints, surgery cancellation, or patient death.

Randomization

With each study patient as a unit of randomization, we randomize immediately following enrollment so that the study patient receives either the intervention or control video (**Figure 2**). Patients are stratified by surgeon through a computer algorithm written in R,[53] which performed a block randomization with a block size of six. We are adopting a stratified approach to randomization as we hypothesize that individual differences in surgeon demeanor will also impact the patient-centeredness of the surgeon-patient communication. We do not anticipate surgeons to recruit an equal number of patients given differences in practice type and volume; however, each surgeon was encouraged to recruit at least three patients to allow for clustering by surgeon in our analysis. The surgeons, patients, companions, Principal Investigator, coders, and data analysts are blinded to the randomization assignment; however, the recruitment staff cannot be blinded as they show the video and provide a video link to study patients.

Study Arms

Patients are randomly assigned to one of two arms: intervention video or control video. Patients are randomized on site by study staff upon completion of patient consent. Both videos are six minutes in duration.

Intervention

Over the past two years, the study team developed a video-based ACP tool for patients pursuing aggressive surgical treatments. The video design process involved extensive engagement with patients and families and key stakeholders such as surgeons, palliative care clinicians, ACP experts, and surgical nurses, and included interviews, focus groups, stakeholder summits, and a de-identified cross-sectional survey regarding potential video content (further manuscripts in process).[54-57] The video features patients, companions, and medical professionals (two surgeons, one anesthesiologist, one SICU nurse) discussing both the course of a typical surgical day – pre-operative area, operating room, and SICU – as well as the importance of preoperative ACP – identifying a medical decision maker, discussing one's wishes with that decision maker, and communicating those wishes to the surgical team prior to the surgery.

Control

The control video is an informational video about the Johns Hopkins surgery program, which was created by the Marketing Department. The video catalogues the history and evolution of surgery at Johns Hopkins Medicine. The video highlights scientific developments and ongoing innovations in patient safety.

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Primary Outcome - Roter Interaction Analysis System (RIAS)

The primary outcome is the surgeon-patient conversation as analyzed using the Roter Interaction Analysis System (RIAS). RIAS a quantitative coding system for medical dialogue, which has demonstrated reliability and predictive validity for patient satisfaction, utilization, and adherence.[58] The coding unit of analysis is a complete thought that varies in length from a single word to a sentence. The RIAS coder is blinded to the randomization assignment of the patient and is unaware of the study hypotheses. RIAS coding has a reliability of > 0.85 in most studies.[58] This study will have one coder for all recordings.

RIAS will also be used to calculate a patient-centeredness summary score, which has been used in past studies with predictive and concurrent validity for a variety of patient and physician outcomes.[59] The patient-centeredness summary score is a ratio of statements that reflect the psychosocial and socio-emotional elements of exchange about the lived illness experience of patients relative to statements that reflect a more biomedical and disease focused perspective. This score reflects the encounter as a whole, rather than an individual's dialogue. A value greater than one indicates a more patient-centered encounter; whereas, a value less than one indicates a more biomedical encounter.

Patient trajectory and secondary outcomes

The study includes four visits with each study patient: baseline visit (V1, non-recorded), presurgical consent visit (V2, recorded), postoperative one week visit (V3, non-recorded), and postoperative one month visit (V4, non-recorded; **Figure 3**).

Baseline Visit (V1)

Once consented for the study, patients complete self-administered measures including sociodemographic measures and a question concerning whether the patient has assigned a medical decision maker and how recently he/she has had a conversation with that medical decision maker about care preferences. Patients also complete the Hospital Anxiety and Depression Scale (HADS)[60] and the Iowa Criteria Goals of Care survey.[61]

Patients are randomized to either the intervention or control video. Patients then immediately view the video they were assigned in the presence of the study staff. Surgeon stakeholders involved in the design of the study recommended this timing for the video viewing. The study staff also provide the patient a web link to the video so that they may show the video to others in their family and/or to view the video again at a later time or place.

Presurgical Consent Visit (V2)

Upon patient arrival in the clinic waiting room prior to their visit with the surgeon, study staff greet the patient, offer to show the patient the video again, and orally consent any companions who may be accompanying the patient. Once the patient is escorted back to an exam room, study staff place two recorders at different places in the room to capture the conversation during this visit. This audiorecording is used for the primary outcome RIAS analysis. For this study protocol, surgeons have agreed that the V2 goal is to discuss the risks and benefits of the upcoming surgery and for the patient to sign surgical consent. Immediately following this conversation, both the surgeon and the patient and/or companion complete the following questionnaires:

Satisfaction Measures

After the visit, the surgeon, patient, and companion each complete a short self-administered satisfaction questionnaire about the visit. The study team has adapted measures developed and used by Roter and colleagues in previous studies to address patient satisfaction with interpersonal and informational aspects of medical visits.[62-65] The patient satisfaction questionnaire includes six items; an eight item version used in a past study had a Cronbach's alpha of 0.89.[66] The clinician satisfaction questionnaire includes six items; an eight-item version used in a past study had a Cronbach's alpha of

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0.83.[67] The companion satisfaction questionnaire includes eight items and has not been used in a past study, though it is directly based on the patient satisfaction questionnaire. The internal reliability of these questionnaires will be estimated with Cronbach's alpha.

Helpfulness Survey

Patients also complete a measure regarding their perceptions of the helpfulness of the video. Volandes et al. used this measure in their previous studies but do not report on the psychometric properties of the tool.[36,38,44-46,48] This measure asks whether the patient was comfortable watching the video, whether the patient perceived the video to be helpful in preparing him/her for surgery, and whether the patient would recommend the video to other patients.

Other V2 Measures

Patients also complete HADS and the Iowa Criteria Goals of Care measure. Companions complete self-administered questions about the nature of their relationship with the patient, as well as a self-administered survey about the helpfulness of the video.

Postsurgical One Week Visit (V3)

Approximately one week after the patients' surgery, a study staff meets with patients while they are still in the hospital, but after they have been transferred from the ICU to another unit. Patients complete the HADS and Iowa Criteria Goals of Care surveys.

Postsurgical One Month Visit (V4)

Approximately one month after the patients' surgery, study staff communicate with patients either in person during the patient's one month follow up with the surgeon or over the phone. The patient completes the HADS and Iowa Criteria Goals of Care surveys. Patients also answer one question regarding whether the patient has assigned a medical decision maker and how recently he/she has had a conversation with that medical decision maker about care preferences.

Medical Record Abstraction

Outside the scheduled study visits, the study team abstract medical record information, which is incorporated as descriptive data on each patient. Information abstracted includes the patient's primary diagnosis, surgical procedure, active medical history (e.g., hypertension, coronary artery disease), hospital admission and discharge (related to the major surgery they received), and any hospital readmission data collected within one month after the surgery. A second study team member independently verifies all medical record abstraction.

DATA COLLECTION

Mode of Data Entry

Study data were collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at Johns Hopkins Medical Institutions.[68] REDCap is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. Patients enter all surveys directly into REDCap[68] on study computers; patients also have the option to complete surveys on paper at any point. Paper surveys are further available in the event of technical difficulties. Patients also have the option to complete questions verbally if they prefer not to input data into the computer or onto a paper form. Surgeon and companion surveys are completed on paper. All paper forms completed are entered into REDCap by one study staff member and independently verified by a second study staff member.

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For medical record abstractions, the team uses information obtained from the hospital electronic medical record systems. Information is abstracted by one study staff member and independently verified by a second study staff member.

STATISTICAL METHODS

Statistical Significance and Software

The team will set the overall level of statistical significance at $P < .05$. All statistical analyses will be performed in Stata statistical software.[69] Analysis will be rerun in R statistical software to confirm results.[53]

Intent-to-Treat

Our study will use an intent-to-treat approach in which all data from study patients in both intervention and control arms are used, regardless of the level of adherence to the study arms. We have also designed the study to minimize the possibility of both patient crossovers between intervention groups, as well as to reduce the chance that patients may see the video to which they are not randomized.

Evaluation of Hypotheses Overview

Descriptive statistics will be calculated to summarize patients' characteristics and other baseline variables. Comparability of the intervention arm and the control arm will be assessed with regard to pre-intervention sociodemographic and health status measures derived from Medical Record Abstraction. While randomization should account for such differences, a two-sample t test/ Mann-Whitney test will be performed to investigate the difference in two means or medians for continuous variables, and Fisher's exact test or Chi-squared test will be used to investigate the difference in proportions for binary or categorical variables. We will therefrom identify and determine possible necessary adjustment for some baseline attributes. Historically, patient gender, age, race, education and health status have been identified as important attributes and are usually adjusted for in the model. Surgeon attributes will be examined similarly.

Further statistical analyses will explore the association between intervention assignment and each of the outcomes. Based on the type of the data, summary univariate (descriptive) statistics (mean, standard deviation, median, interquartile range, max, min, count, percentage) of all outcomes stratified by intervention assignment will be provided. Descriptive time trend plots (multiple visits) stratified by intervention assignment will be presented for outcomes that are measured at multiple visits. These plots will allow for the visual comparison of change patterns before and after the intervention in the two arms. Differences in outcomes between two arms at each visit will be tested by two-sample t test/Mann-Whitney test or Fisher's exact test/Chi-squared test, based on the data types of the outcomes.

For the primary outcome and some of the secondary outcomes, the descriptive statistical analyses will be followed by regression analyses, using mixed effects generalized linear models with link functions chosen that are specific to the data types of the outcomes. The data will have a two-level structure, being defined by individual patient nested within surgeons. To address the potential unmeasured influence of surgeon-level attributes on patient-level outcomes, we will model the variable "surgeon" as a random intercept. In most cases, the parameter of interest is the coefficient of the arm indicator, to be estimated as the intervention effect. All standard errors will be computed using the robust method.

Hypothesis 1

Specifically, the primary outcome, patient-centeredness of patient-surgeon conversations during a pre-surgical consent visit as measured through the Roter Interaction Analysis System (RIAS), is a continuous variable. Therefore, mixed effects linear regression models will be used, adjusting for relevant covariates, with inclusion of a random intercept for surgeon to account for the correlation of outcome values from patients of the same surgeon.

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Hypothesis 2

The secondary outcome *HADS* consists of two subscales, symptoms of anxiety and symptoms of depression. Subscale scores range from 0, indicating no distress, to 21, indicating maximum distress; a score higher than 7 indicates clinically meaningful anxiety or depression.[60] We will therefore consider these two outcomes as two binary variables indicating the absence or presence of clinically meaningful anxiety or depression. HADS will be measured at all four visits. To examine the effect of the intervention on these two outcomes, mixed effects logistic regression models will be used, adjusting for baseline scores and other relevant covariates, with inclusion of a surgeon random intercept. This model will be used to assess the difference in HADS subscale scores between the two arms at V2, V3, and then at V4. To assess the robustness of our estimates, an alternative model with the inclusion of interaction terms between arm indicator and visit indicator will be used to estimate the difference in differences from baseline to later visits between the two arms. This will provide us information on the changes in HADS scores across visits within each arm as well as how the change patterns differ between the two arms.

Hypothesis 3

The secondary outcome *Video Helpfulness* will be measured at V2, and will be summarized into two categories, helpful vs. not helpful. A mixed effects logistic regression, adjusting for relevant covariates, with a surgeon random intercept will be used to compare the helpfulness of the intervention video and the control video.

Hypothesis 4

The frequencies the intervention video and control video are watched by patients outside of the medical clinic (i.e., the extent to which patients choose to watch the video on their own time outside of direct interaction with the study's staff) will be presented for comparison.

Other Outcomes and Hypotheses

Goals of Care (IOWA Goals of Care) has two questions. The first asks patients to check their current medical goals relating to their surgery. The second asks patients to list and rank the top three goals. Goals of care data are to be collected at all four visits. We will stratify the data by intervention assignment, and then calculate frequencies and percentages of goals of care chosen and being ranked as top three goals at each visit to assess the changes in goals of care across visits and differences between the two arms.

Patient and Surgeon Satisfaction will be measured at the end of V2. The satisfaction score, as the sum of the scores of six questions (all in a Likert scale), ranges from 6 to 30, with a higher score indicating higher level of satisfaction. The intervention effects on patient satisfaction score and surgeon satisfaction score (surgeon's perception of patient's satisfaction level) will be examined separately by mixed effects linear regression models, adjusting for relevant covariates, with inclusion of a random intercept for surgeon. Future analyses will also explore whether discrepancy exists between patients', companions', and surgeons' perception.

Medical Decision Maker Designation will be measured at baseline and V4. It is an ordered categorical variable consisting of four possible answer options: (1) No, I don't have a medical decision maker; (2) Yes, I have a medical decision maker, but we have not specifically talked about this [what medical decisions they should make for me]; (3) Yes, I have a medical decision maker, and our talk about this [what medical decisions they should make for me] was over six months ago; and (4) Yes, I have a medical decision maker, and our talk this [what medical decisions they should make for me] was within the last six months. We will construct a binary variable indicating whether there is an upward change in medical decision maker designation from V1 to V4. A mixed effects logistic regression, adjusting for baseline value and other relevant covariates, with a surgeon random intercept will be used to examine the difference in change patterns between the two arms.

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DATA MONITORING

Data Security

During the data collection period, only the study team has access to the REDCap site that links the IDs to study patients. The electronic dataset and recordings are stored on an encrypted computer that is password protected with a secure server. All paper copies of the consent form are stored in a locked filing cabinet.

Study Management

We use standard processes to enhance data quality and reduce bias. We strive to have consistent recruitment staff at each study site, and all staff are required to follow the protocol document when interacting with patients. We monitor for data completeness on our REDCap data collection site to reduce missing or incomplete data, inaccuracies, and measurement bias and excessive variability. If we find missing data, we will run exploratory analyses to determine the missing data pattern, and then run appropriate analyses to address the problem and account for it in our models.

DESIGN JUSTIFICATIONS

Sample Size Calculation

The sample size calculation was based on a measure of patient-centeredness that was generated from the Roter Interaction Analysis System (RIAS). This measure incorporates the verbal contributions of patients, surgeons, and companions. Steinwachs et al.[67] used this patient-centeredness variable as the primary outcome in a study testing the effectiveness of a 20-minute computer-based intervention to activate patients to address a quality of care with their providers.[67] The intervention group experienced visits with significantly higher levels of patient-centeredness than the control group with an effect size of 0.6 (Cohen's d).[67]

With a 0.6 effect size, the required sample size is 72 patients (36 per group) for a one-tailed test of study hypotheses (power =.8 and alpha =.05). The study team determined that only a one-tailed test was necessary given that we are testing whether the intervention improves patient-centered communication. Based on the previous study,[67] we hypothesize that we would obtain recordings for 80-90% of recruited patients, with any discrepancies likely stemming from patient attrition, technology failure, and/or scheduling miscommunication. Accounting for an 80% recordings rate, the study team will need to recruit 90 patients to obtain the desired number of 72 recordings.

Once recruitment is complete, a power analysis will be performed to determine whether a conclusive finding or pattern of findings is due to insufficient power or the intervention.

Superiority Design

We powered our study for a one-tailed test as we believe that the intervention video will have a likely impact on the outcome.

Study Organization and Institutional Assurances

A Data and Safety Monitoring Board (DSMB) will independently review preliminary results after 50% of the data has been collected to determine whether the intervention is causing undue harm to the patients or their companions. In addition, per standard processes at our institution, the study will undergo a yearly audit. The hospital legal division was involved to ensure proper procedures for developing a video for research purpose and proper use of media releases.

Dissemination Plan for Results

This trial is registered and described on clinicaltrials.gov, and results will be posted on that website. Results will also be presented and discussed at relevant professional society academic meetings and through publication in scientific journals. The full data set will be available from the study principal

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investigator, per reasonable request. In accordance with ethical publication practices, authorship related to any presentations or publications will be based on individuals having contributed substantial time and/or intellectual content (i.e. study design, analysis, project conceptualization, etc.) related to the results being presented.

ETHICS AND DISSEMINATION

This study is a two-arm, randomized superiority trial comparing the effectiveness of an ACP video tool as compared to a control video at increasing the patient-centeredness of presurgical consent conversations between surgeons and patients preparing for major cancer surgery. The risk to participants is low.

The current study examines how ACP might be incorporated into surgical settings. As patients undergoing major surgery are at risk for perioperative morbidity and mortality, it is appropriate for these patients to initiate ACP prior to surgery. While the surgical consent process involves an explanation of the risks and benefits of the surgery, previous research[70] suggests that surgeons may have difficulty discussing detailed ACP wishes. Using an ACP video, this study hopes to empower patients to have more meaningful presurgical contemplation and conversation with both family members and their surgical team concerning their goals and wishes prior to major surgery.

If effective, the ACP video could be easily disseminated among patients, family members, surgery clinics, and/or other pertinent stakeholders. Timing of when the patient watches the video in relation to their surgery and/or their visit(s) with the surgeon can be determined in future studies or per individual decision by the patient or surgeon. In planning this study, participant surgeons noted practice variations within general "standard-of-care" including that some surgeons routinely met with patients at least twice before the day of surgery, while others would meet only once. For the purpose of this study, participant surgeons agreed on the above-described standardized format of two pre-surgery visits and therefore, timing of when the patient watched the video was standardized to be immediately after the surgeon recommended that the patient be scheduled for surgery.

In keeping with the principles of patient-centered outcomes research, both the intervention video and the resulting randomized control trial to assess its impact have been designed with extensive input from patients, family members, surgeons, health researchers, and other stakeholders. This trial is also overseen by a readily available patient/family co-investigator who communicates at least monthly with the study team and reviews study progress as well as participates in data evaluation. Thus, the current investigation is patient-centered not only in outcomes, but also in facilitation and data analysis.

Potential Contributions of this Study

To the best of our knowledge, this is the first investigation to explore the impact of a video ACP tool on surgeon, patient, and family communication prior to major surgery. A strength of this study is that the intervention video and resulting randomized control trial were both developed based on input from patients, companions, surgeons, health services researchers, and other stakeholders. Ultimately, the results of this RCT may demonstrate that easy-to-disseminate videos may activate patients and improve the patient-centeredness of surgeon/patient interactions.

Limitations

Several limitations regarding the study should be noted. First, the intervention video was initially conceptualized for a pancreatic cancer surgical population, potentially creating an issue for the generalizability of the video to a wider surgical population. Although the video was initially developed for the pancreatic cancer setting, the severity of pancreatic cancer surgery is analogous to other high-mortality/high-morbidity cancer surgeries. Moreover, the video itself does not specifically discuss cancer or pancreatic cancer. Thus, the intervention video should be relevant to a range of surgical patients and their families and is being evaluated among a group of patients with diverse cancer diagnoses.

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Second, the selected outcomes and timeframe of the study may not be able to fully capture the effect of the intervention as the impact of the surgery and video may persist beyond the one month time frame of the study. In order to mitigate this concern, data for multiple patient-centered outcomes is collected, many of which have been previously validated and used in surgical settings. These outcomes enable multi-faceted evaluation of the intervention. Additionally, results will be examined at several time-points, including both pre-operatively (V1, V2) and post-operatively (V3, V4). Yet, as other studies have shown benefit of ACP discussions as far as 12 months after hospitalization and patient death,[71] we might also hypothesize further benefits of the intervention to be apparent just before and after patient death, which is outside of the current trial timeframe.

Third, surgeon level factors will likely influence study outcomes. As all surgeons were privy to a general overview of the study and were provided with the opportunity to watch the intervention and control videos prior to agreeing to participate, the surgeons who ultimately decided to participate in the study may be biased in their pre-existing support for ACP. It is also possible that surgeons may have their own unconscious selection biases when referring patients to the study.

Fourth, one of the participating surgeons was featured in the intervention video. It is therefore possible that patients of this surgeon who are randomized to watch this video might surmise they are in the intervention group, which might impact their outcomes. In order to best account for these potential sources of bias, study randomization is nested within surgeon site of recruitment. Further, the analysis plan's designation of the surgeon as a random intercept should address the potential unmeasured influence of surgeon-level attributes on patient-level outcomes.

A final limitation of the study is that it can not control for the effect of a patient's medical course on study outcomes. Both presurgical factors such as diagnosis, as well as postsurgical factors such as surgical course or change in prognosis, might contribute to anxiety and depression, as well as to a patient's goals of care.

AUTHORS' CONTRIBUTIONS

RAA is the study principal investigator and she directed all study activities and coordinated between team members.

Study design: RAA, SRI, TY, MW, AEV, JFPB, DLR

Analysis design: RAA, SRI, TY, NLC, DLR

Protocol generation: RAA, SRI, NLC, AMCC, TY

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DATA SHARING: Datasets will be available on clinicaltrials.gov and/or per reasonable request to the study Principal Investigator.

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Figure legends

Figure 1. Trial Timeline

Figure 2. Trial Enrollment Diagram

Figure 3. Data Collection Plan

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Figure 1: Trial Timeline

Utilizing Advance Care Planning Videos to Empower Perioperative Cancer Patients and Families:
The Protocol for a Patient-Centered Outcomes Research Institute-funded Study

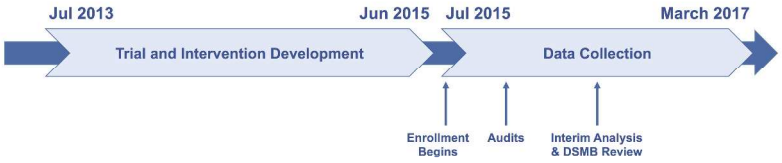

Figure 1. Trial Timeline

474x207mm (300 x 300 DPI)

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Figure 2: Trial Enrollment Diagram

Utilizing Advance Care Planning Videos to Empower Perioperative Cancer Patients and Families: The Protocol for a Patient-Centered Outcomes Research Institute-funded Study

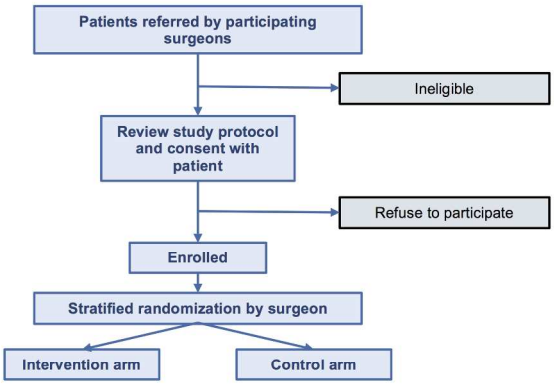

Figure 2: Trial Enrollment Diagram

279x361mm (300 x 300 DPI)

Figure 3: Data Collection Plan

Utilizing Advance Care Planning Videos to Empower Perioperative Cancer Patients and Families: The Protocol for a Patient-Centered Outcomes Research Institute-funded Study

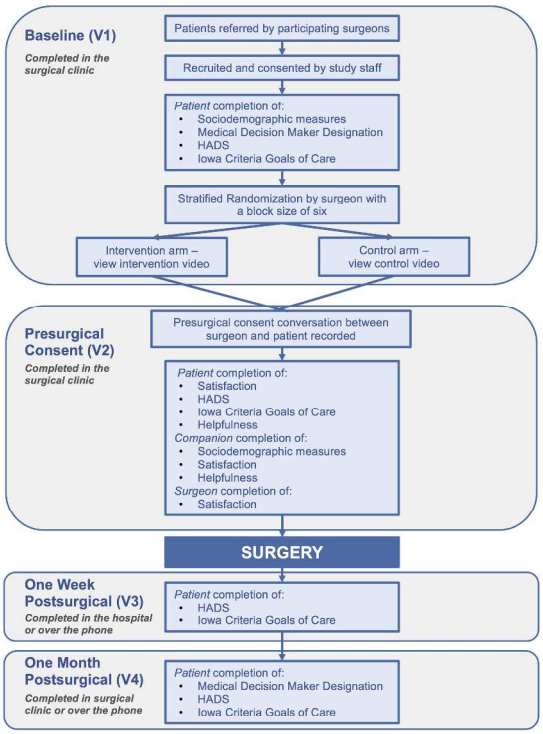

Figure 3. Data Collection Plan

339x381mm (300 x 300 DPI)

APPENDIX: Consent Forms

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A. Provider Consent Form

JOHNS HOPKINS MEDICINE

Approved June 24, 2015

Date: June 24, 2015
Principal Investigator: Rebecca Aslakson, MD PhD
Application No.: IRB00047112

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Utilizing advance care planning videos to empower perioperative cancer patients and families

(Consent for Providers)

Application No.: IRB00047112

Sponsor: Patient-Centered Outcomes Research Institute (PCORI)

Principal Investigator: Rebecca Aslakson MD PhD
Johns Hopkins Hospital
600 N. Wolfe Street
Meyer 296
Baltimore, Maryland 21287
Phone: 410-955-9080
Fax: 410-955-8978

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- If you receive routine medical treatment (including medical or laboratory tests) in the study or if you are taking part in the study at the Clinical Research Unit, information about your research study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital,

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Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.

- The Johns Hopkins School of Medicine Institutional Review Board (IRB) sometimes reviews studies that are conducted at other institutions. These other institutions are solely responsible for conducting the study safely and according to the protocol that the Johns Hopkins IRB has approved. Information about how to contact the investigator at the institution that is responsible for the study is included in this form. When another institution is conducting the study, the word "we" in this consent form may include both Johns Hopkins and the participating institution.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

The purpose of this study is to test whether a video for advance care planning might help patients and family members get the most out of talking to their doctors. We want to understand how this video might change the way patients might talk to their doctors.

You have been asked to join this study because you provide medical care to patients in one of the participating surgical clinics at Johns Hopkins Hospital. All providers seeing patients in these surgical clinics will be invited to take part in this study.

How many people will be enrolled in this study?

We plan to enroll approximately 90 patient participants

3. What will happen if you join this study?

If you agree to be in this study, you will be asked to complete a 5 minute background survey before we start enrolling patients.

For approximately one year, we will be inviting patients you designate to participate in this study. These patients require a surgical procedure. If you agree to take part, you will be asked to participate whenever one of your eligible patients agrees to participate.

We will ask to audiotape the consent visit with each participant. Our research staff will take care of starting and stopping the audio recorder. The audio recorder will be in a clearly visible place in the room and you can opt-out of the recording at any time by turning off the audio recorder. After the visit is over we will ask you to complete a short survey (1-5) questions about the visit.

Our research team will transcribe the audiotape and analyze the transcript.

At the end of the study, every provider who participates will receive a composite analysis of their communication with patients in the study.

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4. What are the risks or discomforts of the study?

There is a risk of self-consciousness or embarrassment associated with having your visit audiotaped.

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There is also a risk of breach of confidentiality if someone listening to the audio tape happens to recognize who you are. Our study team has built in several steps to protect your data. Once the audiotape is transcribed you will be identified only by a study ID number.

5. Are there benefits to being in the study?

There are no guaranteed benefits to taking part in this study. The results of this study may lead to improvements in doctor patient communication.

6. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not want to join you will continue to provide medical care to your patients as is standard procedure. If you do not join, your employment at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

No.

8. Will you be paid if you join this study?

No.

9. Can you leave the study early?

If you wish to leave the study you must notify a member of the study team.

10. How will your privacy be protected?

The study team will do everything they can to keep all study information private. Only code numbers, not your name, will be used on documents that list your answers to questions. The tape recording of your visit with the patient will be labeled with a study code number. Your name will be linked to this ID number in a separate file with a password. Only members of our study team will have access to this file. The file with your name will be destroyed once we have finished data collection. All study data and tape recordings will be kept in a locked file cabinet. Audiotapes will be destroyed at the end of the study. No names will be included when we type the notes of the consent visit.

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, gender and demographics about you.

Under some conditions, people in charge of making sure that the research is done properly may review your study records. This might include people from the NIH, the JHU Institutional Review Board or the Federal Office for Human Research Protections. All of these people are required to keep your identity confidential.

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11. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Aslakson at 410-955-9080. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. Aslakson, 410-955-9080 during regular office hours.

d. What happens to Data and that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.

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12. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time
Signature of Person Obtaining Consent	(Print Name)	Date/Time
Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required)	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

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B. Patient Consent Form

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If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Utilizing advance care planning videos to empower perioperative patients and families

Application No.: IRB00047112

Sponsor: Patient-Centered Outcomes Research Institute (PCORI)

Principal Investigator: Rebecca Aslakson MD PhD
Johns Hopkins Hospital
600 N. Wolfe Street
Meyer 296
Baltimore, Maryland 21287
Phone: 410-955-9082 | Fax: 410-955-8978

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

This research is being done to see whether viewing a video before you consent to your surgery might help you or your family get the most out of talking with your surgeon. We want to understand how this video might change the way you talk to your surgeon. You are being asked to join this study because you are scheduled to undergo a surgical procedure at the Johns Hopkins Hospital. We are asking about 90 other patients like you to take part in this study.

People may join the study if they are: aged 18 and older; have study surgeons who are scheduled to have a surgical procedure; identified by study surgeons to the study team; willing to give informed consent, able to speak English; reasonably able to read a newspaper or book (without sight impairment); reasonably able to listen to radio, television (without hearing impairment).

How many people will be in this study?

We plan to enroll approximately 90 patient participants.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things. First, we will ask you some questions about yourself and ask you to fill in a survey about how you are feeling (questions about anxiety and depression-called the Hospital Anxiety and Depression Survey (HADS) and about your goals of care. This should take about 15 minutes. We will ask you to view a short video that takes about 5 minutes to view. There are two videos in this study and you will be randomized to see only one of them, similar to flipping a coin.

The video can be seen either on a DVD disc we can give to you, a web link, or you can view the video on an electronic device such as an iPad that we can temporarily provide to you when you watch the video at Johns Hopkins. We are using one of two different videos, you will view only one. You will be assigned by chance (like through a coin toss) to view one video or the other. Your surgeon will not know which video you viewed.

When you come to visit your surgeon to sign the consent form for your surgery we will ask to audiotape this visit. Everyone who comes with you to the consent for your surgery visit must be 18 years of age or older and also be willing to be audiotaped for the study in order for you to take part. The audio recorder will be in a clearly visible place in the room and you can opt-out of the recording at any time by turning off the audio recorder. After your visit with your doctor we will ask you to stay for about 30 minutes to answer some questions about what you thought about your visit and to answer some questions about yourself and to fill in a survey about how you are feeling (HADS) and about your goals of care.
After this visit is over we will type out what you and the doctors say on the tape. We will listen to the tape to see how you and the doctor talked to each other.

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About one week after your surgery we will contact you either in person if you are in the hospital or via phone to ask you to fill in a few surveys about how you are feeling (HADS and goals of care). In about

person if you are visiting your surgeon at this time or we will call you via phone. Each of these visits or calls will take about 20 minutes.

You will be in this study for about one month.

Future Follow-up and Research

We would like your permission to possibly follow-up with you on your medical course following surgery.

Please initial your choice below:
_____ Yes, you may contact me in the future to follow-up on my medical course.
_____ No, I do not want you to contact me in the future to follow-up on my medical course.

We would like your permission to contact you about other studies that you may be eligible for in the future.

Please initial your choice below:
_____ Yes, you may contact me in the future about other studies.
_____ No, I do not want you to contact me about other studies

4. What are the risks or discomforts of the study?

Video: Viewing the video or answering our questions may make you feel tired or worried. You may stop the video any time you want.
Audiotape: During the part of the study where the audiotape is on, you have the option of turning it off if you choose.
Surveys: You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

As this is a placebo-controlled study (i.e., there is a control video), there is a risk that you may not receive the video that we are testing for effectiveness. The assignment to the control branch is not anticipated to impact your continuing standard clinical care.

Your surgeon knows you are taking part of this study but does not know which video you will be watching.

In the case of an emergency, your doctor can quickly find out the branch of the study to which you are assigned.

5. Are there benefits to being in the study?

There are no direct benefits to you from taking part in this study.

The purpose of the video is to help patients and family members have a meaningful discussion with the

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6. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

The video will be provided to you free of charge. If you are given a DVD disc, you can keep it.

8. Will you be paid if you join this study?

After you complete the last study visit you will be given a $25 dollar gift card.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

10. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your

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The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

11. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers at Johns Hopkins.

12. What does a conflict of interest mean to you as a participant in this study?

A researcher and Johns Hopkins have a financial or other interest in this study.

In some situations, the results of this study may lead to a financial gain for the researcher and/or Johns Hopkins. This financial interest has been reviewed in keeping with Johns Hopkins' policies. It has been approved with certain conditions, which are intended to guard against bias and to protect participants.

If you have any questions about this financial interest, please talk to Madeleine Moore at 410-614-4633. This person is a member of the study team, but does not have a financial interest related to the study. You may also call the Office of Policy Coordination (410-516-5560) for more information. The Office of Policy Coordination reviews financial interests of investigators and/or Johns Hopkins.

13. What treatment costs will be paid if you are injured in this study?

Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

- If you have health insurance: The costs for any treatment or hospital care you receive as the result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you.

- If you do not have health insurance: You will be billed for the costs of any treatment or hospital care you receive as the result of a study-related injury.

By signing this form you will not give up any rights you have to seek compensation for injury.

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14. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

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- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Aslakson at 410-955-9082. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. Aslakson at 410-955-9082 during regular office hours.

d. What happens to Data that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.

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15. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time
Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

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C. Oral Consent Form

JOHNS HOPKINS MEDICINE

Approved September 10, 2015

Date: September 10, 2015
Principal Investigator: Rebecca Aslakson MD PhD
Application No.: IRB00047112

ORAL CONSENT SCRIPT

Protocol Title: Utilizing advance care planning videos to empower perioperative cancer patients and families

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PURPOSE

You are invited to take part in a research study. The purpose of this study is to determine how viewing a video may impact discussion between your family member and their doctor. You are being asked to participate because you came with your family member to visit his/her doctor before surgery. This visit is being audiotaped and we are inviting you to participate in the audiotaped part of the study and to complete a short survey immediately afterwards.

PROCEDURES

During the visit with the surgeon your family member has agreed to have the visit audio-recorded. An audio-recording device will be turned on during the visit and the visit will be audio-taped. The visit is primarily between your family member and his/her doctor but you may participate in the discussion and ask questions or give answers. A written version of the audiotape will be made and persons who participated in the discussion will be given a special code and no names will be used.

RISKS/DISCOMFORTS: There is no anticipated risk for your participation. All of the discussion in the doctor visit will be kept confidential. During the visit you may feel uncomfortable knowing that the discussion is being audio-recorded. If there is something you do not want to say or something you do not want to answer you do not have to. If there is something on the short survey that you do not want to answer, you do not have to.

BENEFITS: There is no direct benefit to you from being in this study. What we learn from this study may help us understand discussions between patients and their doctor before surgery.

VOLUNTARY PARTICIPATION

You do not have to agree to be in this study. If you do not want to join the study, it will not affect your family members' care at Johns Hopkins. You may refuse to answer any questions that you do not want to answer. If you have any questions about your rights as a research participant, or if you think you have not been treated fairly, you may call the Johns Hopkins Institutional Review Board (IRB) at 410-955-3008.

HIPAA DISCLOSURE: The study team may collect information about you which would include your name, your relation to the patient, your current job status, gender, race, age and educational level.

People at Johns Hopkins who are involved in the study or who need to make sure the study is being done correctly may ask to see the information. They may need to send your information to people outside of Johns Hopkins for the same reason.

These people will use your information for the purpose of the study. We will continue to collect information about you until the end of the study unless you tell us that you have changed your mind. If you change your mind and don't want your information used for the study anymore, you can call The Johns Hopkins Institutional Review Board at 410-955-3008. Just remember, if we have already used your information for the study, the use of that information cannot be cancelled. We try to make sure that everyone who needs to see your information uses it only for the study and keeps it confidential - but, we cannot guarantee this.

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