Study Title: Understanding decision making about high risk surgery: a qualitative study of shared decision making by patients and their clinical teams

Internal Reference Number / Short title: Understanding shared decision making about high risk surgery

Ethics Ref: 19/EE/0033

IRAS Ref: 256208

Date and Version No: 18th December 2018, version 1.0

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Funder:	National Institute of Health Research [RP-PG-0218-20001]
Chief Investigator Signature:	

Conflicts of interest: There are no conflicts of interests.

Confidentiality Statement: This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host organisation, and members of the Research Ethics Committee, HRA (where required) unless authorised to do so.

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1. SYNOPSIS

Study Title	Understanding decision making about high risk surgery: a qualitative study of shared decision making by patients and their clinical teams	
Internal ref. no. / short title	Understanding decision making about high risk surgery	
Study Design	Qualitative study, combining individual and group interviews with analysis of video-recorded consultations	
Study Participants	NHS patients contemplating surgery for major colorectal, joint-replacement or coronary bypass surgery, their clinicians and (where appropriate) families/carers	
Planned Sample Size	Up to 105 patients and 60 clinicians	
Research aims	**Aims**	**Objectives**
	1. To understand the reasons and motivations of patients contemplating major surgery, and of their doctors to offer this treatment, including perceptions of the potential positive and negative outcomes of surgery, and to explore if/how these change over time. 2. To appreciate what shared decision making means for patients, families and clinical teams and examine how this is put into practice. 3. To document the information patients and doctors exchange before and after surgery, and how this shapes shared decision making. 4. To extend current theory on shared decision making for	1. Identify 3-5 sites undertaking major cardiac, joint replacement or bowel surgery, and video record up to fifteen shared decision making encounters between high-risk patients and their doctors across these surgical areas. 2. Interview the same patients, their surgeons and the anaesthetists involved in pre-assessment after shared decision making encounters, and again 3-6 months later, to explore reasoning, motivations and reflections on the decision making process. 3. Use analysis of interview and video data to generate draft decision-making scenarios to inform discussion in subsequent focus groups. 4. Conduct up to 9 focus groups with a different group of patients (who have had or declined major surgery), and 3 with a different groups of surgeons and anaesthetists involved in pre-assessment, to generate wider consensus on the draft scenarios for shared decision making for major surgery.

	high risk patients offered major surgery	5. Draw on relevant social theory (e.g. collaborative deliberation[22]) to analyse the process of shared decision making for high risk patients, including interactional and communicative features, and extend current theory to support transfer of learning for this patient group. 6. Report key findings from the study, including a typology of shared decision making for major surgery and revised theory, to inform a wider programme of research on *Optimising Shared decisIon-making for high RIsk major Surgery* (OSIRIS).
Planned Study Period	1st February 2019 to 31st July 2020	

2. ABBREVIATIONS

CI	Chief Investigator
CRF	Case Report Form
CTRG	Clinical Trials & Research Governance, University of Oxford
GCP	Good Clinical Practice
HRA	Health Research Authority
ICF	Informed Consent Form
NHS	National Health Service
NRES	National Research Ethics Service
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SDM	Shared decision making
SOP	Standard Operating Procedure

3. BACKGROUND AND RATIONALE

Surgical treatments are offered to more patients than ever before, with approximately 1.5 million major surgical procedures performed each year in the UK.[1] This is a particular concern for the 250,000 NHS patients (usually over 75 and with chronic disease) at high risk of post-operative complications who undergo major surgery each year.[2] Even when surgery and anaesthesia are straightforward, one in three high-risk patients still develops medical complications such as pneumonia or myocardial infarction in the days following surgery.[3] These complications delay recovery, with prolonged hospital stays and a decline in functional independence once patients return home. Critically, many high-risk surgical patients never recover from these adverse effects, suffering significant reductions in long-term quality of life and survival.[3 4] For many, surgery is not the successful treatment they hoped for. Feelings of guilt or regret over the decision to undergo surgery are commonplace.[5] Doctors recognise the urgent need to improve decision making for this patient group but clearly feel ill-equipped to tackle this.[6] The problem is becoming more frequent as more patients living with severe chronic disease are offered surgical treatments. In sum, many older people in the UK are having high-risk surgery (i.e. major surgery with high-risk patients) and are often regretting the decision they made to have such surgery.

Past research has shown that communication practices often inadequately support preoperative decision making about major surgery. Most patients prefer to share in decision making but have often not been afforded the chance to do so.[7] Studies suggest that surgeons rarely employ a fully collaborative decision-making process,[8 9] instead, relying on standard practices (e.g. informed consent) or usual communication practices (e.g. employ a 'fix-it' model by describing the patient's disease as an isolated abnormality linked directly with a surgical solution) to disclose procedural risks and help patients make choices.[10] Over the past ten years there has been a trend towards a more active partnership between doctors and patients in reviewing treatment options. Standards expected by doctors' regulatory bodies in respect of the consent process have arguably sought to restructure the nature of the doctor–patient relationship from paternalism to shared decision-making.[11-13] This has been mirrored by a wider move towards active participation on the part of patients and their families in decisions about care. Shared decision making, a collaborative process in which patients and providers work together to find a mutually agreed-upon treatment plan,[14] aims to reduce decision conflict and improves decision quality for patients. Legal cases such as Montgomery v Lanarkshire Health Board have accelerated the evolution of shared decision making with a substantial shift in the professional and legal standards for consent since 2015. Shared decision making has become the standard to which the General Medical Council (GMC) now requires doctors to adhere. However, despite a wealth of research on shared decision making,[15 16] limited attention has been paid to-date to the decision making process for high-risk patients.

A small number of studies of shared decision making for high-risk patients considering surgery have originated from the US and Canada.[9 17-19] Two have focussed on how surgeons and patients discuss options in the event that post-operative complications are severe or life threatening. Analysis of audio-recorded shared decision making encounters for high-risk surgery identified

significant communication gaps regarding potentially severe post-operative complications. [17 19] Follow up interviews in the same studies revealed assumptions (on the part of patients and clinicians) that surgeons shared patients' values and expectations and would advise them accordingly, and that surgeons often regarded decisions about surgery as needing to be guided by their expertise and experience, rather than an individual and preference sensitive choice.

Another study from the same group underscores the challenge for patients of incorporating their values and beliefs into shared decision making for high-risk surgery.[18] In this study most patients agreed that surgery should only be considered when it could improve quality of life. However, when faced with a decision in a life-saving surgery scenario the majority chose surgery with likely subsequent functional impairment over palliation, citing lack of belief in the surgeons prognosis ('there must be a better outcome available') and a feeling that 'choosing death' was unacceptable on moral or religious grounds. In the same study, surgeons discussed the challenge of 'surgical momentum', i.e. once a patient is on a pathway toward surgery, the expectations of the patient and their family makes it hard to divert them away from a surgical intervention, even when they recognise the high-risk of potentially severe post-operative complications. The language used, particularly the focus on 'fixing' a problem with surgery, was also found to close down potentially important discussions about the value of surgery and how it may fit with a patients overall values and goals.[9]

These North American studies suggest that patients often do not realise that they have a choice about whether to have surgery or not, have mis-matched expectations about what may happen after surgery and have often not had the opportunity to discuss what they would wish to happen, with regards to end of life decisions, if complications were very severe.[20] Other research has focused on the information needs of patients considering oesophogastric surgery for cancer and found a mis-match between what surgeons discussed in consultations and what patients wanted.[21] In particular, patients in this study wanted to have less technical information about the procedure and more discussion of long-term effects on their quality of life and survival. Moreover, there were some important differences in the information needs and expectations of patients, highlighting the need to tailor shared decision making to suit the patient.

In sum, the small amount of high-quality work that has been produced has largely been undertaken in the USA or Canada. Whilst there is potential learning that can be transferred, there are important cultural and health service differences that limit this transfer. To our knowledge, there is currently only one published paper on this topic reporting a UK-based study,[21] albeit within a very specific surgical population. Research that is designed to enable understanding of the shared decision making process for this patient group in a UK context is therefore both timely and necessary.

This protocol sets out plans for an in-depth qualitative study - combining individual and focus group interviews with observation of shared decision making encounters - that seeks to extend our understanding of the shared decision-making practices for patients contemplating high risk surgery. Our focus is deliberately on high risk patients contemplating one of three major surgical procedures: major joint surgery, intra-abdominal surgery and cardiac surgery, and on

understanding how the motivations, expectations and communicative approaches of patients, their doctor and (where appropriate) carers or families combine to shape decisions about treatment. These patients are typically older with long-term disease. One in three high-risk patients choosing surgery will experience serious medical complications leading to long-term decline in health and quality of life. Awareness of these long-term risks is poor amongst both doctors and patients. Consequently, many high-risk patients do not receive the information they need to make an informed decision about surgery.

Our aim in this study is to identify the key influences on the shared decision making process within and between the three patient groups (i.e. those undergoing major joint, intra-abdominal and cardiac surgery), and to feed into a larger programme of research, funded by the National Institute of Health Research, focused on *Optimising Shared decision-makIng for high RIsk major Surgery* (OSIRIS). Key findings from the study that will inform OSIRIS include a typology of shared decision making for major surgery and revised theory on shared decision-making.

Our focus in this study is on high-risk patients (usually older and with long-term disease) who are offered major surgery. From hereon in we use the terms 'high risk surgery' and 'major surgery' interchangeably to reflect this

4. RESEARCH QUESTIONS, AIMS AND OBJECTIVES

Research questions

1. How do patients, their families and clinical teams approach and negotiate shared decision making for major surgery?
2. Having had (or declined) major surgery, how do patients, their families and clinical teams reflect on the decisions they made?

Research Aims

1. To understand the reasons and motivations of high-risk patients contemplating major surgery, and of their doctors to offer this treatment, including perceptions of the potential positive and negative outcomes of surgery, and to explore if/how these change over time.
2. To appreciate what shared decision making means for patients, families and clinical teams and examine how this is put into practice.
3. To document the information patients and doctors exchange before and after surgery, and how this shapes shared decision making.
4. To extend current theory on shared decision making for high-risk patients offered major surgery.

Operational Objectives

1. Identify 3-5 sites undertaking major cardiac, joint replacement or bowel surgery, and video record up to fifteen shared decision making encounters between high-risk patients and their doctors across these surgical areas.
2. Interview the same patients, their surgeons and the anaesthetists involved in pre-assessment after shared decision making encounters, and again 3-6 months later, to explore reasoning, motivations and reflections on the decision making process.
3. Use analysis of interview and video data to generate draft decision-making scenarios to inform discussion in subsequent focus groups.
4. Conduct up to 9 focus groups with a different group of patients (who have had or declined major surgery), and 3 with a different groups of surgeons and anaesthetists involved in pre-assessment, to generate wider consensus on the draft scenarios for shared decision making for major surgery.
5. Draw on relevant social theory (e.g. collaborative deliberation[22]) to analyse the process of shared decision making for high risk patients, including interactional and communicative features, and extend current theory to support transfer of learning for this patient group.
6. Report key findings from the study, including a typology of shared decision making for major surgery and revised theory, to inform a wider programme of research on *Optimising Shared decisIon-making for high RIsk major Surgery* (OSIRIS).

5. STUDY DESIGN

This is a qualitative study, combining video-recording of shared decision making encounters for major surgery, with individual and focus group interviews with patients, their families and doctors.

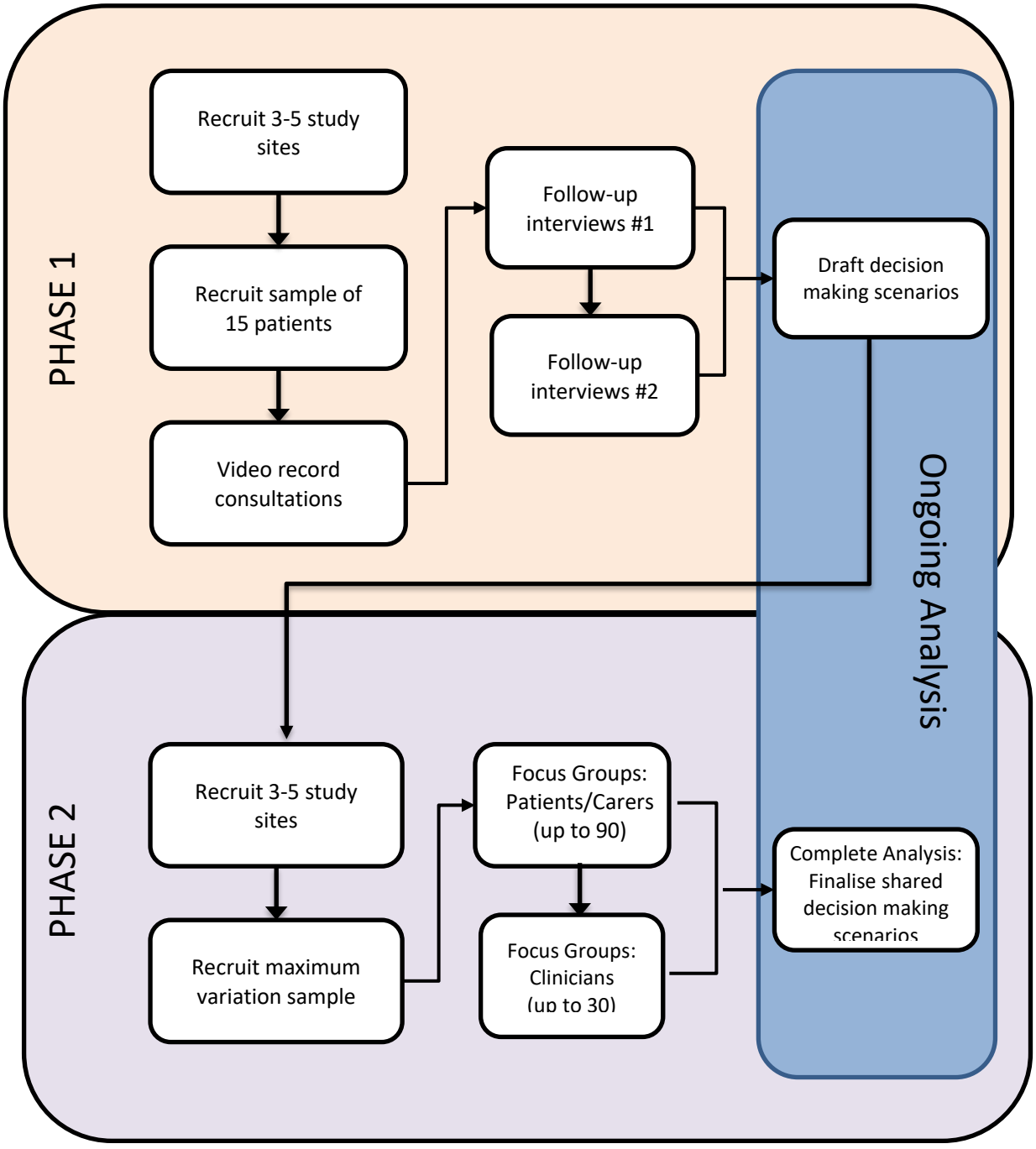
The study is informed by relevant theory and literature on collaborative deliberation, shared decision making and sense-making.[22-25] Whilst significant research has already been conducted on shared decision making generally, to-date this is extremely limited in the field of high risk major surgery (see above). We therefore use qualitative methods to explore in-depth how patients, their families and doctors negotiate shared decision making (including interactional, communicative and informational aspects of decision making) and reflect back on the decisions they made.

The study has two phases (see Figure 1). Phase 1 involves video-recording shared decision making encounters about major surgery, between patients, their carers/families and doctors in order to understand the content and interactional flow of these discussions; followed by individual interviews with patients and their doctors (immediately after the encounter and again 3-6 months later) in order to understand the reasoning for and reflections on people's decisions. Participants

will therefore be involved in the study for a short time overall (estimated half a day in total), but spread over a period of up to 6 months. Data from Phase 1 will be used to generate a series of draft decision-making scenarios which will inform subsequent discussion in Phase 2.

Phase 2 of the study involves focus groups with a wider maximum variation sample of different patients and clinicians in order to generate consensus about emerging findings from Phase 1 and to finalise the shared decision making scenarios developed from Phase 1 to inform further research.

Figure 1 – Study flow chart



6. PARTICIPANT IDENTIFICATION

Phase 1 – interviews and video-recording of shared decision making encounters

In phase 1 of the study we will purposively select 3-5 NHS hospitals undertaking three major surgical procedures - major joint surgery, intra-abdominal surgery and cardiac surgery - and ensuring a mix of urban/rural locations and surgical volume. We have deliberately focused on three different surgical procedures in order to account for how disease context influences the decisions which patients and doctors make. Major joint replacement for osteoarthritis is a symptomatic treatment (pain, mobility) which will not prolong life, whilst coronary artery bypass grafting may prolong life at a population level, but for the individual patient this benefit is not guaranteed and colorectal surgery for bowel cancer, which is essential if the patient is to survive the disease. The process of seeking consent for surgery is likely to be different across these, and by organisation (e.g. some specialities and hospitals offer one stop assessment clinics for high risk surgery run by anaesthetists, others work by specialty). Decision making may be more straightforward if the index disease is the only consideration, but high-risk patients with shortened life expectancy due to age, chronic disease, or frailty are more influenced by past experiences and have a more complex combination of long-term outcomes to consider.

Working with clinical teams from across hospitals, we will select a maximum variation, purposive-sample of a total of 15 high-risk patients aged ≥60 years with an age-adjusted Charlson co-morbidity score[26] ≥4, contemplating major colorectal, joint-replacement, or coronary artery bypass surgery (anticipating five from each surgical group including, where feasible, at least one patient in each group who has declined surgery), with adequate variation in age, gender and social circumstances (including travel time to the hospital). We will only include those patients who are aware of their diagnosis and have already had the possibility of surgery mentioned to them.

Phase 2 – focus groups

In phase 2 of the study we will purposively select 3-5 NHS hospitals undertaking major joint surgery, intra-abdominal surgery and cardiac surgery, following the same criteria as phase 1 (with at least one being different from those in phase 1 to ensure we capture diverse views and experiences of shared decision making) to test findings from phase 1 with a wider group of different patients and doctors via focus groups. We will recruit a purposive maximum variation sample of up to 90 high-risk patients (up to 9 focus groups) across the study who have undergone or declined surgery in one of these areas in the past 12 months and ensuring a mix of age, gender, social circumstances and surgical outcomes. We will exclude patients who have participated in phase 1 of the study. Where patients with severe complications are unable to participate in focus groups, we will invite them to nominate someone who can represent their views, and if they would like their carer to attend with them then we will invite them to do so. In addition, we will recruit a purposive sample of up to 30 doctors (up to 3 focus groups) caring for patients having these types of surgery (ensuring a mix of age, gender, clinical experience, role and location).

In this phase of the study we anticipate that data saturation might be achieved prior to recruiting 90 patients and 30 doctors (hence qualification of 'up to 90' and 'up to 30'). We will therefore conduct our analysis iteratively, on a group-by-group basis, and cease data collection either at the point at which data saturation is achieved or where we have recruited the required numbers, whichever comes first.

In both phases, we will exclude patients from the study where they lack capacity to give consent or where their English is not sufficient to enable participation in an individual or group interview.

7. STUDY ACTIVITIES

A detailed description of study activities is provided in the sections below. See Appendix A for study timeline.

7.1. Recruitment

Phase 1 – interviews and video-recording of shared decision making encounters

We will work with lead clinicians for major joint surgery, intra-abdominal surgery and cardiac surgery in each of the selected NHS hospitals to fully appreciate the process of decision making about surgery and to then (a) identify and recruit patients, and (b) identify and recruit relevant members of the clinical team. We describe each of those processes below:

(a) recruiting patients

Our lead contact in each clinical area will be the site PI, likely to be an anaesthetist with an interest in high-risk surgery, who will assist us in recruiting a number of surgeons responsible for *major joint surgery, intra-abdominal surgery and cardiac surgery*. As set out in Figure 1, patients will be identified by each of these surgeons as potential participants following their referral into the clinic, review of their notes (and potential multidisciplinary team meeting) and proposed offer of surgery (Stage 1, Figure 1). These will be people who are aware of their diagnosis and will already have had the possibility of surgery mentioned to them. The clinical team will inform each patient about the research and ask if they would be interested in finding out more about the study and what participation would involve. Should the patient wish to find out more then the surgical team will provide a copy of the Letter of Invitation and Patient Information Sheet and seek permission to pass patient contact details to a named researcher on the study team. The researcher will follow up within 7 days, either by email, phone or post (whichever is preferred) to provide further information on the study and formally invite participation in the study (Stage 2). Those patients electing to participate will be asked to meet the research at the time of their next appointment and to prepare to consent to the study at that time at. We will also ask patients if anyone will accompany them to their appointment and, if so, if we or they can contact them to provide details of the study. The research team will then seek consent – with the patient and anyone

accompanying them to their appointment - in writing on the day of the patient's appointment (Stage 3).

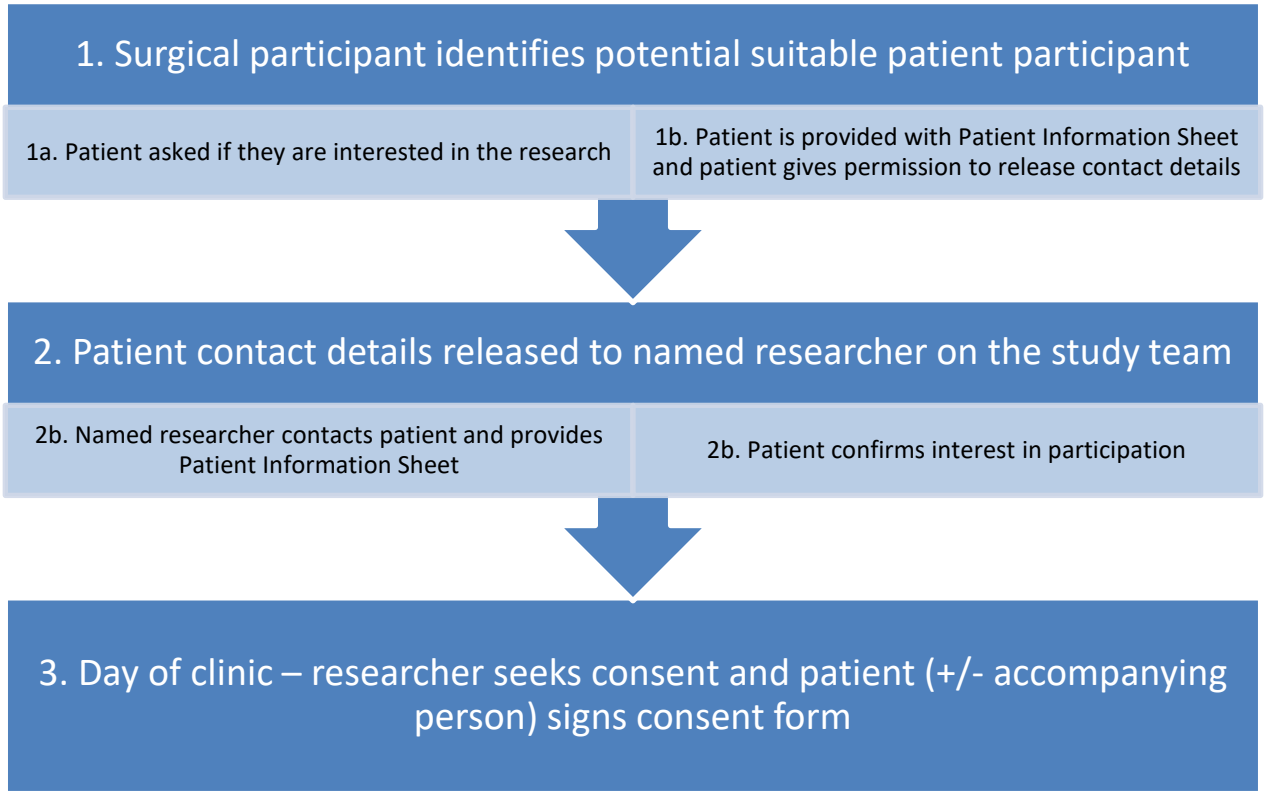


Figure 2: Summary of patient recruitment for Phase 1

Informal discussions with surgeons and anaesthetists to-date indicate that the above process is operationally feasible and is likely (where patients and clinicians consent) to capture the majority of shared decision making encounters. However, decision making does not always unfold in the ways that clinicians or researchers might expect (e.g. not every clinic will operate in exactly the same way, and not every decision that patients take about surgery will take place in consultation with the surgeon). We have proposed a level of flexibility within the recruitment process enabling us, where appropriate, to follow the patient to an alternative consultation (e.g. with an anaesthetist in a 'high risk' clinic dedicated to this group of patients, or with a clinical nurse specialist). We also recognise that there will likely be some instances (e.g. for colorectal cancer) where the patient is not aware of their diagnosis when invited into the clinic to meet with the surgeon and explore options (where this is the case, we will *not* contact patients at this stage, but wait until they are aware of their diagnosis). The flexibility will not alter the route to identifying and recruiting patients (via the surgeon and clinical team – Stage 1-, only the timing of where we provide information (Stage 2). We will ensure that, as with other participants in the study, we give potential participants sufficient time to consider relevant information before (should they choose) consenting in to the study (Stage 3) and collecting

data. Where timing of consultations does not allow us to give sufficient time between giving information and seeking consent, we will not seek to involve these patients in the study.

(b) recruiting relevant members of the clinical team

On approaching each NHS hospital, we will make contact with the site PI (likely an anaesthetist or surgeon). It is the site PI who will then put us in touch with other surgeons responsible for major joint surgery, intra-abdominal surgery and/or cardiac surgery and the anaesthetists who pre-assess for them in each site, enabling us to identify those interested in participating in the study. It is at this point that surgeons will be provided with a Clinician Information Sheet and interested participants will have a chance to discuss (remotely or face-to-face) any questions about the study, before confirming their participation. At this point we will seek written consent from surgeons to participate in the study.

As set out above, surgeons will identify potential patient participants. As patients confirm participation and return to the clinic for their appointment and follow-up (research) interview so we will also identify up to two other perioperative clinicians involved in their care (e.g. clinical nurse specialist, anaesthetist). We will contact these clinicians at their work place directly, providing a Clinician Information Sheet, allowing sufficient time (7 days) to consider participation and answering any questions they may have about the study. Should they agree, we will formally recruit them into the study and arrange an interview at the start of which we seek written informed consent.

Phase 2 – focus groups

We will work with lead clinicians for major joint surgery, intra-abdominal surgery and cardiac surgery in each of the selected NHS hospitals (see section 6) to (a) identify and recruit patients who have undergone or declined high-risk surgery. We will work with each of the selected NHS hospitals as well as the Royal College of Surgeons, Royal College of Anaesthetists and Royal College of Nursing to (b) identify and recruit clinicians involved in decision making about high risk surgery. We describe each of those processes below:

(a) recruiting patients

Working with selected hospitals and their clinical leads for major joint surgery, intra-abdominal surgery and cardiac surgery, we will identify all patients who have either undergone or declined surgery in the previous 12 months. Again, working with the hospital, we will invite a purposive, maximum variation sample to participate in focus groups (likely 2-3 per hospital, with the usual care team sending invites on behalf of the research team) seeking a mix of age, gender, social circumstances and surgical outcomes.

Recruitment to focus groups is known to involve significant time and effort. We will therefore adopt the following three-pronged approach, adjusting this in liaison with each site according to the work of the clinical team and flow of patients:

1. A named researcher will spend time on site (in the relevant clinic waiting area) during dedicated clinic times, approaching patients prior to or after their appointment to provide details of the study and invite them to participate.
2. To access those patients that attend clinic when the researcher is not present, we will place posters in the relevant hospital clinics inviting people to contact us if they have considered major joint surgery, intra-abdominal surgery or cardiac surgery in the previous 12 months.
3. Letters from the research team will be sent via the hospital – along with a copy of the Patient Information Sheet – inviting patients to contact us if they are interested in participating.

In all three instances, when we approach patients in the clinic or patients contact us outside of the clinic, we will provide (by email or post) a copy of the Patient Information Sheet if they do not already have it. In both instances, should patients (or their nominated carer) wish to take part we will then seek written informed consent (via email or post) prior to the focus group.

Where people are interested but unable to physically attend a focus group, we will invite them to nominate a carer who is able to speak on their behalf. The carer will then be consented to the study in their own right.

Our aim is to recruit widely and ensure a mix of people in each focus group (rather than, say, all under 75 or all male). To facilitate this we will regularly review (e.g. fortnightly) sampling across sites and across the three approaches outlined above against our sampling criteria. Where we have a good spread we will continue as planned, where particular groups (e.g. over 75s) are under-represented, we will actively seek out participants (using 1 and 3 above) from those groups to maximum variation.

(b) recruiting relevant members of the clinical team

We will identify perioperative clinician (surgeons, anaesthetists and clinical nurse specialists) involved in the pre-assessment and provision of major joint surgery, intra-abdominal surgery and cardiac surgery across the selected hospitals and professional organisations (see Royal Colleges detailed above). We will invite a maximum variation sample of those clinicians to participate in focus groups (likely held at their hospital, at a time convenient for them and/or at one of the Royal Colleges). We will send an email invitation to all clinicians (sent by the Royal Colleges, i.e. ensuring the research team does not access any personal information about those contacted prior to their contacting the team with an interest in participating), attaching a copy of the Professional Information Sheet and asking them to confirm directly with the research team if they are happy to participate. Where we have not had a response, we will wait at least 7 days before following up. We will make it clear in the covering email to clinicians that should they not respond initially then they will receive a further reminder email. Where clinicians confirm they are happy to participate, we will seek written informed consent prior to the focus group.

7.2. Informed Consent

In phase 1 and phase 2 of the study, we will seek written informed consent from all patients (and in some cases family members of carers) and clinicians. Written and verbal versions of the Information Sheets and Informed Consent will be presented to all participants detailing no less than: the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, or future work, and with no obligation to give the reason for withdrawal.

Patient participants will be allowed as much time as possible ahead of their surgery to consider the information, and the opportunity to ask questions of the researcher, the lead clinician, another member of the clinical team or other independent parties to decide whether they will participate in the study. Clinician participants will be given up to 7 working days to consider the information, and the opportunity to ask questions of the researcher to decide whether they will participate in the study.

To take informed consent in phase 1: for patients, we will seek informed consent in writing as we connect with them before their clinic appointment. For surgeons, we will do this in writing as they confirm initial participation in the study; and for other clinicians we do this at the start of interviews. We will take written consent for all data collection points when we initially record and/or interview patients and clinicians, asking participants to sign and date the latest approved version of the informed consent form before any study specific activities are undertaken.

In phase 1 of the study we will seek consent both at the point at which we video-record the consultation and conduct an initial interview, and when we conduct a follow-up interview 3-6 months later. We have included this second process of consent for both patients (and carers, where relevant) and clinicians because of the period of time (up to 6 months) between first and second interviews, and the potential for participants' circumstances to change significantly. We will also still need a follow-up consent process if a carer is to be interviewed instead of the participant (if, for example the participant is too unwell or there has been any loss of capacity). We discussed this with our study steering group and patient representative who confirmed this second consent process as a useful and reassuring step.

To take written informed consent in phase 2: for patients and clinicians we will do this before the focus groups.

In both phases of the study, written informed consent will be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who will obtain the consent will be suitably qualified and experienced, and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be given to the participant. The original signed form will be retained at the study site.

7.3. Screening and Eligibility Assessment

Surgeons and their teams will be identified via the relevant site PI. All clinicians involved in the decision making process for the major surgical procedures of interest and providing informed consent will be eligible to be included in the study.

Members of the relevant surgical teams in each site will review patient notes for eligibility in terms of: English-speaking patients aged ≥60 years with an age-adjusted Charlson co-morbidity score ≥4, contemplating major colorectal, joint-replacement, or coronary artery bypass surgery, that are aware of their diagnosis and have capacity to consent will be eligible to be included in the study. Within these eligibility criteria, we will be guided by the clinical judgement of the relevant surgeon in each site as to the suitability of patients for the study.

As set out in section 6, we know that clinical pathways and decision making processes vary across the areas of major surgery we are interested in. Hence, until the research team begins working with sites and more fully appreciates different clinical pathways, it is difficult to say precisely which member of the clinical team will review patient notes for eligibility. However, it is likely that this will be undertaken by the relevant participating surgeon and/or their clinical nurse specialist at the time the patient are referred into the clinic. We envisage this will be done in collaboration with the local site PI.

7.4. Data Collection

We plan two phases of data collection. Phase 1 involving observation of consultations combined with interviews, with up to 15 patients, their family/carers and clinical teams; and Phase 2 involving focus groups with a different group of up to 90 patients and carers and up to 30 clinicians. Further detail on data to be collected in each phase of the study is provided below.

<u>Phase 1: Interviews and observations</u>

In phase 1 of the study we propose video-recording shared decision making encounters between clinicians and patients (also carers where appropriate/requested) and conducting follow up interviews. Data collection will therefore consist of the following two elements:

1. *Video-recording of shared decision making encounter relating to high risk surgery*: we will video record (with consent) consultations that involve decision making about major surgery for all those who agree to participate in the study, seeking to capture verbal and non-verbal interaction, and enabling detailed insight into the decision making process in terms of the content of consultations (e.g. information exchanged) and the interaction between clinician and patient. This will inform in-depth analysis of the key features and processes of shared decision making (see section 8).

   Video-recording consultations will involve the researcher placing one or two (depending on the layout of each consultation room) small video cameras in the consultation room and recording the consultation. Where the patient agrees, the researcher will remain in the room

to observe the consultation and making notes (placing themselves discreetly off to one side). This is usual in studies involving qualitative observation as it enables a unique opportunity to appreciate each consultation as it unfolds in real time, which provides additional insights above and beyond video-recording alone. Where the patient prefers, the researcher will leave the consultation room immediately after starting the video-recorder/s and then wait to be invited back into the room after the consultation has taken place.

Clinical pathways for major surgery vary. We will not know how each pathway works – and hence exactly which consultation we will record with which member of the clinical team in each site - until we have gained access within each site and spoken with the relevant clinical team. For some participants (likely those offered cardiac and major joint surgery), the consultation that we record will be with their surgeon; it will have come following a series of contacts with the health service that means that each patient is aware of their diagnosis and that surgery is an option, and will involve discussion (and likely a decision) about that surgery. For other participants (likely those offered bowel surgery), the consultation that we record may be with another member of the clinical team. This is because they will have been referred to the surgeon without any prior knowledge of a diagnosis. A key criterion for patients to be included in the study is that they are aware of their diagnosis (see sections 6 and 7.3), hence we will not approach these patients until they have met with their surgeon and are aware of their diagnosis. It is likely that these patients will have already discussed the option of surgery. In these cases we will seek to video-record a different consultation (e.g. with the anaesthetist or specialist nurse).

2. *Follow-up interviews x2 (separately with patients and clinicians) after the decision making encounter:* we will conduct narrative interviews with patients and clinicians (and carers where relevant) at two points after their consultation: #1 as soon as practically possibly after their consultation (and wherever possible before their surgery); and #2 up to 3-6 months later. As is usual in narrative interviews (see e.g. Muller 1999), the researcher will use a topic guide to guide each interview, but will also respond to the participant, following their lead on the areas they wish to discuss, e.g. asking questions in a different order to allow the participant to tell their story in the way they choose and at their own pace. Collection of interview data will enable a detailed understanding from both a patient and clinician perspective of:
   - interview #1: the relevant condition, how it has unfolded, experiences of the consultation and thoughts and expectations about surgery (if this is the option they choose); and
   - interview #2: experiences since surgery, reflections back on the decision to have surgery (or not, if this is the option they choose), and perspectives on the decision making process several months after.

   Together this data will inform development of detailed case studies for each patient case, enabling the team to appreciate the way in which decision making unfolds over time, what and who informs decision making about surgery and how, and how people's experiences of different conditions and settings shapes the decision making process. It will also enable the

study team to identify possible regret. There is currently a dearth of evidence on the full range of post-operative complications that a patient may experience, hence this is an important part of the study. Given this dearth of evidence, it is worth noting that (a) any expression of regret about decision making will be based upon a post-hoc experience of events for which each clinical team could not have reasonably advised them about; and (b) this lack of evidence on mid to long term complications and quality of life issues to support improved shared decision making is exactly the issue that the wider OSIRIS programme, of which our study is the first phase, is attempting to address.

We will adopt a narrative approach for all interviews, using a topic guide to prompt discussion and encouraging each interviewee to recount the details of their experiences (e.g. of their condition, or of decision making about surgery) in their own way and in their own time. We anticipate that interviews with patients (and carers, where relevant) will last up to one hour, and clinicians up to 40 minutes. All interviews will be audio-recorded with consent.

We will conduct all follow-up interviews with clinicians in each site. Where a clinician has more than one patient in the study, we will aim to discuss multiple patients in a single interview so as to reduce the time burden on the clinician.

We will offer patients (and carers, where relevant) an option to conduct one or both interviews either in the hospital (and working with the clinical team to find a private, comfortable and accessible location), at home or in a place of their choosing.

Phase 2: Focus groups

In phase 2 of the study we will conduct focus groups with a different set of patients, carers and clinicians – up to 9 groups with patient and up to 3 with clinicians. The data generated from analysis of the videos and interviews in Phase 1 will be used to generate a series of draft decision-making scenarios which will form the basis of discussion across the focus groups, as well as testing out and refinement with a broader group of participants. Subsequent analysis of focus group data will allow the research team to finalise the decision-making scenarios and to extend earlier analysis from Phase 1 (see section 8).

Patients and carers will be recruited via three routes in each site (see section 7.1). We will therefore hold each group either at or close by (e.g. local community centre) to each participating site, involve 8-10 patients or carers in each group and last no more than 90 minutes. Perioperative clinicians (surgeons, anaesthetists and clinical nurse specialists) will be recruited from the selected hospitals and Royal Colleges. Focus groups involving 8-10 clinicians will therefore be held either at their hospital, at a time convenient for them and/or at one of the Royal Colleges, and last no more than 60 minutes. Refreshments will be provided for all groups.

The same topic guide will be used across all focus groups, guiding each participant to briefly introduce themselves and say what their experience is of making decisions (or supporting others in their decision-making) about major surgery, before reviewing the draft decision making

scenarios developed from the earlier phases of the study. In their respective groups, we will ask patients, carers and clinicians to share their thoughts on the draft scenarios, relate them to their own experiences and use them to reflect on the process of shared decision making more broadly.

7.5. Discontinuation/Withdrawal of Participants from Study

Each participant will have the right to withdraw from the study at any time.

Where patients or clinicians withdraw from Phase 1 of the study, wherever possible we will discuss with them the option that we exclude some or all of their data (i.e. video- or audio-recordings, as well as related transcripts) for that participant from analysis. Should those withdrawing wish then we will exclude all of their data. Phase 1 involves a small number of cases hence every effort will be made to replace any participants who have withdrawn.

Where patients or clinicians withdraw from Phase 2 of the study, we will stop involvement in the study with immediate effect. Where those seeking withdrawal from the study have already taken part in a focus group we will not be able to withdraw the data for that participant from analysis. This is because Phase 2 employs focus groups which are designed to collectively produce data for the study through group (not individual) discussion.

The reason for withdrawal (where given) will be recorded.

7.6. Definition of End of Study

The end of study is the date of the last follow up interview of the last participant in Phase 1 or the completion of the final focus group in Phase 2, whichever is later.

8. ANALYSIS

We will use narrative as a key analytic device in our study, enabling us to bring together accounts, encounters and perspectives on shared decision making about high risk surgery in a way that tells the story over time and from multiple perspectives.

In phase 1 we will begin by developing vignettes of each decision making scenario, detailing for each case (i.e. patient, carers and clinicians): how their condition developed and led them to access services, the process of gaining a diagnosis and discussing possible surgery, the exchange of information about surgery and expectations allied to that, reflections on risk, the involvement of others in decision making about surgery, the experience of surgery and post-operative care, and the outcomes of surgery (both immediately afterwards and up to 6 months later) as well as post-hoc reflections on decision making in light of those outcomes.

We will supplement this with detailed analysis of decision making encounters. Video-recordings provide a powerful dataset for analysis, allowing us to zoom in and slow down decision making in

order to examine interactions, judgements and interpretations,[27] the bodily conduct of participants, and the ways in which objects (e.g. patient records, consent forms) come to gain significance at particular moments.[28] Recordings will be transcribed, either by a researcher on the team and/or a named transcriber with a contractual agreement with the university to provide transcription services (e.g. using ELAN, a freely available transcription programme, commonly used by linguists). This will allow us to capture granular (verbal and non-verbal) detail of interaction (and to easily view and review this repeatedly, a requirement of linguistic analysis[27]) and, where helpful, to annotate audio and video streams at the level of a sentence, comment or other linguistic feature. Transcription programmes like ELAN allow repeated viewing and tagging of data digitally (ensuring immersion in the full video and audio, which is often key to analysis[28]), as well as production of a textual transcript meaning that we can engage indirectly with the data via transcripts of each consultation.

Grounded in the ethnography of communication (an approach that aims to produce systematic and richly contextualised descriptions of the communicative genres, events and practices that are observed in a particular culture[29]) we will then examine our data in depth to: identify key features of shared decision making encounters, examine the way 'communicative competence'[30] shapes shared decision making (i.e. how participants in shared decision making encounters deploy their tacit understanding of a particular communicative event, and what competencies are needed to maximise the benefits of the encounter), and attend to the contextual factors (e.g. clinic space, presence of carers, preceding exchange of information) that shape the decision making process. Detailed analysis of interaction will be iterative and guided by established techniques developed for the micro-analysis of face-to-face interaction. The issues that are likely to repay close analysis include (but are not limited to): interruptions and repair (how participants deal with interactional problems); the use of questions (e.g. whether and how patients as well as clinicians use them) and, the expression of affect (particularly when clinicians need to communicate complicated or sensitive information).

We will synthesize the different data sets from Phase 1 into vignettes, drawing on video-recordings to understand communication and interaction, and on interviews and field notes to understand the clinical, organisational, material and cultural context in which shared decision making takes place. Guided by existing theory on shared decision making,[22 25] we will compare and contrast across vignettes to examine similarities and differences in shared decision making, paying particular attention to the ways in which participants seek to achieve constructive interpersonal engagement, recognition of alternative actions, comparative learning, preference construction and elicitation, and preference integration (i.e. the key components of Collaborative Deliberation[22]). Finally we will develop 3-5 draft shared decision making scenarios, emerging from identification of patterns in our emerging analysis about how shared decision making variably unfolds amongst different groups, in different settings and for different kinds of surgery.

In Phase 2, we will test out our draft shared decision making scenarios with a wider group of different patients, their carers and clinicians in a series of up to 12 focus groups. All data will be audio-recorded and transcribed (with consent). We will use thematic and comparative analysis to

generate a detailed understanding of the choices that patients, their families/carers and clinicians make about high risk surgery, and the factors that shape decision making. We will revise the decision making scenarios in light of wider consensus (or challenge) about the importance placed on short- medium- and long term outcomes after different types of surgery. Finally we will synthesise analyses across our datasets, seeking to extend current theory on shared decision making to the specific context of high risk surgery.

9. DATA MANAGEMENT

9.1. Access to Data

Data will be stored on a secure server at the University of Oxford and be accessible only to members of the research team.

Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

9.2. Data Recording and Record Keeping

This is a qualitative study, involving collection of video-recordings of shared decision making encounters, audio-recordings and transcripts of interviews and focus groups, and field notes. A data log will be set up (using Excel) to log details of each piece of data (including patient ID, data type, date collected and by whom) and connections between them (each video and allied patient and clinician interviews constituting a single case). All data will de-identified (unless explicit consent has been granted to do otherwise, e.g. with regard to video data) with raw data stored on a dedicated area (accessible only to the research team) on a secure server at the University of Oxford along with a 'key' (i.e. a list of ID numbers and names) which connects the identifiable and de-identified data.

Data collection and storage will follow the University policy on Data Quality and Data Quality Assurance [http://www.admin.ox.ac.uk/pras/aboutus/dataquality/], Management of Research Data and Records [http://researchdata.ox.ac.uk/university-of-oxford-policy-on-the-management-of-research-data-and-records/] and Information Security [https://www.infosec.ox.ac.uk/guidance-policy]. We will also follow the Nuffield Department of Primary Care Health Sciences Information Governance framework, which sets out procedures and structures to comply with the University regulations using the Department information systems. In accordance with these policies, all confidential and personal data (including names, addresses, telephone numbers) will be kept on the department's secure network and only accessible to members of the department directly involved in the project. We will keep research data (video, audio and transcripts) and related materials (e.g. consent forms) for a period of up to six years after the end of the study. This is in line with relevant guidance (e.g. MRC Good Research Practice) to maximise the potential benefit and impact of research e.g. by providing sufficient time to analyse all of the data and write papers and reports.

We will seek permission to use extracts from data collected in (video-recorded) observations and (audio-recorded) interviews in publications, reports and presentations. These will be academic outputs targeted primarily to academic and clinical audiences (though we also hope to report to patient groups). It is likely that at least one of those publications will be open access, meaning it will be freely available to anyone to access via the internet. Data extracts (e.g. quote from a transcript, still from a video) are used routinely in research outputs and teaching materials as they provide an essential means of evidencing analysis and demonstrating findings, as well as real world examples of key findings. We will not use video in open access publications, only (with consent) stills from video and quotes from transcripts; but plan to use video (with consent) in conference presentations and teaching/training on shared decision making. Potentially identifiable material from this study will not be used in published or publicly accessible outputs unless express written consent has been given (e.g. permission to use direct quotes, video clips or stills will be sought). In the case of video recordings, we will provide participants with the option of their video data being anonymised or not and act according to their wishes. copies of consent forms will be stored with these as a record of evidence of consent to either anonymise or not.

10.QUALITY ASSURANCE PROCEDURES

All members of the research team will be required to complete training in information and research governance.

The study team will meet regularly to review study progress against the protocol, projected milestones and relevant regulations. In addition a Study Steering Committee will be established and meet 6 monthly to ensure oversight.

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

11.ETHICAL AND REGULATORY CONSIDERATIONS

This study raises a number of ethical issues, these are detailed below along with the procedures we have put in place to address them.

a) Confidentiality and anonymity

All data collected as part of the study will remain confidential. We will ensure that anonymity of all participants' (both individuals and organisations) is maintained, unless express consent is given to deanonymise (e.g. video, stills). Participants will be identified only by pseudonym on study documents and any electronic database. All documents will be stored securely and only accessible by study staff and authorised personnel (see Data Management, section 9, for

further detail). The study will comply with the data protection regulation which requires data to be de-identified as soon as it is practical to do so.

In the unlikely event that a participant (either patient or clinician) or researcher identifies an area of significant concern (such as a patient safety or safeguarding concern) that requires escalation/notification, then the researcher would ensure that the participant was aware that the researcher would need to share their concerns according to the relevant procedures within the organisation responsible. Should a patient raise a potential complaint about their care during the course of the research, the researcher would signpost them to the relevant processes to follow for their respective organisation. The research team would not be involved in assessing or resolving complaints (as noted in section 11.3 below).

In phase 2 of the study we plan to conduct a series of focus groups, with patients and their families as well as clinicians. We will assure confidentiality and anonymity on the part of the study team. Given that these are group discussions we are unable to guarantee confidentiality and anonymity on the part of other participants. However, we will set out 'ground rules' at the start of each group, emphasising expectations for anonymity and confidentiality for everyone participating. This will likely be particularly relevant for clinical colleagues who may find it challenging to discuss shared decision making and/or high risk surgery with peers, particularly where they have had negative experiences. We will remain sensitive to that possibility.

b) Recruiting patients and gaining informed consent

In phase 1 of the study we propose recruiting patients via clinical teams conducting *major joint surgery, intra-abdominal surgery and cardiac surgery*. Patients will be identified by each surgeon as potential participants following their referral into the clinic and review of their notes. The clinical team will ask each patient if they are interested in participating in the research and, where this is the case, provide a copy of the Patient Information Sheet and seek consent to release contact details to a named researcher on the study team. The surgical team will then pass contact details to the researcher who will get in touch with the patient in the following 14 days, inviting participation in the study and ensuring time to discuss the study and ask any questions about potential participation. In the event that the patient confirms participation they will be invited to provide written consent on the day of the patient's appointment with the surgeon.

Given that the initial identification of each patient – and initial approach - will be made by the clinical team it will be important to emphasise that the study is based at University of Oxford, is separate from the work of the clinic, and involvement has no bearing on patients' usual care. We will make that clear in the Patient Information Sheet, and in any discussions with patients. We will also make it clear that it is fine for all participants to withdraw from the study at any time, including in these early recruitment stages, and that this will not impact on their care.

In phase 2 of the study, we propose conducting up to nine focus groups with patients, their families or carers (and up to 3 with perioperative clinicians). As is usual for focus groups with patients/carers, we will offer reimbursement to all participants. Care will be needed to ensure that this is not regarded as an inducement. In consultation with our patient liaison, we therefore plan to offer a £10 voucher (e.g. from Amazon) in acknowledgement of the time and contribution to this aspect of the study, and to reimburse reasonable travel expenses on production of receipts, or a mileage allowance provided as appropriate.

c) Involvement of patients and their families at a time of potential distress

The focus of this study is on shared decision making for high risk surgery. We therefore propose including patients and their families in research at a time when they are potentially feeling emotionally and physically vulnerable and needing to make potentially life-changing decisions about their health and care. We will need to be extremely sensitive to this and build in safeguards to ensure we protect participating patients from distress as some (possibly many) will be at a challenging time in their life (e.g. ensuring that recruitment and consent is as straightforward as possible for those wishing to take part; framing questions about care and experiences of surgery sensitively, particularly where post-operative outcomes are not as positive as hoped for; inviting patients to involve family members or other carers in interviews; and consistently approaching participants with empathy and respect). Similarly, we will need to be sensitive to the potential impact on researchers who will potentially be spending extended periods of time with people who will at best be chronically ill and/or in pain, and at worst at the end of life.

The Chief Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki, relevant regulations and Good Clinical Practice.

11.1. Approvals

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to the Health Research Authority, and host institution(s) for written approval.

The Chief Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

11.2. Reporting

The Chief Investigator shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required), host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

11.3. Other Ethical Considerations

As noted in section 11 (a) above, it is possible that the research team become aware of a potential complaint by a patient. Should a patient tell us that they are thinking of making a complaint, or to ask us about the process for making a complaint, we will signpost them to the relevant Patient Advice and Liaison Service (PALS) for the organisation responsible for their care. We will not get involved in supporting a patient in making a complaint, or in assessing or attempting to resolve the complaint.

In the unlikely event that a participant (patient or clinician) identifies an area of significant concern (e.g. patient safety or safeguarding issue) or we observe such an event, we will report this following the procedures within the organisation concerned. We would ensure that the participant concerned is aware that we are doing this.

We view ethics as an on-going consideration within the study, as opposed to something to be addressed (and approved) only at the start of the research. We therefore plan to include ethics as a rolling agenda item within study team meetings to ensure a protected space for members of the team to discuss ethical issues within the study. We will co-opt colleagues to study team meetings to provide additional support in discussing ethical issues that may arise.

12.FINANCE AND INSURANCE

The study is funded by the National Institute of Health Research, via a Programme Grant for Applied Health Research.

The University of Oxford maintains Public Liability and Professional Liability insurance which will operate in this respect.

13.DISSEMINATION AND OUTPUTS

We plan the following outputs:

1. For researchers: one publication in a high quality, internal peer-reviewed journal (e.g. Social Science & Medicine) summarising the main findings from the study and refined theory of shared decision making in the context of high risk surgery;
2. For clinicians and decision-makers: a briefing paper/blog outlining the typology of decision making scenarios for high risk surgery and next stages of the OSIRIS research programme;
3. For patients and their families: a summary of key findings relating to decision making and how this will inform research and practice going forward; and
4. For funders/sponsor/regulators: progress and final reports, as required.

Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. All publications will acknowledge that the study was funded by the National Institute for Health Research and include the relevant wording (as per

contract). Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged (with permission).

The study will inform a wider programme of work on *Optimising Shared decisIon-making for high RIsk major Surgery*, led by Professor Rupert Pearse at Queen Mary, University of London. Findings from the qualitative study will be reported in the form of a typology of decision making scenarios for major surgery. Combined with research to determine what happens to patients during the years after surgery, this will inform the co-design, with patients and doctors, of a decision support intervention to be tested in a clinical trial with a view to providing an accurate forecast of the long-term outcomes which matter most to patients.

Ownership of IP generated by employees of the University vests in the University. The protection and exploitation of any new IP is managed by the University's technology transfer office, Oxford University Innovations.

14.REFERENCES

1. Abbott TEF, Fowler AJ, Dobbs TD, et al. Frequency of surgical treatment and related hospital procedures in the UK: a national ecological study using hospital episode statistics. *Br J Anaesth* 2017;119(2):249-57. doi: 10.1093/bja/aex137 [published Online First: 2017/09/01]

2. Pearse RM, Moreno RP, Bauer P, et al. Mortality after surgery in Europe: a 7 day cohort study. *The Lancet* 2012;380(9847):1059-65. doi: 10.1016/S0140-6736(12)61148-9

3. International Surgical Outcomes Study Group. Global patient outcomes after elective surgery: prospective cohort study in 27 low-, middle- and high-income countries. *British Journal of Anaesthesia* 2016;117(5):601-09. doi: 10.1093/bja/aew316

4. Khuri SF, Daley J, Henderson W, et al. The Department of Veterans Affairs' NSQIP: the first national, validated, outcome-based, risk-adjusted, and peer-controlled program for the measurement and enhancement of the quality of surgical care. National VA Surgical Quality Improvement Program. *Annals of Surgery* 1998;228(4):491-507.

5. Doherty C, Saunders MNK. Elective surgical patients' narratives of hospitalization: The co-construction of safety. *Social Science & Medicine* 2013;98:29-36. doi: https://doi.org/10.1016/j.socscimed.2013.08.014

6. Bougeard A-M, Brent A, Swart M, et al. A survey of UK peri-operative medicine: pre-operative care. *Anaesthesia* 2017;72(8):1010-15. doi: doi:10.1111/anae.13934

7. Institute of Medicine. Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life. Washington, DC: The National Academies Press 2015.

8. Braddock CI, Hudak PL, Feldman JJ, et al. "Surgery Is Certainly One Good Option": Quality and Time-Efficiency of Informed Decision-Making in Surgery. *JBJS* 2008;90(9):1830-38. doi: 10.2106/jbjs.G.00840

9. Kruser JM, Pecanac KE, Brasel KJ, et al. “And I think that we can fix it”: Mental Models used in High-Risk Surgical Decision Making. *Annals of surgery* 2015;261(4):678-84. doi: 10.1097/SLA.0000000000000714

10. Taylor LJ, Rathouz PJ, Berlin A, et al. Navigating high-risk surgery: protocol for a multisite, stepped wedge, cluster-randomised trial of a question prompt list intervention to empower older adults to ask questions that inform treatment decisions. *BMJ Open* 2017;7(5) doi: 10.1136/bmjopen-2016-014002

11. Charles C, Gafni A, Whelan T. Decision-making in the physician–patient encounter: revisiting the shared treatment decision-making model. *Social Science & Medicine* 1999;49(5):651-61. doi: https://doi.org/10.1016/S0277-9536(99)00145-8

12. Fovargue S, Miola J. One step forward, two steps back? The GMC, the common law and ‘informed’ consent. *Journal of Medical Ethics* 2010;36(8):494-97. doi: 10.1136/jme.2009.032862

13. General Medical Council. Consent guidance: Patients and doctors making decisions together. Available at: http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp. London: GMC, 2008.

14. Boss EF, Mehta N, Nagarajan N, et al. Shared Decision Making and Choice for Elective Surgical Care:A Systematic Review. *Otolaryngology–Head and Neck Surgery* 2016;154(3):405-20. doi: 10.1177/0194599815620558

15. Légaré F, Adekpedjou R, Stacey D, et al. Interventions for increasing the use of shared decision making by healthcare professionals. *Cochrane Database of Systematic Reviews* 2018(7) doi: 10.1002/14651858.CD006732.pub4

16. Légaré F, Stacey D, Turcotte S, et al. Interventions for improving the adoption of shared decision making by healthcare professionals. *Cochrane Database of Systematic Reviews* 2014(9) doi: 10.1002/14651858.CD006732.pub3

17. Pecanac KE, Kehler JM, Brasel KJ, et al. It's big surgery: preoperative expressions of risk, responsibility, and commitment to treatment after high-risk operations. *Ann Surg* 2014;259(3):458-63. doi: 10.1097/SLA.0000000000000314 [published Online First: 2013/11/21]

18. Nabozny MJ, Kruser JM, Steffens NM, et al. Constructing High-stakes Surgical Decisions: It's Better to Die Trying. *Ann Surg* 2016;263(1):64-70. doi: 10.1097/SLA.0000000000001081 [published Online First: 2015/01/08]

19. Nabozny MJ, Kruser JM, Steffens NM, et al. Patient-reported Limitations to Surgical Buy-in: A Qualitative Study of Patients Facing High-risk Surgery. *Ann Surg* 2017;265(1):97-102. doi: 10.1097/SLA.0000000000001645 [published Online First: 2016/12/24]

20. Steffens NM, Tucholka JL, Nabozny MJ, et al. Engaging patients, health care professionals, and community members to improve preoperative decision making for older adults facing high-risk surgery. *JAMA Surgery* 2016;151(10):938-45. doi: 10.1001/jamasurg.2016.1308

21. McNair AGK, MacKichan F, Donovan JL, et al. What surgeons tell patients and what patients want to know before major cancer surgery: a qualitative study. *BMC Cancer* 2016;16:258. doi: 10.1186/s12885-016-2292-3 [published Online First: 2016/04/03]

22. Elwyn G, Lloyd A, May C, et al. Collaborative deliberation: a model for patient care. *Patient Educ Couns* 2014;97(2):158-64. doi: 10.1016/j.pec.2014.07.027 [published Online First: 2014/09/02]

23. Elwyn G, Durand MA, Song J, et al. A three-talk model for shared decision making: multistage consultation process. *BMJ* 2017;359:j4891. doi: 10.1136/bmj.j4891 [published Online First: 2017/11/08]

24. Boland R. Decision Making and Sensemaking. Handbook on Decision Support Systems 1 International Handbooks Information System. Berlin, Heidelberg Springer 2008.

25. Rapley T. Distributed decision making: the anatomy of decisions-in-action. *Sociol Health Illn* 2008;30(3):429-44. doi: 10.1111/j.1467-9566.2007.01064.x [published Online First: 2008/01/16]

26. Charlson M, Szatrowski TP, Peterson J, et al. Validation of a combined comorbidity index. *Journal of Clinical Epidemiology* 1994;47:1245-51.

27. Bezemer J, Cope A, Korkiakangas T, et al. Microanalysis of video from the operating room: an underused approach to patient safety research. *BMJ Qual Saf* 2017;26(7):583-87. doi: 10.1136/bmjqs-2016-005816

28. Pearce C. Doctors, Patients and Computers, the New Consultation (PhD thesis). . Melbourne, Australia: Department of General Practice, The University of Melbourne 2007.

29. Gumperz J, Hymes D. Directions in Sociolinguistcs: The Ethnography of Communication. New York: Basil Blackwell 1972.

30. Hymes D. On communicative competence. In: Pride JB, Holmes J, eds. Socolinguistics: Selected Readings. Harmondsworth: Penguin 1972:269-93.

