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Improving outcomes from high-risk surgery: A study protocol to evaluate patient-centred advanced care planning

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3 **Improving outcomes from high-risk surgery: A study protocol to evaluate patient-**
4 **centred advanced care planning**
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ABSTRACT

Introduction. Patients who are frail, have multiple co-morbidities or have a terminal illness often have poor outcomes from surgery. However, sole specialists may recommend surgery in these patients without consultation with other treating clinicians or allowing for patient goals. The Patient-Centred Advanced Care Planning (PC-ACP) model of care provides a framework in which a multi-disciplinary advanced care plan is devised to incorporate high-risk patients' values and goals. Decision-making is performed collaboratively by patients, their family, surgeons, anaesthetists, intensivists and surgical case managers. This study aims to evaluate the feasibility of this new model of care, and to determine potential benefits to both patients and clinicians. **Methods and analysis.** After being assessed for frailty, patients will complete a patient-clinician information engagement survey pre-treatment and at six months follow-up. Patients (and/or family members) will be interviewed about their experience of care pre-treatment and at three and six month follow-ups. Clinicians will complete a survey on workplace attitudes and engagement both pre- and post-implementation of PC-ACP and be interviewed, following each survey, on the implementation of PC-ACP. We will use process mapping to map the patient journey through the surgical care pathway to determine areas of improvement and to identify variations in patient experience. **Ethics and dissemination.** This study has received ethical approval. Results will be communicated to the participating hospital, presented at conferences and submitted for publication in a peer-reviewed Medline-indexed journal.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study will evaluate the implementation of a new surgical model to improve surgical decision-making for high-risk patients in a real-world hospital setting.
- The new surgical model has the potential to improve patient satisfaction and interdisciplinary engagement across specialties, by involving patients, their families and clinicians from various disciplines in decision-making. It also has the potential to decrease the costs of prolonged or inappropriate treatments.
- This evaluation will assess patient and clinician experience of the new surgical model to inform future implementation of the new model.
- Participant attrition will be a key challenge for this study due to the high risk of poor outcomes in the patient population. In order to minimise the effects of attrition, family members may be interviewed on patients' behalf.
- This study is a feasibility evaluation and not a clinical trial. It has a small sample size and will not provide information on the impact of the new surgical model on patient outcomes.

INTRODUCTION

Frail, high-risk patients presenting for surgery pose a complex problem. For them, surgery can offer hope, but also the potential for many adverse events.[1 2] Patients who are frail, have a terminal illness, or have multiple comorbidities have poorer outcomes from surgery than other patients.[3-6] However, decisions made by a sole specialist do not always take into account the high likelihood of multisystem complications facing these patients. Additionally, during the perioperative period, advance directives tend to be poorly managed, particularly Do Not Resuscitate (DNR) orders for post-operative care.[7 8] These factors

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3 may lead to high-risk patients receiving non-beneficial surgical treatments or treatments that
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5 do not align with their goals.[9]
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8 One of the study authors (SS) has developed a decision-making process for surgical
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10 patients who are identified prior to surgery as being at high-risk of postsurgical complications
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12 or poor outcomes. A multi-disciplinary advanced care plan is then devised collaboratively
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14 with patients, their families, surgeons, anaesthetists, intensivists, surgical case managers and
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16 other relevant clinicians. This process is designed to ensure treatments are in keeping both
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18 with patient goals and values and with what is medically appropriate. Similar models have
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20 been welcomed by stakeholders[10] and shown to be beneficial for cardiac and cancer care.[1
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26 The proposed model, Patient-Centred Advanced Care Planning (PC-ACP), allows for
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28 more extensive planning and may lead to safer and more effective care. The PC-ACP process
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30 provides a framework for logical engagement and communication with the patient and
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32 between clinical teams. If the model of care is shown to be beneficial, it may lead to better
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34 outcomes for high-risk patients presenting for surgery. Our project will implement this
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36 decision process in an Australian hospital, initially as a pilot study where PC-ACP will be
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38 trialled for patients undergoing elective surgery in the fields of cardiac surgery, general
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40 surgery, vascular surgery and orthopaedics.
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50 **The PC-ACP intervention**

51 Patients at high-risk of poor surgical outcomes require extra care to safeguard their journey
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53 through the surgical process. Delivering high quality and maximally effective care to these
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55 patients requires a multi-specialty approach. The PC-ACP intervention (Figure 1) consists of
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57 a new decision-making process that leads to a multidisciplinary advanced care plan for high-
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3 risk surgery patients. The decision tree constitutes a framework for engagement and
4 collaboration, not just with clinicians, but also with patients and families. It is intended to
5 explore patients' goals and values and facilitate discussion on whether surgery aligns with
6 those goals. Early work with colleagues from cardiothoracic surgery suggests this approach
7 provides an improved cohesive response and more effective care.
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14 15 16 17 18 **Project overview and scope**

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20 This project aims to evaluate the feasibility of the new PC-ACP model of care and identify
21 potential benefits to both patients and clinicians. Results from this study will inform future
22 guidelines for surgery on patients at high risk of adverse events or poor outcomes due to
23 frailty, multiple co-morbidities or terminal illness.
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30 31 32 **METHODS AND ANALYSIS**

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34 The study will involve several stages of surveys and interviews with both patients and staff
35 (Figure 2) and process mapping. We will use this triangulated qualitative and quantitative
36 approach to determine the effectiveness of the new decision-making intervention. Two main
37 types of data will be examined: patient experience and clinician experience. Patient
38 experience data will also be used to map the patient journey (see Data analysis).
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49 50 **Study setting**

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52 The study will take place at a public tertiary referral hospital in Queensland, Australia, at
53 which PC-ACP will be implemented. Recruitment of participants and patient frailty
54 assessments will take place within the relevant hospital departments. Surveys will be
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3 completed online or on paper at a convenient location. Interviews will be conducted at the
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5 hospital, participants' homes or over the phone, as participant circumstances permit.
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10 **Participants**

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12 Participants will consist of high-risk surgical patients, nominated family members and staff
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14 members involved in treating these patients (surgeons, anaesthetists, intensivists and surgical
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16 case managers). Inclusion criteria for patients, family members and staff members are listed
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18 in Table 1. Patients meeting the inclusion criteria will be invited to participate in the study,
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20 which involves responding to two surveys and participating in three interviews. Each patient
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22 will have the option of nominating a family member to participate in interviews, either
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24 alongside the patient, or on their behalf. Recruitment of patients and family members will
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26 continue until approximately ten patients (or nominated family members) have completed all
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28 surveys and interviews.
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34 All clinical staff members at the participating hospital, who meet the inclusion criteria
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36 (Table 1), will be invited to complete two surveys. One survey will be conducted at the
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38 commencement of the study, and the other following implementation of the PC-ACP. After
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40 each survey, up to ten responders will be invited to participate in a follow-up interview.
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42 Clinical participants will be drawn from four groups of staff: surgeons, anaesthetists,
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44 intensivists and surgical case managers. Interviewees will be purposively selected to ensure at
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46 least one member of each group is interviewed.
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Table 1. Inclusion criteria

Patients	Patient presenting for surgery with one or more of the following: two or more co-morbidities, terminal illness, frailty identified by treating clinician
Patient family members	Nominated by patient as next-of-kin or surrogate for patient care decision-making in advance care directive or similar
Staff members	A minimum of 50% of time working as surgical case manager (including nursing staff), surgeon, anaesthetist, intensivist, etc. for high-risk surgical patients

Recruitment

Patients (and/or families)

Surgeons working in the vascular surgery, cardiac surgery, general surgery and orthopaedics departments will be invited via letter to identify patients who meet the inclusion criteria (Table 1) and refer them to investigators. The investigators will verbally inform these patients and their families about the research and provide written information about the study to those who are interested (see Figure 2, top orange box). Patients and family members will be informed of the voluntary nature of their involvement, and that non-participation will not affect their medical care or their relationship with the hospital. They will be provided with a copy of the participant information sheet. Those who elect to participate will be assessed for frailty and invited to complete a survey either on paper or online. Patients completing the survey on paper will be given a paper consent form and survey and patients completing the survey online will be given a link for consent and survey completion. Both paper and

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3 electronic consent forms will include tick-boxes via which participants can indicate their
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5 consent to be contacted for three semi-structured interviews and a six-month follow-up
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7 survey.
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10 Patients who consent to be contacted will then be invited to participate in a series of
11
12 three interviews. If the patient is unable to participate due to illness or incapacity, the family
13
14 member responsible for their care decisions may elect to be interviewed on their behalf.
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16 Patients may also choose to have a family member participate alongside them in their
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18 interview. The family member approached will be the person named on the patient's advance
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20 care directive or hospital paperwork as next-of-kin or legal guardian (Table 1).
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26 Staff members

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29 The investigators will verbally inform staff members who meet the inclusion criteria (Table
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31 1) about the research and provide written information about the study to those who are
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33 interested. Staff members will be informed of the voluntary nature of their involvement, and
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35 that non-participation will not affect job performance appraisal. They will be provided with a
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37 copy of the participant information sheet. Those who elect to participate will be invited to
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39 complete an online survey and given a link for consent and survey completion. The consent
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41 form will include tick-boxes with which participants can indicate their consent to be
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43 contacted for a follow-up interview, a six-month follow-up survey and a six-month follow-up
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45 interview.
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50 Up to ten staff members who complete the survey and consent to be contacted for
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52 follow-up will then be invited to participate in a semi-structured interview (Figure 2, blue
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54 boxes at top left). Investigators will purposively select potential interviewees, using
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56 demographic survey data to ensure all groups of staff are represented in the interview sample.
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3 At six months post-implementation, participating staff members who consent to be
4 contacted will be invited to participate in a post-implementation survey and up to ten survey
5 responders will again be selected for follow-up interviews (Figure 2, blue boxes at bottom
6 left). Recruitment and selection will follow the same procedure as the initial survey and
7 interview.
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14 15 16 17 **Data collection**

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20 Data collection will involve both quantitative and qualitative methods, with two major
21 components: patient experience and clinician experience. Each component will involve
22 several surveys and interviews over a six month period.
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30 Patient frailty assessment

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33 Surgeons will refer patients they deem to be frail to this study. However, the participating
34 hospital has no standard method of assessing frailty, and each surgeon may base their
35 assessment on different criteria. Thus, investigators will independently assess the frailty of all
36 participating patients using The Edmonton Frail Scale.[12] This scale has been shown to be a
37 valuable tool for assessing frailty in high-risk surgical patients[13 14] and the British
38 Geriatrics Society recommends its use to assess frailty in all older patients presenting for
39 elective surgery.[15] The scale consists of ten domains, each scored with 0, 1, or 2 points.
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41 Two domains are practical: cognition, which involves drawing a clock with the hands pointed
42 to a designated time, and functional performance, which measures how long the patient takes
43 to stand up from a chair, walk three metres and return to sit in the chair. The remaining
44 domains consist of questions about general health status, functional dependence, social
45 support, medication use, nutrition, mood, and continence. Scores for each domain are added
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3 to give a total frailty score out of 17, where 0-5 = not frail, 6-7 = vulnerable, 8-9 = mild
4 frailty, 10-11 = moderate frailty, and 12-17 = severe frailty.
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10 Patient experience

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12 Patient experience will be measured using the Patient Clinician Information Engagement
13 (PCIE) survey[16] pre-treatment and at six months follow-up (Figure 2, blue boxes at bottom
14 right). This validated survey examines patients' feelings of being informed about their
15 treatment and information engagement between the patient and their clinician. This survey
16 has demonstrated that feeling informed at baseline positively predicts decision satisfaction for
17 patients at twelve months follow-up.[16] The pre-treatment PCIE survey consists of thirteen
18 fixed response components. The first five questions, measured by a five-point Likert scale
19 from 1 (strongly disagree) to 5 (strongly agree) ask about patients' feelings of being
20 informed. The following eight Yes/No questions ask about patients' information seeking and
21 engagement with their clinician in the first few months after their diagnosis of the condition
22 requiring surgery. The post-treatment PCIE survey consists of two five-point Likert scale
23 questions about patients' feelings of being informed, followed by eight Yes/No questions
24 about patients' information engagement in the past 6 months after their diagnosis. Both
25 patient surveys will also collect information on basic demographics (age, gender, education,
26 and living arrangements) and the proposed surgery. Participants will have the option of
27 completing the PCIE on paper or online using Qualtrics.[17]
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49 Patient experience will also be explored via three semi-structured interviews. These
50 interviews will be with patients and/or their nominated family member throughout their
51 journey through the surgical process, at pre-treatment and three and six month follow-ups
52 (Figure 2, blue boxes at bottom right). The patient interview schedule is informed by the
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3 Cambridge University Hospitals NHS Foundation Trust question set and guidance for patient
4 feedback interviews.[18] Interviewees will be asked about the patient's journey through the
5 surgical care pathway and their level of satisfaction with the processes of care. Patient semi-
6 structured interview questions are presented in Appendix A.
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12 After consent has been obtained, a mutually convenient time will be arranged with
13 each participant for a face-to-face interview in a private room. If a face-to-face interview is
14 impractical, the participating patient or family member may be interviewed over the
15 telephone. Interviews will be audio recorded for transcription. Before starting the interview,
16 the interviewer will remind participants about the implications of their consent and that they
17 can ask to stop the audio recording at any time. Depending on participant responses, it is
18 anticipated that each patient interview will take up to 60 minutes.
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31 Clinician experience

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33 Clinician experience will be measured using a revised version of the Safety Attitudes
34 Questionnaire (SAQ), [19 20] at pre- and post-implementation of the new model of care
35 (Figure 2, blue boxes at top and bottom left). Over the last decade, the SAQ has emerged as
36 an accepted standard for measuring clinician attitudes and engagement in the workplace.
37 There are several versions of the survey; each optimised to a particular healthcare work
38 environment. We will use the version specifically developed for the Operating Theatre (OR).
39 The SAQ begins with a Collaboration and Communication section in which participants rate
40 the quality of communication and collaboration with various hospital staff (e.g. surgical staff,
41 OR nurses), measured on a five-point Likert scale from 1 (very low) to 5 (very high). The
42 remainder of the SAQ consists of 58 questions measuring attitudes in six domains
43 (Teamwork Climate, Safety Climate, Job Satisfaction, Stress Recognition, Perceptions of
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3 Management and Working Conditions), using a five-point Likert scale from 1 (disagree
4 strongly) to 5 (agree strongly).
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8 In the revised version of the SAQ (OR Version) used in this study, Communication
9 and Collaboration ratings have been reduced from fifteen to nine. Ratings for irrelevant or
10 inapplicable hospital staff have been removed or amended to fit with the Australian
11 healthcare system, and ratings for patients and patients' families have been added to satisfy
12 the study aims. In addition, the clinician survey only includes the three SAC domains relevant
13 to this study: Teamwork Climate, Safety Climate and Job Satisfaction. Revising the survey in
14 this manner maintains the integrity and validity of the tool while ensuring it collects data only
15 on the aspects of team functioning relevant to the study. The revised survey is approximately
16 half the length of the original, with 26 domain questions instead of the original 58. From
17 previous experience with this instrument, we estimate that it will take clinicians no more than
18 ten minutes to complete the survey. The clinician survey will also collect information about
19 clinicians' demographics (e.g. age, gender) and professional experience (e.g. position, years
20 in specialty). Participants will complete the survey online using Qualtrics.[17]
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37 Clinician experience with the PC-ACP will also be explored via semi-structured
38 interviews following each survey with up to ten survey responders. Clinical participants will
39 be asked about their experiences of applying the new decision-making process in their
40 workplace and barriers or enablers to its implementation. The procedure for clinician
41 interviews will match the procedure for face-to-face patient interviews. Depending on
42 participant responses, it is anticipated that each staff interview will take up to 30 minutes.
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51 Clinician semi-structured interview questions are presented in Appendix B.
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56 Data analysis

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Survey data

All data will be de-identified and coded for analysis. Patients' frailty score from 0 to 17 on the Edmonton Frail Scale[12] will form part of patient pre-treatment demographic data. All demographic data will be analysed via descriptive statistics and will be taken into account in the analysis of survey and interview data.

Pre-treatment and six-month follow-up patient surveys will be analysed and compared as per published procedures[16] and via descriptive statistics to identify changes in patient satisfaction and feelings of being informed, and to determine whether pre-treatment information seeking and engagement with clinicians predicts later satisfaction. Patient survey data will also inform process mapping. Patient frailty scores and patient demographics, such as details of proposed surgery or medical condition, will be included in survey analysis to discover whether these factors relate to any changes in patient goals and satisfaction from pre-treatment to six months follow-up.

Clinician surveys will be analysed as per published procedures for the SAQ[19 20] and via descriptive statistics. Pre- and post-implementation surveys will be compared using statistical t-tests. This analysis will help ascertain clinician satisfaction with the PC-ACP model of care and identify any changes to workplace communication and culture resulting from the new model of care. Clinician demographics, such as professional role and experience, will be included in the analysis of clinician survey data to determine whether these factors relate to changes in workplace communication and culture as a result of PC-ACP implementation.

Interview data

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3 Patient, family member, and clinician interviews will be transcribed verbatim for analysis.
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5 Key themes from each sample will be identified by inductive interpretive analysis using the
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7 'constant comparative method'[21]. This method will be somewhat modified to allow for the
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9 semi-structured nature of the interview data. Using this method of coding, we will organise
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11 the interview data into data segments, which will then be formally linked. This process will
12
13 allow themes to emerge and reveal potential relationships between data sets. This method will
14
15 permit us to probe this real-world, complex system using multifaceted qualitative data from
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17 interviews. Coded patient and family member interview data will inform process mapping.
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21 Clinician interviews will be coded with particular focus on barriers and enablers
22
23 associated with implementing PC-ACP. These will be analysed according to the Theoretical
24
25 Domains Framework.[22] This framework for understanding behaviour change was
26
27 developed to both evaluate and inform implementation and has been successfully used in the
28
29 context of healthcare. It includes 14 domains, each with several component constructs:
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31 knowledge; skills; social/professional role and identity; beliefs about capabilities; optimism;
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33 beliefs about consequences; reinforcement; intentions; goals; memory, attention and decision
34
35 processes; environmental context and resources; social influences; emotion and behavioural
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37 regulation.[22] Coding clinician interview data in line with this framework will ensure a
38
39 complete account of barriers and enablers to implementation is obtained. Without this
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41 theoretical guidance, some less obvious but important barriers or enablers may be missed.
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49 Mapping the patient journey

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52 Process mapping[23] will be used to map the journey of each patient through the surgical
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54 care pathway. This technique aims to identify the main components of the process, any
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56 critical or leverage points for process improvement and the extent to which the process varies
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3 between patients. Visualising the process helps identify process inefficiencies (e.g., parallel
4 or redundant processes) that are barriers to providing coordinated patient care. We will map
5 the processes comprising the patient journey through the new PC-ACP model of care, based
6 on de-identified data from the three stages of patient interviews and pre-treatment and six-
7 month follow-up patient surveys. In this way, patient data will be used to develop a narrative
8 outline of steps within the PC-ACP process and construct flowcharts outlining the main
9 stages of the patient journey.
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22 **ETHICS AND DISSEMINATION**

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24 This study is considered to be low risk for participants. Surveys and interview questions are
25 not anticipated to be controversial or overly intrusive. Ethical approval has been obtained
26 from the Human Research Ethics Committee (HREC) associated with the participating
27 hospital (HREC/16/xxx/100; Figure 2, first green box), and hospital governance approval has
28 also been obtained (SSA/16/xxx/193; Figure 2, third green box). The data will be stored in a
29 re-identifiable form until the completion of data collection, with a unique code for each
30 participant. Findings will not be reported in a manner that enables individual participant
31 responses to be identified. If groups (e.g. surgeons) consist of fewer than five members,
32 responses will be combined with those from other groups in reports.
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45 Given the high risk of adverse events in the patient population involved in this study,
46 one major ethical consideration is the possibility of distressing families of participants by
47 contacting patients who have died during their treatment. To avoid this situation,
48 investigators will contact the hospital to establish that the patient is alive, prior to contacting
49 him or her at three- and six-month follow-up. In the event of patient death, study
50 investigators who are clinicians at the participating hospital will approach family members
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3 and invite them to participate in interviews. Because these investigators are experienced at
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5 communicating with families of deceased patients, this method of approaching family
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7 members will help safeguard their dignity. Interviewing family members about the patient's
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9 experience of care may be helpful to the grieving process. Nevertheless, this procedure will
10
11 be carefully managed to ensure it will not be upsetting for families. Family members will
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13 only be invited for interviews, not the follow-up patient survey.
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17 Results of this study will outline levels patient satisfaction with PC-ACP, specify
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19 barriers and enablers to implementation and highlight critical points in the process for
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21 improvement. At the end of the project, draft and final evaluation reports will be
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23 disseminated to the participating hospital. These reports will present key findings from the
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25 study and recommendations for ongoing implementation of PC-ACP in high-risk surgical
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27 patients. Macquarie University investigators will present the findings and implications of the
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29 study to the hospital executive so that implementation of PC-ACP at the site can be
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31 optimised. Study findings and implications of interest to an academic audience will be
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33 submitted for publication in peer-reviewed Medline-indexed journals and presented at
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35 academic conferences and workshops.
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45 **CONCLUSION**

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48 By introducing patient-centred decision-making to the surgical process, the new
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50 model of care has the potential to enhance the patient experience and improve the journey
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52 through the surgical process for patients at high risk of poor outcomes. Under the new model,
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54 clinicians will share responsibility for health outcomes with patients, and patients will only be
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56 admitted for surgery if it meets their goals and values better than alternative treatments.
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Therefore, the new process may help prevent potentially avoidable hospital admissions. Seeking feedback from patients, family members and clinicians involved with the new model of care means the future implementation of this model will meet patients' needs while also mitigating barriers and profiting from enablers to implementation. Thus, this study will facilitate the best future implementation of PC-ACP.

FOOTNOTES

Contributors

SS conceived and developed the PC-ACP model of care. RCW and SS devised the study design, protocol and plan and contributed to the development of the manuscript. AS contributed to the study design and protocol, led the ethics applications and led the development of the manuscript. BB contributed to the study design and the development of the manuscript. PL contributed to the study design and planning. JN provided clinical expertise and advice. SS and PL will provide on-site management of the study. RCW, AS and BB will be involved in data collection and analysis. All authors have read and approved the final version of this manuscript.

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Competing interests

1
2
3 We have read and understood the *BMJ* policy on declaration of interests and declare that we
4
5 have no competing interests.
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10 **Data sharing statement**

11
12 Data will be made publicly available to the extent that individual participants or participating
13
14 hospitals cannot be identified, in accordance with requirements of the approving Human
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16 Research Ethics Committees.
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20 **Exclusive licence statement**

21
22 I Amanda Selwood the Corresponding Author of this article contained within the original
23
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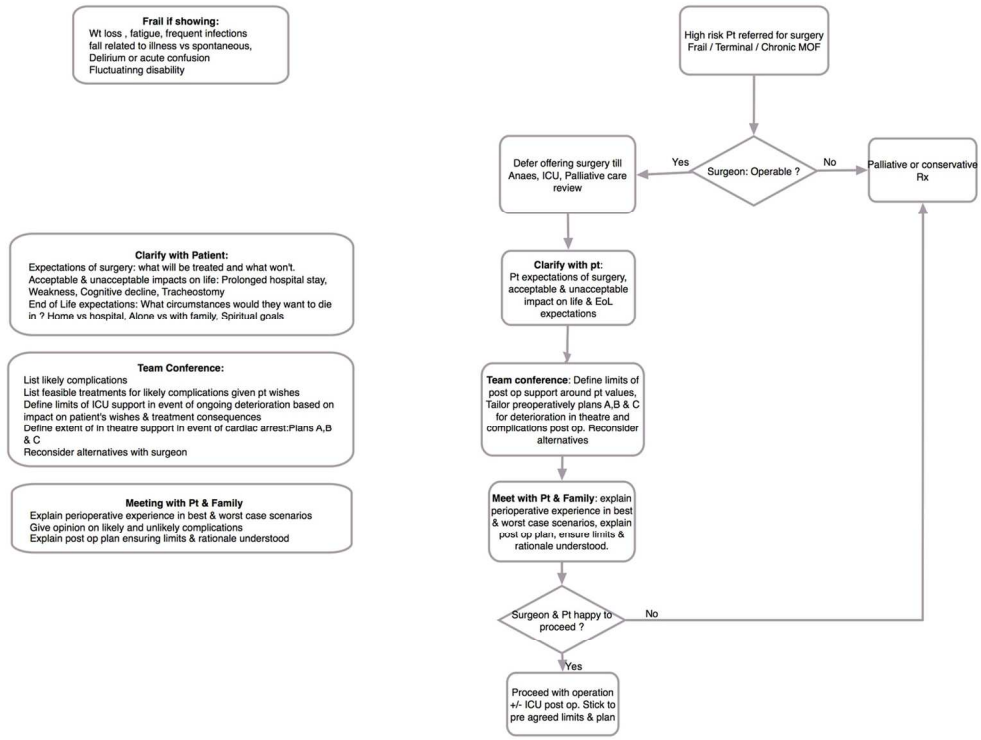
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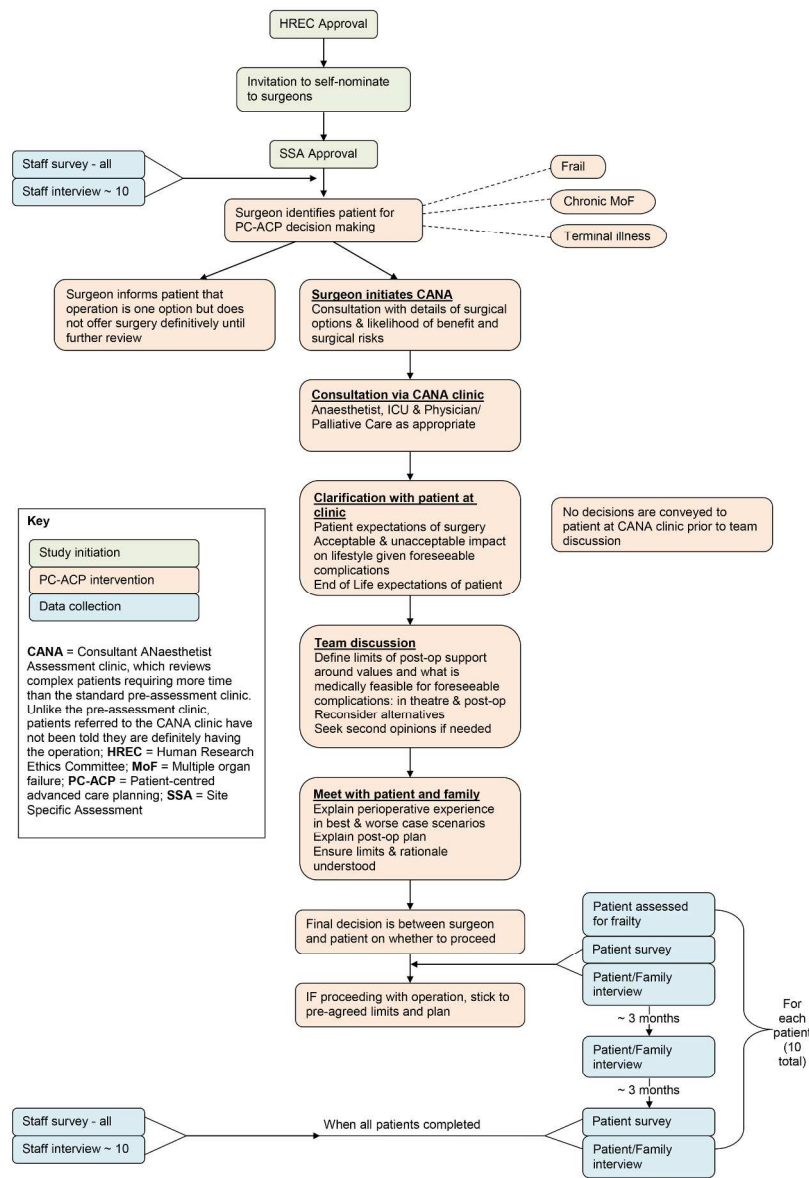
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Patient-Centred Advanced Care Planning
Figure 1
127x95mm (300 x 300 DPI)



Study outline
 Figure 2
 223x313mm (300 x 300 DPI)

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Appendix A: Patient semi-structured interview questions

Guidance:

- Keep the interview as short as possible.
- Stop if the patient is distressed, confused or uncomfortable. Seek help to calm the patient.
- Do not identify the patient in any written records.

The information collected will be demographic information and responses to the following questions.

A: Introduction

- Do you remember having a chat with [*name of member(s) of advanced care planning team*] about those things that are important to you?
- I would like to talk to you about how you felt about the process. But, firstly, I must make it clear that giving your honest answers to my questions won't affect your care, your treatment or your rehabilitation plan in any way. This also applies if you decide not to talk to me.

Secondly, what you say will not be used to criticise [*name of member(s) of advanced care planning team*]. He/she/they is/are happy that I am talking to you. By agreeing to talk to me, you are providing useful information that we hope will improve all patients' care.

B: Questions

- How long have you been in hospital/under the care of [*name of member(s) of advanced care planning team*]?
- Have you been under the care of [*name of member(s) of advanced care planning team*] or had surgery before?

If 'yes', prompt for the patient's view of how they have been involved in the past.

- Can you tell me about your meeting sessions with the [*name of member(s) of advanced care planning team*]?

How helpful were they for you?

Were you satisfied with the outcome of the sessions?

- Did you feel that the [*name of member(s) of advanced care planning team*] listened to you and understood what was important to you?

[Whether 'yes' or 'no'] Can you give an example?

- Have you planned any actions (tasks) with the [*name of member(s) of advanced care planning team*] to achieve things that are important to you?

Examples, please.

- Can you tell me about your experience of working with the [*name of member(s) of advanced care planning team*] towards these goals?

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3 What worked well?

4 Were there any challenges?

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6 • How confident did you feel that the [*name of member(s) of advanced care planning team*]
7 could help you to achieve your goals or, if not, that the [*name of member(s) of advanced*
8 *care planning team*] could get appropriate support from someone who could?
9
10 • Do you know or believe that what you have discussed has been acted on?
11 What has happened as a consequence?
12
13 • How involved have you felt that you have been in what has happened since?
14 Do you want more or less involvement? Please expand on this answer.
15
16 • Sometimes the things that are important to you will change over time. Did anything
17 change in importance to you after your initial discussion?
18 If so, how flexible was the [*name of member(s) of advanced care planning team*] in
19 supporting you to meet your new priorities?
20
21 • Is there any other support that you would like, that would help you achieve your goals?
22
23 • Do you have any comments on how helpful the forms were, when you had your
24 discussions with the [*name of member(s) of advanced care planning team*]?
25
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27
28 C: Demographic Information (on each occasion)

29
30 This information will not be linked to any participant's name. A number will be assigned as a
31 code reference for analysis purposes.
32

- 33
34 1. Patient Code (to match data from before/after surveys)
35 2. Gender, Age (18-50, 51-60, 61-70, 71-80, 81-105yrs)
36 3. Max education level (Primary school, Year 10, Year 12, bachelor degree,
37 postgraduate degree)
38 4. Place of primary residence (lives alone, lives with family, nursing home, other)
39 5. Proposed surgery/primary medical condition requiring surgery
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Appendix B: Clinician semi-structured interview questions

Interview Schedule

The information collected will be demographic information and responses to the following questions.

A: Background

- What do you understand by the term ‘shared decision making’?
- Have you had previous experience with shared decision making in the past:
 - Sharing decision making with other clinicians?
Examples, please.
 - Sharing decision making with patients?
Examples, please.

B: Shared decision making

- Do you think it is important to share decision making about patient care with other clinicians? Why/why not?
- Do you think it is important to share decision making about patient care with patients and their families? Why/why not?

C: PC-ACP Process (show clinician diagram and explain the process)

- What are your views on the proposed PC-ACP process?
- Are there advantages to using this process? If so, what are they?
- Are there disadvantages to using this process? If so, what are they?
- Do you see benefits for the patient in using this process? If so, what are they?
- Have you used/tried to use a process similar to this in the past? If so, what were your experiences?

D: Barriers and Enablers

- Did you experience (or anticipate) any barriers to applying the ideas from the PC-ACP process at Townsville Hospital?
- What made it (or would make it easier) to apply the ideas from the PC-ACP process at Townsville Hospital?
- Did you learn (or anticipate learning) anything new, interesting, useful or unexpected as a result of introduction of the PC-ACP process at Townsville Hospital?

E: Sustainability

- Do you believe that the PC-ACP process at Townsville Hospital is sustainable? Why/why not?

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- Do you believe that training is required to implement the PC-ACP process at Townsville Hospital? If so, what sort of training and who should be trained?
 - Was there any impact of implementation of the PC-ACP process at Townsville Hospital on your job satisfaction?
 - Would you like to make any other comments about your experiences in relation to the PC-ACP process at Townsville Hospital?

F: Demographic Information

This information will not be linked to any participant's name. A number will be assigned as a code reference for analysis purposes.

1. Gender, Age (bracket)
2. Profession (Surgeon, Anaesthetist, Intensivist, Palliative Care, Other)
3. Your professional level at TTHS
4. Time since specialist qualification to practice in this field
5. Time in this organisation

BMJ Open

Improving outcomes from high-risk surgery: a multi-method evaluation of a patient-centred advanced care planning intervention

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-014906.R1
Article Type:	Protocol
Date Submitted by the Author:	18-Jan-2017
Complete List of Authors:	Selwood, Amanda; Macquarie University, Australian Institute of Health Innovation Senthuran, Siva; Townsville Hospital and Health Service; James Cook University College of Medicine and Dentistry Blakely, Brette; Macquarie University, Australian Institute of Health Innovation Lane, Paul; Townsville Hospital and Health Service North, John; Princess Alexandra Hospital Clay-Williams, Robyn; Macquarie University, Australian Institute of Health Innovation
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Patient-centred medicine, Surgery
Keywords:	SURGERY, advanced care planning, frailty, implementation, decision-making, patient-centred care

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3 **Improving outcomes from high-risk surgery: A multi-method evaluation of a patient-**
4 **centred advanced care planning intervention**
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11 Amanda Selwood¹, Siva Senthuran^{2,3}, Brette Blakely¹, Paul Lane², John North⁴, Robyn Clay-
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46 **WORD COUNT**
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49 Abstract: 230
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55 **Keywords:** surgery, advanced care planning, frailty, implementation, decision-making,
56 patient-centred care
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ABSTRACT

Introduction. Patients who are frail, have multiple co-morbidities or have a terminal illness often have poor outcomes from surgery. However, sole specialists may recommend surgery in these patients without consultation with other treating clinicians or allowing for patient goals. The Patient-Centred Advanced Care Planning (PC-ACP) model of care provides a framework in which a multi-disciplinary advanced care plan is devised to incorporate high-risk patients' values and goals. Decision-making is performed collaboratively by patients, their family, surgeons, anaesthetists, intensivists and surgical case managers. This study aims to evaluate the feasibility of this new model of care, and to determine potential benefits to both patients and clinicians. **Methods and analysis.** After being assessed for frailty, patients will complete a patient-clinician information engagement survey pre-treatment and at six months follow-up. Patients (and/or family members) will be interviewed about their experience of care pre-treatment and at three and six month follow-ups. Clinicians will complete a survey on workplace attitudes and engagement both pre- and post-implementation of PC-ACP and be interviewed, following each survey, on the implementation of PC-ACP. We will use process mapping to map the patient journey through the surgical care pathway to determine areas of improvement and to identify variations in patient experience. **Ethics and dissemination.** This study has received ethical approval from Townsville Hospital and Health Service HREC (HREC/16/QTHS/100). Results will be communicated to the participating hospital, presented at conferences and submitted for publication in a peer-reviewed Medline-indexed journal.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study will evaluate the implementation of a new surgical model to improve surgical decision-making for high-risk patients in a real-world hospital setting.
- The new surgical model has the potential to improve patient satisfaction and interdisciplinary engagement across specialties, by involving patients, their families and clinicians from various disciplines in decision-making. It also has the potential to decrease the costs of prolonged or inappropriate treatments.
- This evaluation will assess patient and clinician experience of the new surgical model to inform future implementation of the new model.
- Participant attrition will be a key challenge for this study due to the high risk of poor outcomes in the patient population. In order to minimise the effects of attrition, family members may be interviewed on patients' behalf.
- This study is a feasibility evaluation and not a clinical trial. It has a small sample size and will not provide information on the impact of the new surgical model on patient outcomes.

INTRODUCTION

Frail, high-risk patients presenting for surgery pose a complex problem. For them, surgery can offer hope, but also the potential for many adverse events.[1 2] Patients who are frail, have a terminal illness, or have multiple comorbidities have poorer outcomes from surgery than other patients.[3-6] However, decisions made by a sole specialist do not always take into account the high likelihood of multisystem complications facing these patients. Additionally, during the perioperative period, advance directives tend to be poorly managed, particularly Do Not Resuscitate (DNR) orders for post-operative care.[7 8] These factors

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3 may lead to high-risk patients receiving non-beneficial surgical treatments or treatments that
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5 do not align with their goals.[9]
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8 One of the study authors (SS) has developed a decision-making process for surgical
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10 patients who are identified prior to surgery as being at high-risk of postsurgical complications
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12 or poor outcomes. A multi-disciplinary advanced care plan is then devised collaboratively
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14 with patients, their families, surgeons, anaesthetists, intensivists, surgical case managers and
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16 other relevant clinicians. This process is designed to ensure treatments are in keeping both
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18 with patient goals and values and with what is medically appropriate. Similar models have
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20 been welcomed by stakeholders[10] and shown to be beneficial for cardiac and cancer care.[1
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26 The proposed model, Patient-Centred Advanced Care Planning (PC-ACP), allows for
27
28 more extensive planning and may lead to safer and more effective care. The PC-ACP process
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30 provides a framework for logical engagement and communication with the patient and
31
32 between clinical teams. If the model of care is shown to be beneficial, it may lead to better
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34 outcomes for high-risk patients presenting for surgery. Our project will implement this
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36 decision process in an Australian hospital, initially as a pilot study where PC-ACP will be
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38 trialled for patients undergoing elective surgery in the fields of cardiac surgery, general
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40 surgery, vascular surgery and orthopaedics.
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50 **The PC-ACP intervention**

51 Patients at high-risk of poor surgical outcomes require extra care to safeguard their journey
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53 through the surgical process. Delivering high quality and maximally effective care to these
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55 patients requires a multi-specialty approach. The PC-ACP intervention (Figure 1) consists of
56
57 a new decision-making process that leads to a multidisciplinary advanced care plan for high-
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3 risk surgery patients. The decision tree constitutes a framework for engagement and
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5 collaboration, not just with clinicians, but also with patients and families. It is intended to
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7 explore patients' goals and values and facilitate discussion on whether surgery aligns with
8
9 those goals. Early work with colleagues from cardiothoracic surgery suggests this approach
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11 provides an improved cohesive response and more effective care.
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15 The process will be triggered by surgeons who identify patients who are 'operable'
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17 but at high risk of adverse events due to frailty, multiple co-morbidities and/or terminal
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19 illness. Unlike the current surgical pathway, this initial decision will be followed by multi-
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21 disciplinary discussions with patients and their families, making explicit any surgical 'buy-
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23 ins', [12] highlighting potential adverse outcomes of surgery and ensuring the patient is both
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25 clear about their choices and able to communicate their values prior to their decision to
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27 undergo surgery.
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31 Changes in patients' preferences throughout their treatment can be accommodated
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33 within the PC-ACP framework as they communicate them; this process is not designed to
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35 elicit a rigid treatment plan. Instead, for patients and their families, it is designed to elicit a
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37 consideration and an understanding of the potential consequences of surgery and additional
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39 follow-up treatments. For clinicians, it is designed to elicit a shared understanding across
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41 disciplines of patients' values and goals so they can be acted upon if necessary in
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43 circumstances when patients are unable to communicate their preferences.
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50 **Project overview and scope**

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53 This project aims to evaluate the feasibility of the new PC-ACP model of care and identify
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55 potential benefits to both patients and clinicians. Results from this study will inform future
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3 guidelines for surgery on patients at high risk of adverse events or poor outcomes due to
4 frailty, multiple co-morbidities or terminal illness.
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10 **METHODS AND ANALYSIS**

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12 The study will involve several stages of surveys and interviews with both patients and staff
13 (Figure 2) and process mapping. We will use this triangulated qualitative and quantitative
14 approach to determine the effectiveness of the new decision-making intervention. Two main
15 types of data will be examined: patient experience and clinician experience. Patient
16 experience data will also be used to map the patient journey (see Data analysis).
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28 **Study setting**

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30 The study will take place at a public tertiary referral hospital in Queensland, Australia, at
31 which PC-ACP will be implemented. Recruitment of participants and patient frailty
32 assessments will take place within the relevant hospital departments. Surveys will be
33 completed online or on paper at a convenient location. Interviews will be conducted at the
34 hospital, participants' homes or over the phone, as participant circumstances permit.
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45 **Participants**

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47 Participants will consist of high-risk surgical patients, nominated family members and staff
48 members involved in treating these patients (surgeons, anaesthetists, intensivists and surgical
49 case managers). Inclusion criteria for patients, family members and staff members are listed
50 in Table 1. Patients meeting the inclusion criteria will be invited to participate in the study,
51 which involves responding to two surveys and participating in three interviews. Each patient
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3 will have the option of nominating a family member to participate in interviews, either
4 alongside the patient, or on their behalf. Recruitment of patients and family members will
5 continue until approximately ten patients (or nominated family members) have completed all
6 surveys and interviews. The study will include patients who receive the PC-ACP model of
7 care, regardless of their decision to proceed with, delay or decline surgery. Including patients
8 who decline surgery as well as those who proceed with it will allow for a wider range of
9 patient experiences within the PC-ACP model of care.”
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19 All clinical staff members at the participating hospital, who meet the inclusion criteria
20 (Table 1), will be invited to complete two surveys. One survey will be conducted at the
21 commencement of the study, and the other following implementation of the PC-ACP. After
22 each survey, up to fifteen responders will be invited to participate in a follow-up interview.
23 Clinical participants will be drawn from four groups of staff: surgeons, anaesthetists,
24 intensivists and surgical case managers. Interviewees will be purposively selected to ensure at
25 least one member of each group is interviewed and will be continued until data saturation is
26 reached.
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Table 1. Inclusion criteria

Patients	Patient presenting for surgery with one or more of the following: two or more co-morbidities, terminal illness, frailty identified by treating clinician
Patient family members	Nominated by patient as next-of-kin or surrogate for patient care decision-making in advance care directive or similar
Staff members	A minimum of 50% of time working as surgical case manager (including nursing staff), surgeon, anaesthetist, intensivist, etc. for high-risk surgical patients

Recruitment

Patients (and/or families)

Surgeons working in the vascular surgery, cardiac surgery, general surgery and orthopaedics departments will be invited via letter to identify patients who meet the inclusion criteria (Table 1) and refer them to investigators. The investigators will verbally inform these patients and their families about the research and provide written information about the study to those who are interested (see Figure 2, top orange box). Patients and family members will be informed of the voluntary nature of their involvement, and that non-participation will not affect their medical care or their relationship with the hospital. They will be provided with a copy of the participant information sheet. Those who elect to participate will be assessed for frailty and invited to complete a survey either on paper or online. Patients completing the survey on paper will be given a paper consent form and survey and patients completing the survey online will be given a link for consent and survey completion. Both paper and

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3 electronic consent forms will include tick-boxes via which participants can indicate their
4
5 consent to be contacted for three semi-structured interviews and a six-month follow-up
6
7 survey.
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10 Patients who consent to be contacted will then be invited to participate in a series of
11
12 three interviews. If the patient is unable to participate due to illness or incapacity, the family
13
14 member responsible for their care decisions may elect to be interviewed on their behalf.
15
16 Patients may also choose to have a family member participate alongside them in their
17
18 interview. The family member approached will be the person named on the patient's advance
19
20 care directive or hospital paperwork as next-of-kin or legal guardian (Table 1).
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26 Staff members

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29 The investigators will verbally inform staff members who meet the inclusion criteria (Table
30
31 1) about the research and provide written information about the study to those who are
32
33 interested. Staff members will be informed of the voluntary nature of their involvement, and
34
35 that non-participation will not affect job performance appraisal. They will be provided with a
36
37 copy of the participant information sheet. Those who elect to participate will be invited to
38
39 complete an online survey and given a link for consent and survey completion. The consent
40
41 form will include tick-boxes with which participants can indicate their consent to be
42
43 contacted for a follow-up interview, a six-month follow-up survey and a six-month follow-up
44
45 interview.
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49
50 Up to fifteen staff members who complete the survey and consent to be contacted for
51
52 follow-up will then be invited to participate in a semi-structured interview (Figure 2, blue
53
54 boxes at top left). Investigators will purposively select potential interviewees, using
55
56 demographic survey data to ensure all groups of staff are represented in the interview sample.
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3 At six months post-implementation, participating staff members who consent to be
4 contacted will be invited to participate in a post-implementation survey and up to fifteen
5 survey responders will again be selected for follow-up interviews (Figure 2, blue boxes at
6 bottom left). Recruitment and selection will follow the same procedure as the initial survey
7 and interview.
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14 15 16 17 18 **Data collection**

19
20 Data collection will involve both quantitative and qualitative methods, with two major
21 components: patient experience and clinician experience. Each component will involve
22 several surveys and interviews over a six month period.
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30 Patient frailty assessment

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32 Surgeons will refer patients they deem to be frail to this study. However, the participating
33 hospital has no standard method of assessing frailty, and each surgeon may base their
34 assessment on different criteria. Thus, investigators will independently assess the frailty of all
35 participating patients using The Edmonton Frail Scale.[13] This scale has been shown to be a
36 valuable tool for assessing frailty in high-risk surgical patients[14 15] and the British
37 Geriatrics Society recommends its use to assess frailty in all older patients presenting for
38 elective surgery.[16] The scale consists of ten domains, each scored with 0, 1, or 2 points.
39 Two domains are practical: cognition, which involves drawing a clock with the hands pointed
40 to a designated time, and functional performance, which measures how long the patient takes
41 to stand up from a chair, walk three metres and return to sit in the chair. The remaining
42 domains consist of questions about general health status, functional dependence, social
43 support, medication use, nutrition, mood, and continence. Scores for each domain are added
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3 to give a total frailty score out of 17, where 0-5 = not frail, 6-7 = vulnerable, 8-9 = mild
4 frailty, 10-11 = moderate frailty, and 12-17 = severe frailty.
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10 Patient experience

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12 Patient experience will be measured using the Patient Clinician Information Engagement
13 (PCIE) survey[17] pre-treatment and at six months follow-up (Figure 2, blue boxes at bottom
14 right). This validated survey examines patients' feelings of being informed about their
15 treatment and information engagement between the patient and their clinician. This survey
16 has demonstrated that feeling informed at baseline positively predicts decision satisfaction for
17 patients at twelve months follow-up.[17] The pre-treatment PCIE survey consists of thirteen
18 fixed response components. The first five questions, measured by a five-point Likert scale
19 from 1 (strongly disagree) to 5 (strongly agree) ask about patients' feelings of being
20 informed. The following eight Yes/No questions ask about patients' information seeking and
21 engagement with their clinician in the first few months after their diagnosis of the condition
22 requiring surgery. The post-treatment PCIE survey consists of two five-point Likert scale
23 questions about patients' feelings of being informed, followed by eight Yes/No questions
24 about patients' information engagement in the past 6 months after their diagnosis. Both
25 patient surveys will also collect information on basic demographics (age, gender, education,
26 and living arrangements) and the proposed surgery. Participants will have the option of
27 completing the PCIE on paper or online using Qualtrics.[18]
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49 Patient experience will also be explored via three semi-structured interviews. These
50 interviews will be with patients and/or their nominated family member throughout their
51 journey through the surgical process, at pre-treatment and three and six month follow-ups
52 (Figure 2, blue boxes at bottom right). The patient interview schedule is informed by the
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3 Cambridge University Hospitals NHS Foundation Trust question set and guidance for patient
4 feedback interviews.[19] Interviewees will be asked about the patient's journey through the
5 surgical care pathway and their level of satisfaction with the processes of care. Patient semi-
6 structured interview questions are presented in Appendix A.
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12 After consent has been obtained, a mutually convenient time will be arranged with
13 each participant for a face-to-face interview in a private room. If a face-to-face interview is
14 impractical, the participating patient or family member may be interviewed over the
15 telephone. Interviews will be audio recorded for transcription. Before starting the interview,
16 the interviewer will remind participants about the implications of their consent and that they
17 can ask to stop the audio recording at any time. Depending on participant responses, it is
18 anticipated that each patient interview will take up to 60 minutes.
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31 Clinician experience

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33 Clinician experience will be measured using a revised version of the Safety Attitudes
34 Questionnaire (SAQ), [20 21] at pre- and post-implementation of the new model of care
35 (Figure 2, blue boxes at top and bottom left). Over the last decade, the SAQ has emerged as
36 an accepted standard for measuring clinician attitudes and engagement in the workplace.
37 There are several versions of the survey; each optimised to a particular healthcare work
38 environment. We will use the version specifically developed for the Operating Theatre (OR).
39 The SAQ begins with a Collaboration and Communication section in which participants rate
40 the quality of communication and collaboration with various hospital staff (e.g. surgical staff,
41 OR nurses), measured on a five-point Likert scale from 1 (very low) to 5 (very high). The
42 remainder of the SAQ consists of 58 questions measuring attitudes in six domains
43 (Teamwork Climate, Safety Climate, Job Satisfaction, Stress Recognition, Perceptions of
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3 Management and Working Conditions), using a five-point Likert scale from 1 (disagree
4 strongly) to 5 (agree strongly).
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8 In the revised version of the SAQ (OR Version) used in this study, Communication
9 and Collaboration ratings have been reduced from fifteen to nine. Ratings for irrelevant or
10 inapplicable hospital staff have been removed or amended to fit with the Australian
11 healthcare system, and ratings for patients and patients' families have been added to satisfy
12 the study aims. In addition, the clinician survey only includes the three SAC domains relevant
13 to this study: Teamwork Climate, Safety Climate and Job Satisfaction. Revising the survey in
14 this manner maintains the integrity and validity of the tool while ensuring it collects data only
15 on the aspects of team functioning relevant to the study. The revised survey is approximately
16 half the length of the original, with 26 domain questions instead of the original 58. From
17 previous experience with this instrument, we estimate that it will take clinicians no more than
18 ten minutes to complete the survey. The clinician survey will also collect information about
19 clinicians' demographics (e.g. age, gender) and professional experience (e.g. position, years
20 in specialty). Participants will complete the survey online using Qualtrics.[18]
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37 Clinician experience with the PC-ACP will also be explored via semi-structured
38 interviews following each survey with up to fifteen survey responders, or until data saturation
39 is reached. Clinical participants will be asked about their experiences of applying the new
40 decision-making process in their workplace and barriers or enablers to its implementation.
41 The procedure for clinician interviews will match the procedure for face-to-face patient
42 interviews. Depending on participant responses, it is anticipated that each staff interview will
43 take up to 30 minutes. Clinician semi-structured interview questions are presented in
44 Appendix B.
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Data analysis

Survey data

All data will be de-identified and coded for analysis. Patients' frailty score from 0 to 17 on the Edmonton Frail Scale[13] will form part of patient pre-treatment demographic data. All demographic data will be analysed via descriptive statistics and will be taken into account in the analysis of survey and interview data.

Pre-treatment and six-month follow-up patient surveys will be analysed and compared as per published procedures[17] and via descriptive statistics to identify changes in patient satisfaction and feelings of being informed, and to determine whether pre-treatment information seeking and engagement with clinicians predicts later satisfaction. Patient survey data will also inform process mapping. Patient frailty scores and patient demographics, such as details of proposed surgery or medical condition, will be included in survey analysis to discover whether these factors relate to any changes in patient goals and satisfaction from pre-treatment to six months follow-up.

Clinician surveys will be analysed as per published procedures for the SAQ[20 21] and via descriptive statistics. Pre- and post-implementation surveys will be compared using statistical t-tests. This analysis will help ascertain clinician satisfaction with the PC-ACP model of care and identify any changes to workplace communication and culture resulting from the new model of care. Clinician demographics, such as professional role and experience, will be included in the analysis of clinician survey data to determine whether these factors relate to changes in workplace communication and culture as a result of PC-ACP implementation.

Interview data

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3 Patient, family member, and clinician interviews will be transcribed verbatim for analysis.
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5 Key themes from each sample will be identified by inductive interpretive analysis using the
6
7 'constant comparative method'[22]. This method will be somewhat modified to allow for the
8
9 semi-structured nature of the interview data. Using this method of coding, we will organise
10
11 the interview data into data segments, which will then be formally linked. This process will
12
13 allow themes to emerge and reveal potential relationships between data sets. This method will
14
15 permit us to probe this real-world, complex system using multifaceted qualitative data from
16
17 interviews. Coded patient and family member interview data will inform process mapping.
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20
21 Clinician interviews will be coded with particular focus on barriers and enablers
22
23 associated with implementing PC-ACP. These will be analysed according to the Theoretical
24
25 Domains Framework.[23] This framework for understanding behaviour change was
26
27 developed to both evaluate and inform implementation and has been successfully used in the
28
29 context of healthcare. It includes 14 domains, each with several component constructs:
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31 knowledge; skills; social/professional role and identity; beliefs about capabilities; optimism;
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33 beliefs about consequences; reinforcement; intentions; goals; memory, attention and decision
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35 processes; environmental context and resources; social influences; emotion and behavioural
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37 regulation.[23] Coding clinician interview data in line with this framework will ensure a
38
39 complete account of barriers and enablers to implementation is obtained. Without this
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41 theoretical guidance, some less obvious but important barriers or enablers may be missed.
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49 Mapping the patient journey

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52 Process mapping[24] will be used to map the journey of each patient through the surgical
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54 care pathway. This technique aims to identify the main components of the process, any
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56 critical or leverage points for process improvement and the extent to which the process varies
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3 between patients. Visualising the process helps identify process inefficiencies (e.g., parallel
4 or redundant processes) that are barriers to providing coordinated patient care. We will map
5 the processes comprising the patient journey through the new PC-ACP model of care, based
6 on de-identified data from the three stages of patient interviews and pre-treatment and six-
7 month follow-up patient surveys. In this way, patient data will be used to develop a narrative
8 outline of steps within the PC-ACP process and construct flowcharts outlining the main
9 stages of the patient journey.
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20 21 **ETHICS AND DISSEMINATION**

22 This study is considered to be low risk for participants. Surveys and interview questions are
23 not anticipated to be controversial or overly intrusive. Ethical approval has been obtained
24 from the Townsville Hospital and Health Service Human Research Ethics Committee
25 (HREC) associated with the participating hospital (HREC/16/QTHS/100; Figure 2, first green
26 box), and hospital governance approval has also been obtained (SSA/16/QTHS/193; Figure 2,
27 third green box). The data will be stored in a re-identifiable form until the completion of data
28 collection, with a unique code for each participant. Findings will not be reported in a manner
29 that enables individual participant responses to be identified. If groups (e.g. surgeons) consist
30 of fewer than five members, responses will be combined with those from other groups in
31 reports.
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48 Given the high risk of adverse events in the patient population involved in this study,
49 one major ethical consideration is the possibility of distressing families of participants by
50 contacting patients who have died during their treatment. To avoid this situation,
51 investigators will contact the hospital to establish that the patient is alive, prior to contacting
52 him or her at three- and six-month follow-up. In the event of patient death, study
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3 investigators who are clinicians at the participating hospital will approach family members
4 and invite them to participate in interviews. Because these investigators are experienced at
5 communicating with families of deceased patients, this method of approaching family
6 members will help safeguard their dignity. Interviewing family members about the patient's
7 experience of care may be helpful to the grieving process. Nevertheless, this procedure will
8 be carefully managed to ensure it will not be upsetting for families. Family members will
9 only be invited for interviews, not the follow-up patient survey.
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19 Results of this study will outline levels patient satisfaction with PC-ACP, specify
20 barriers and enablers to implementation and highlight critical points in the process for
21 improvement. At the end of the project, draft and final evaluation reports will be
22 disseminated to the participating hospital. These reports will present key findings from the
23 study and recommendations for ongoing implementation of PC-ACP in high-risk surgical
24 patients. Macquarie University investigators will present the findings and implications of the
25 study to the hospital executive so that implementation of PC-ACP at the site can be
26 optimised. Study findings and implications of interest to an academic audience will be
27 submitted for publication in peer-reviewed Medline-indexed journals and presented at
28 academic conferences and workshops.
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48 CONCLUSION

49 By introducing patient-centred decision-making to the surgical process, the new
50 model of care has the potential to enhance the patient experience and improve the journey
51 through the surgical process for patients at high risk of poor outcomes. Under the new model,
52 clinicians will share responsibility for health outcomes with patients, and patients will only be
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3 admitted for surgery if it meets their goals and values better than alternative treatments.
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5 Therefore, the new process may help prevent potentially avoidable hospital admissions.
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7 Seeking feedback from patients, family members and clinicians involved with the new model
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9 of care means the future implementation of this model will meet patients' needs while also
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11 mitigating barriers and profiting from enablers to implementation. Thus, this study will
12
13 facilitate the best future implementation of PC-ACP.
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20 FOOTNOTES

24 Contributors

25
26 SS conceived and developed the PC-ACP model of care. RCW and SS devised the study
27
28 design, protocol and plan and contributed to the development of the manuscript. AS
29
30 contributed to the study design and protocol, led the ethics applications and led the
31
32 development of the manuscript. BB contributed to the study design and the development of
33
34 the manuscript. PL contributed to the study design and planning. JN provided clinical
35
36 expertise and advice. SS and PL will provide on-site management of the study. RCW, AS and
37
38 BB will be involved in data collection and analysis. All authors have read and approved the
39
40 final version of this manuscript.
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48 Funding

49
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51
52 grant number RG/2015/21.
53
54
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56
57

58 Competing interests

1
2
3 We have read and understood the *BMJ* policy on declaration of interests and declare that we
4
5 have no competing interests.
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10 **Data sharing statement**

11
12 Data will be made publicly available to the extent that individual participants or participating
13
14 hospitals cannot be identified, in accordance with requirements of the approving Human
15
16 Research Ethics Committees.
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20 **Exclusive licence statement**

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22 I Amanda Selwood the Corresponding Author of this article contained within the original
23
24 manuscript which includes any diagrams & photographs, other illustrative material, video,
25
26 film or any other material howsoever submitted by the Contributor(s) at any time and related
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Figure 1

Patient-centred advanced care planning

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3 Figure 2
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6 PC-ACP study outline
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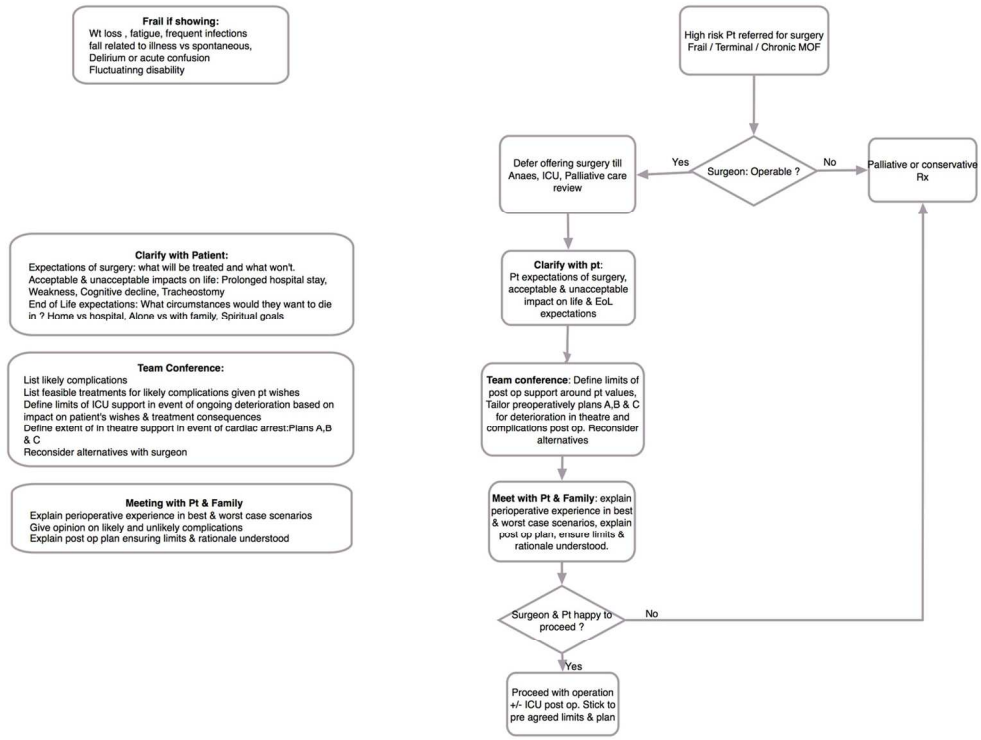
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9 Green boxes = Study initiation
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12 Orange boxes = PC-ACP intervention
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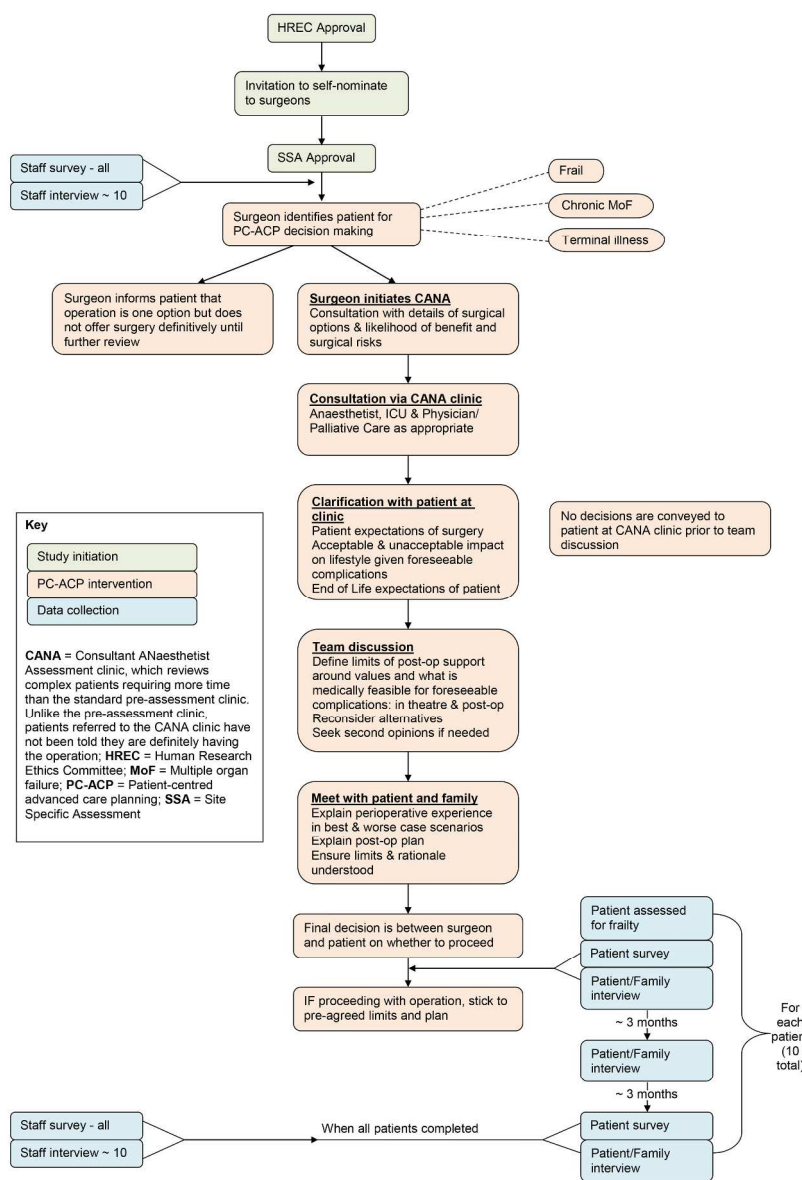
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15 Blue boxes = Data collection
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21 **CANA** = Consultant ANaesthetic Assessment clinic, which reviews complex patients
22 requiring more time than the standard pre-assessment clinic. Unlike the pre-assessment clinic,
23 patients referred to the CANA clinic have not been told they are definitely having the
24 operation; **HREC** = Human Research Ethics Committee; **MoF** = Multiple organ failure; **PC-**
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29 **ACP** = Patient-centred advanced care planning; **SSA** = Site Specific Assessment
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Patient-Centred Advanced Care Planning
Figure 1
127x95mm (300 x 300 DPI)



Study outline
Figure 2
223x313mm (300 x 300 DPI)

Appendix A: Patient semi-structured interview questions

Guidance:

- Keep the interview as short as possible.
- Stop if the patient is distressed, confused or uncomfortable. Seek help to calm the patient.
- Do not identify the patient in any written records.

The information collected will be demographic information and responses to the following questions.

A: Introduction

- Do you remember having a chat with [*name of member(s) of advanced care planning team*] about those things that are important to you?
- I would like to talk to you about how you felt about the process. But, firstly, I must make it clear that giving your honest answers to my questions won't affect your care, your treatment or your rehabilitation plan in any way. This also applies if you decide not to talk to me.

Secondly, what you say will not be used to criticise [*name of member(s) of advanced care planning team*]. He/she/they is/are happy that I am talking to you. By agreeing to talk to me, you are providing useful information that we hope will improve all patients' care.

B: Questions

- How long have you been in hospital/under the care of [*name of member(s) of advanced care planning team*]?
- Have you been under the care of [*name of member(s) of advanced care planning team*] or had surgery before?
If 'yes', prompt for the patient's view of how they have been involved in the past.
- Can you tell me about your meeting sessions with the [*name of member(s) of advanced care planning team*]?
How helpful were they for you?
Were you satisfied with the outcome of the sessions?
- Did you feel that the [*name of member(s) of advanced care planning team*] listened to you and understood what was important to you?
[Whether 'yes' or 'no'] Can you give an example?
- Have you planned any actions (tasks) with the [*name of member(s) of advanced care planning team*] to achieve things that are important to you?
Examples, please.
- Can you tell me about your experience of working with the [*name of member(s) of advanced care planning team*] towards these goals?

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What worked well?

Were there any challenges?

- How confident did you feel that the [*name of member(s) of advanced care planning team*] could help you to achieve your goals or, if not, that the [*name of member(s) of advanced care planning team*] could get appropriate support from someone who could?
- Do you know or believe that what you have discussed has been acted on?
What has happened as a consequence?
- How involved have you felt that you have been in what has happened since?
Do you want more or less involvement? Please expand on this answer.
- Sometimes the things that are important to you will change over time. Did anything change in importance to you after your initial discussion?
If so, how flexible was the [*name of member(s) of advanced care planning team*] in supporting you to meet your new priorities?
- Is there any other support that you would like, that would help you achieve your goals?
- Do you have any comments on how helpful the forms were, when you had your discussions with the [*name of member(s) of advanced care planning team*]?

C: Demographic Information (on each occasion)

This information will not be linked to any participant's name. A number will be assigned as a code reference for analysis purposes.

1. Patient Code (to match data from before/after surveys)
 2. Gender, Age (18-50, 51-60, 61-70, 71-80, 81-105yrs)
 3. Max education level (Primary school, Year 10, Year 12, bachelor degree, postgraduate degree)
 4. Place of primary residence (lives alone, lives with family, nursing home, other)
 5. Proposed surgery/primary medical condition requiring surgery
- For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

Appendix B: Clinician semi-structured interview questions

Interview Schedule

The information collected will be demographic information and responses to the following questions.

A: Background

- What do you understand by the term ‘shared decision making’?
- Have you had previous experience with shared decision making in the past:
 - Sharing decision making with other clinicians?
Examples, please.
 - Sharing decision making with patients?
Examples, please.

B: Shared decision making

- Do you think it is important to share decision making about patient care with other clinicians? Why/why not?
- Do you think it is important to share decision making about patient care with patients and their families? Why/why not?

C: PC-ACP Process (show clinician diagram and explain the process)

- What are your views on the proposed PC-ACP process?
- Are there advantages to using this process? If so, what are they?
- Are there disadvantages to using this process? If so, what are they?
- Do you see benefits for the patient in using this process? If so, what are they?
- Have you used/tried to use a process similar to this in the past? If so, what were your experiences?

D: Barriers and Enablers

- Did you experience (or anticipate) any barriers to applying the ideas from the PC-ACP process at Townsville Hospital?
- What made it (or would make it easier) to apply the ideas from the PC-ACP process at Townsville Hospital?
- Did you learn (or anticipate learning) anything new, interesting, useful or unexpected as a result of introduction of the PC-ACP process at Townsville Hospital?

E: Sustainability

- Do you believe that the PC-ACP process at Townsville Hospital is sustainable? Why/why not?

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- Do you believe that training is required to implement the PC-ACP process at Townsville Hospital? If so, what sort of training and who should be trained?
- Was there any impact of implementation of the PC-ACP process at Townsville Hospital on your job satisfaction?
- Would you like to make any other comments about your experiences in relation to the PC-ACP process at Townsville Hospital?

F: Demographic Information

This information will not be linked to any participant's name. A number will be assigned as a code reference for analysis purposes.

1. Gender, Age (bracket)
2. Profession (Surgeon, Anaesthetist, Intensivist, Palliative Care, Other)
3. Your professional level at TTHS
4. Time since specialist qualification to practice in this field
5. Time in this organisation