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

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Protocol paper for BMJ Open

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

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ABSTRACT (293/300)

Introduction

Surgical treatments are being offered to more patients than ever before, and increasingly to high-risk patients (typically over 75, with multi-morbidity). Shared decision making is seen as essential practice. However, little is currently known about what ‘good’ shared decision making involves nor how it applies in the context of surgery for high-risk patients (typically older patients with multi-morbidity). This new study aims to identify how high-risk patients, their families and clinical teams negotiate decision making for major surgery.

Methods and analysis

Focusing on major joint replacement, colo-rectal and cardiac surgery, we use qualitative methods to explore how patients, their families and clinicians negotiate decision making (including interactional, communicative and informational aspects and the extent to which these are perceived as shared) and reflect back on the decisions they made. Phase 1 involves video-recording 15 decision making encounters about major surgery between patients, their carers/families and clinicians; followed by up to 90 interviews (with the same patient, carer and clinician participants) immediately after a decision has been made and again 3-6 months later. Phase 2 involves focus groups with a wider group of (up to 90) patients and (up to 30) clinicians to test out emerging findings and inform development of shared decision making scenarios.

Ethics and dissemination

The study forms the first part in a six-year programme of research, *Optimising Shared decision-makIng for high RIsk Surgery* (OSIRIS). Ethical challenges around involving patients at a challenging time in their lives will be overseen by the programme steering committee, which includes strong patient representation and a lay chair. In addition to academic outputs, we will produce a typology of decision making scenarios for major surgery to feed back to patients, professionals and service providers and inform subsequent work in the OSIRIS programme.

Key words: shared decision making, distributed decision making, high risk, adult surgery, communication, qualitative research,

ARTICLE SUMMARY

Strengths and limitations of this study

- New study focused on decision making about major surgery with high-risk patients.
- Novel qualitative design, combining video-recording of decision making encounters, with individual and group interviews.
- Guided by theory, which recognises that decisions about surgery rarely occur at neat ‘decision points’, involve various stages of deliberation, and are shaped by interaction with many (clinical and non-clinical) individuals.
- Informs a programme of work, *Optimising Shared decision-makIng for high RIsk Surgery*, including development of a decision support intervention to improve shared decision making about elective major surgery.

Word count (exc title page, abstract, references, figures and tables): 3999 (4000 is max)

INTRODUCTION

Shared decision making aims to bring patient values and preferences together with clinician expertise to determine the best care package for the individual concerned. It is not new, building on influential work published since the 1980s (eg, [1-3]). The recent prominence given to shared decision making has accompanied a broader shift towards 'patient-centred care', along with a rise in patient advocacy and increased involvement of patients and the public in the distribution of health care resources [4-9]. In the UK, following a landmark legal case (Montgomery vs Lanarkshire Health Board) [10], standards in respect of the consent process have shifted away from what a body of professionals deem relevant (paternalism) to what a reasonable patient would want or need to know (shared decision making) [11-13].

In surgery, shared decision making is espoused as an essential practice on the basis that it can improve patient satisfaction, moderate use of surgery and reduce costs. It is considered crucial at a time when surgical treatments are offered to more patients than ever before, and increasingly offered to older patients who are likely at higher risk of poor postoperative outcomes. Around 1.5 million major surgical procedures are now performed each year in the UK [14], with 250,000 at high risk of post-operative complications [15]. Even when surgery and anaesthesia are straightforward, one in three high-risk patients develops serious medical complications such as pneumonia or myocardial infarction in the days following surgery [16]. These complications delay recovery, with prolonged hospital stays and a decline in functional independence once patients return home. Critically, many high-risk patients never recover from these adverse effects, suffering significant reductions in long-term quality of life and survival [16, 17]. For some, surgery is not the successful treatment they hoped for, with feelings of guilt or regret over the decision to undergo surgery commonplace [18]. Doctors recognise the need to help improve decision making for this patient group but often feel ill-equipped to do so [19], with surgeons and anaesthetists currently lacking the expertise to make informed judgements about the risks such patients face and so concerned about shared decision making. The problem is becoming more frequent as more patients living with severe chronic disease are offered surgical treatments. In sum, many older people are having high-risk surgery (ie, major surgery with high-risk patients) and are sometimes regretting doing so, with this problem likely to increase in the future.

Shared decision making is perceived as a potential means of addressing this but the impact of shared decision making is currently unclear. Three systematic reviews [20-22] have shown that patients and clinicians generally value it and that it has potential to both improve the quality of decisions (largely via improved information sharing and increased knowledge [21]), and lessen conflict in decision making about preference-sensitive surgery (ie, where there is no one best available treatment, but two or more available options). Overall reviews suggest that it is the quality of the decision making process, over the decision itself, that is key to improving outcomes. However, studies have tended to focus on a small number of clinical areas (eg, breast cancer, osteoarthritis); orient to decision making between the patient and physician alone; and assess outcomes allied to decision making rather than the process or experience *per se* (eg, of the 24 studies identified by Boss et al [21], 17 measured outcomes on the effectiveness of the decision aid without directly assessing doctor-patient interactions). Few studies have linked surgical outcomes and decision making processes, considered potentially relevant demographic characteristics (eg, age, socioeconomic status, ethnicity), or conducted follow up to consider what decisions mean in the context of peoples' lives after having made their decision to undergo surgery or not. Recently, some authors have called for a more multi-faceted approach that further considers organisational and system-level, as well as social and temporal aspects, of shared decision making; including, for instance: relevant guidelines, workflows and interactions across the clinical team (eg, involving anesthetists), the extended care pathway (eg, from pre-operative assessment through to postoperative de/prescribing), and the influence of wider social relations (eg, families) [4, 23] [24-26].

Interactions between clinicians and patients prior to making a decision about surgery are important (eg, we know that good communication is associated with increased professional and patient satisfaction [27]), but rarely the focus of research. To date there has been limited research on communication between clinicians and patients in the context of shared decision making for surgery. What little there is has shown that communication practices often inadequately support preoperative shared decision making about surgery. Most (but not all) patients prefer to share in decision making but do not always have the chance to do so [8]. Surgeons rarely employ a fully collaborative decision-making process [28, 29], instead disclosing procedural risks and helping patients make choices by relying on standard practices (eg, informed consent) or communication practices such as the ‘fix-it’ model, describing the patient’s disease as an isolated abnormality linked directly with a surgical solution [30].

Of the literature on shared decision making for surgery, only a small number of North American studies focus on high-risk patients [31-34]. 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 [31, 33]. Follow up interviews 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, over individual and preference-sensitive choice.

One study underscored the challenge for patients of incorporating their values and beliefs into shared decision making for high-risk surgery [32]. 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. Surgeons discussed the challenge of ‘surgical momentum’, ie, 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 potential risk of severe post-operative complications. The language used, particularly the focus on ‘fixing’ a problem, was found to close down discussions about the value of surgery and how it may fit with patients’ overall values and goals [35]. Other research on the information needs of patients found a mis-match between what surgeons discussed in consultations and what patients wanted to know [27]. In particular, patients wanted less technical information and more discussion of long-term effects on their quality of life and survival. This resonates with recent legal judgments emphasising that, “*The doctor’s duty is not fulfilled by bombarding the patient with technical information*” [10].

In sum, the literature on shared decision making for surgery is in its infancy, tends to focus on information giving as the key component of shared decision making, and employs quantitative assessments of the outcomes of decision making over qualitative understanding of processes and experiences. Studies relevant to surgery for high-risk patients are limited in number and suggest that high-risk patients often do not realise that they have a choice about whether to have surgery or not and have mismatched expectations about what may happen after surgery.

Research that enables understanding of shared decision making for high-risk patients is therefore timely and necessary. In this new study we seek to identify the key influences on the shared decision making process for high-risk patients who are offered surgery asking:

1. How do patients, their families and clinical teams approach and negotiate 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?

METHODS AND ANALYSIS

Origins, design and governance of the study

The study forms part of a six-year programme of work, *Optimising Shared decision-makIng for high RIsk Surgery* (OSIRIS, https://osiris-programme.org/) funded by the National Institute for Health Research in England. OSIRIS comprises four interlinked projects leading to the development and testing of a decision support intervention, to improve shared decision making about elective major surgery between doctors and patients at high-risk of adverse long-term outcomes. The OSIRIS programme has significant governance oversight including a shadow steering committee, with patient and public membership and a lay chair, which meets six-monthly and feeds into the main programme steering committee. An OSIRIS collaborators group includes a wide range of stakeholders from NHS, professional bodies, academia, policy and patients.

In this study we use qualitative methods to explore in-depth how patients, their families and clinicians negotiate decision making and reflect back on the decisions they made. The study has two phases. Phase 1 involves video-recording decision making encounters about major surgery, between patients, their carers/families and clinicians to understand the content and flow of decision making about surgery; followed by interviews (immediately after and 3-6 months later) to understand reasoning for and reflections on those decisions. Phase 2 involves focus groups with a wider group of patients and clinicians to test out emerging findings and inform development of shared decision making scenarios.

Theoretical and conceptual framework

Our research is framed by practice theory, recognising that decisions about surgery are distributed over time and space (ie, they rarely occur at neat ‘decision points’ or in single consultations) [36], involve varied stages of (potentially collaborative) deliberation [37], and are shaped by interaction with a range of actors and artefacts [38]. This guided us to focus on decision-making-in-action, seeing the process of decision making and the activities and events allied to it (eg, consultations, clinics, letters, family discussions), as something that happens through an on-going process of communication and collaborative articulation of what major surgery might mean for all those involved. We draw on 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 [39]) to understand how meanings about surgery are constructed, the influence of moral and ethical dimensions and how communication and interaction unfold.

Finally, given that healthcare is heavily institutionalised, and behaviour is often ritualised (ie, we know, and play out, the roles expected of us as clinicians, patients and so on), we draw on the notion of ‘organisational routines’ [40], defined as ‘recognizable, repetitive patterns of interdependent action carried out by multiple actors’ [41]. Routines are how organisational life is patterned, hence studying these can provide key insights into how shared decision making may (or may not) be integrated in to the three surgical areas of interest.

Sampling and data collection

Surgical areas

The OSIRIS programme focuses on three different surgical procedures: major joint, intra-abdominal and cardiac surgery. We plan to examine how the context of the differing conditions influences the decisions that patients and doctors make, how these decisions are made in the light of different ways of organising treatments and resources, and the multiple and varied points at which patients and clinicians come together to consider and make decisions about surgery.

Major joint replacement for osteoarthritis is a symptomatic treatment which will not prolong life but can improve quality of life for those with significant pain and reduced mobility. It is likely to be considered and discussed within primary care, as well as specialist musculoskeletal services, as part of a potentially long-term process of considering surgery with an orthopaedic team. Coronary artery bypass grafting may prolong life at a population level, but for the individual patient this benefit is not guaranteed, especially for frailer or multi-morbid patients. Increasingly, less invasive, percutaneous coronary interventions have created a range of options for patients with ischaemic heart disease. There are however a range of short and long term risks associated with both choices (eg, percutaneous options offer fewer short term risks to patients but have inferior long term outcomes compared to surgery for more severe ischaemic heart disease). Colorectal surgery for bowel cancer is essential and requires relatively rapid decisions about treatment. Following diagnosis patients, relatives and clinicians are faced with choices about the nature of the procedure (including a potential for palliative surgery) and the need for adjunct radio- or chemotherapy.

Preliminary work with clinicians to map out the decision making processes across conditions/sites (Figures 1-3) has highlighted variation in how services are organised (eg, variation in the anaesthetic pre-operative assessment offered) and the distributed nature of decision making (ie, taking place over time, in multiple settings, involving multiple discussions with, potentially, many people [36, 37]). This means that the process of decision making about surgery is likely to be different across the three surgical specialties of interest (see Figures 1-3) and also across settings. Our focus on high-risk patients due to age, chronic disease, or frailty means that decision making is also likely to be influenced by past experiences (eg, prior surgery and/or serious illness) and have a more complex combination of long-term outcomes to consider.

FIGURES 1-3 ABOUT HERE

Phase 1 –video-recording of decision making encounters, plus follow-up interviews

In phase 1 we will purposively select three NHS hospitals that are undertaking at least two of the three surgical procedures of interest. Working with clinical teams we will recruit a maximum variation, purposive-sample of 15 high-risk patients aged ≥60 years with an age-adjusted Charlson co-morbidity score [42] of ≥4, who are contemplating surgery (anticipating five from each surgical group including, where feasible, one patient who has declined surgery), with adequate variation in age, gender and social circumstances and including travel time to the hospital.

We will video-record up to 15 consultations that involve decision making about major surgery for all those who agree to participate, seeking to capture verbal and non-verbal interaction, and enabling detailed insight into the decision making process in terms of the content of consultations (eg, information exchanged) and the interaction (eg, between clinician and patient). This will involve the researcher placing one or two video cameras in the consultation room and recording the consultation. Where the patient agrees, the researcher will remain in the room. This is usual in qualitative studies, enabling appreciation of each consultation as it unfolds in real time.

Pathways for major surgery vary (Figures 1-3). We will not know how decision making processes unfold – and hence exactly which consultation we will record - until we have gained access to each site and clinical team. For some participants the consultation that we record will be with their surgeon and will follow a series of contacts with the health service. For others, the consultation we record may be with another member of the clinical team (eg, anaesthetist) who has had a critical role in the decision-making process.

We will subsequently conduct narrative interviews with patients and clinicians (and carers where relevant) at two points (Table 1). The first will be as soon as practically possibly after their consultation (and wherever possible before their surgery), the second 3-6 months later. We will adopt a narrative approach [43], encouraging interviewees to recount the details of their experiences (eg, of their condition, or decision making about surgery) in their own way and in their own time. Interviews will last up to one hour and be audio-recorded.

Interview data across multiple perspectives will enable a detailed understanding of the relevant condition, how it has unfolded, experiences of decision making and the context within which decisions were made, and thoughts and expectations about surgery (if this is the option chosen); as well as experiences since having or declining surgery, and reflections back on the decision made.

TABLE 1 ABOUT HERE

Phase 2 – focus groups

We will purposively select up to 3 NHS hospitals undertaking major joint surgery, intra-abdominal surgery and cardiac surgery, using the same criteria as phase 1. We will recruit a purposive maximum variation sample of up to 90 high-risk patients (up to 9 focus groups), excluding any patients recruited in phase 1, 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. Where patients with severe complications are unable to participate, we will invite them to nominate someone who can represent their views and/or have a carer attend with them.

Working with Royal Colleges, we will also recruit a purposive sample of up to 30 surgeons, doctors, anaesthetists and clinical nurse specialists (up to 3 focus groups) caring for patients having these types of surgery, ensuring a mix of age, gender, clinical position and experience, role and location.

Focus groups with patients and carers will be held at or close by (eg, local community centre) to participating sites, involve 8-10 patients or carers in each. Those involving clinicians will be held at central locations (eg, one of the Royal Colleges). The same topic guide will be used across groups, guiding participants to introduce themselves and say what their experience is of making decisions (or supporting others in decision making) about major surgery, before reviewing draft decision making scenarios developed from phase 1. We plan to ask patients, carers and clinicians to share 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. Focus groups will be audio-recorded and transcribed.

Analysis and synthesis

Table 1 summarises different data sources and how these will be analysed and synthesised to provide detailed decision making scenarios and inform the wider OSIRIS programme.

In phase 1 we will develop summaries for each case (ie, patient, family/carers and clinicians), detailing 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 or of living with the condition having declined surgery; as well as post-hoc reflections on decision making in light of outcomes following surgery or the decision to decline.

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 the decision making process to examine interactions, judgements and interpretations [44], the bodily conduct of participants, and the ways in which objects (eg, consent forms) come to gain significance at particular moments [45]. Recordings will be transcribed (eg, using ELAN, a specialist programme used by linguists) to allow us to capture granular (verbal and non-verbal) detail of interaction, repeatedly view and tag data digitally (ensuring immersion in the full video and audio at the level of a sentence, comment or other linguistic feature, which is often key to analysis [45]), and produce a textual transcript meaning that we can engage indirectly with the data via transcripts of each decision making encounter.

We will then examine video data in depth to: identify key features of shared decision making encounters, examine the way 'communicative competence' [46] shapes shared decision making (ie, how participants deploy their tacit understanding of a particular communicative event, and competencies needed to maximise the benefits of the encounter), and attend to the contextual factors (eg, clinic space, presence of carers, preceding exchange of information) that shape decision making. Analysis of interaction will be informed by ethnography of communication (see above) 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): openings (how participants initially frame the consultation) interruptions and repair (how participants deal with interactional problems); the use of questions (eg, 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 data 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 (see above) we will compare and contrast across vignettes to examine similarities and differences in 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 (ie, the key components of Collaborative Deliberation [37]). Finally we will develop 3-5 draft decision making scenarios, emerging from identification of patterns in our emerging analysis about how decision making variably unfolds amongst different groups, in different settings and for different kinds of surgery; as well as the extent to which this might be regarded as 'shared'.

We will use thematic and comparative analysis to analyse focus group data, generating a detailed understanding of the choices that patients, families/carers and clinicians make about surgery, and the factors that shape decision making. We will revise 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 (or no surgery). Finally we will synthesise analyses across our datasets, seeking to extend current theory on decision making for high-risk patients offered surgery (Table 1).

Patient and public involvement

We are committed to patient and public involvement in all stages of the research. Patients with lived experience of major surgery are included in the OSIRIS programme leadership and steering committee. A patient panel has already been established, providing patients with the space to discuss the research, and feed directly into the main steering committee. Patients will be invited to participate in workshops early in the programme to refine our research design, guide the team on how best to approach sensitive topics with patients, and help to refine research tools (eg, topic guides). Later in the OSIRIS programme these patient networks will help to co-design a decision support intervention. Patient co-applicants will act as co-authors for scientific and lay reports.

ETHICS AND DISSEMINATION

The research has received ethical approval from South Central Oxford C Research Ethics Committee (19/SC/0043). At the time of writing we have recruited all three sites and gained local governance approval.

An important ethical issue relates to the involvement of patients (and by extension family/carers) at a time when they might be feeling emotionally and physically vulnerable and needing to make potentially life-changing decisions. We have sought to address this by ensuring that recruitment/consent is as straightforward as possible, framing questions about care and experiences of surgery sensitively, and inviting patients (should they wish) to involve family members or other carers in interviews. Working closely with clinical teams, we will be sensitive to the different clinical pathways and the ways in which information and diagnoses are shared with patients, and have planned an observation period with each site in phase 1 to appreciate the referral and decision making process about major surgery before recruiting patients.

We plan dissemination within and outside of the OSIRIS programme. For the former we will produce 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 that matter most to patients. For the latter, we will produce research publications and conference presentations for academics, including a refined theory of shared decision making relevant to high-risk patients in the context of surgery. For service providers, policymakers and regulators, we propose succinct and accessible summaries of key findings including summaries of decision making scenarios and provisional operational guidance. For patients and families/carers, we will produce a leaflet and web download summarising findings and setting out what to expect when making a decision about major surgery.

Author contributions:

SS conceptualised the study and wrote the first draft of the paper. GH and TS contributed to study design and will be collecting and analysing data across the study. JD, JE, EA and ME have contributed to understanding surgical pathways, developing decision making maps and approaches to recruitment. RP and JP are co-directors of the OSIRIS programme, of which this study is part. LE is lay chair of the OSIRIS shadow steering group and, as such, has fed into the design and conduct of the study. All authors had input to revisions of the paper and approved the final manuscript.

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Competing interests statement:

We have read and understood the BMJ Group policy on declaration of interests and declare the following interests: SES, GH, TS, JP, EA, JD, ME, JE, LE declare no interests. RP has received research grants and/or honoraria from Edwards Lifesciences, Intersurgical, BBraun and GlaxoSmithkline.

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Figure 1 - Example decision making map for colorectal surgery

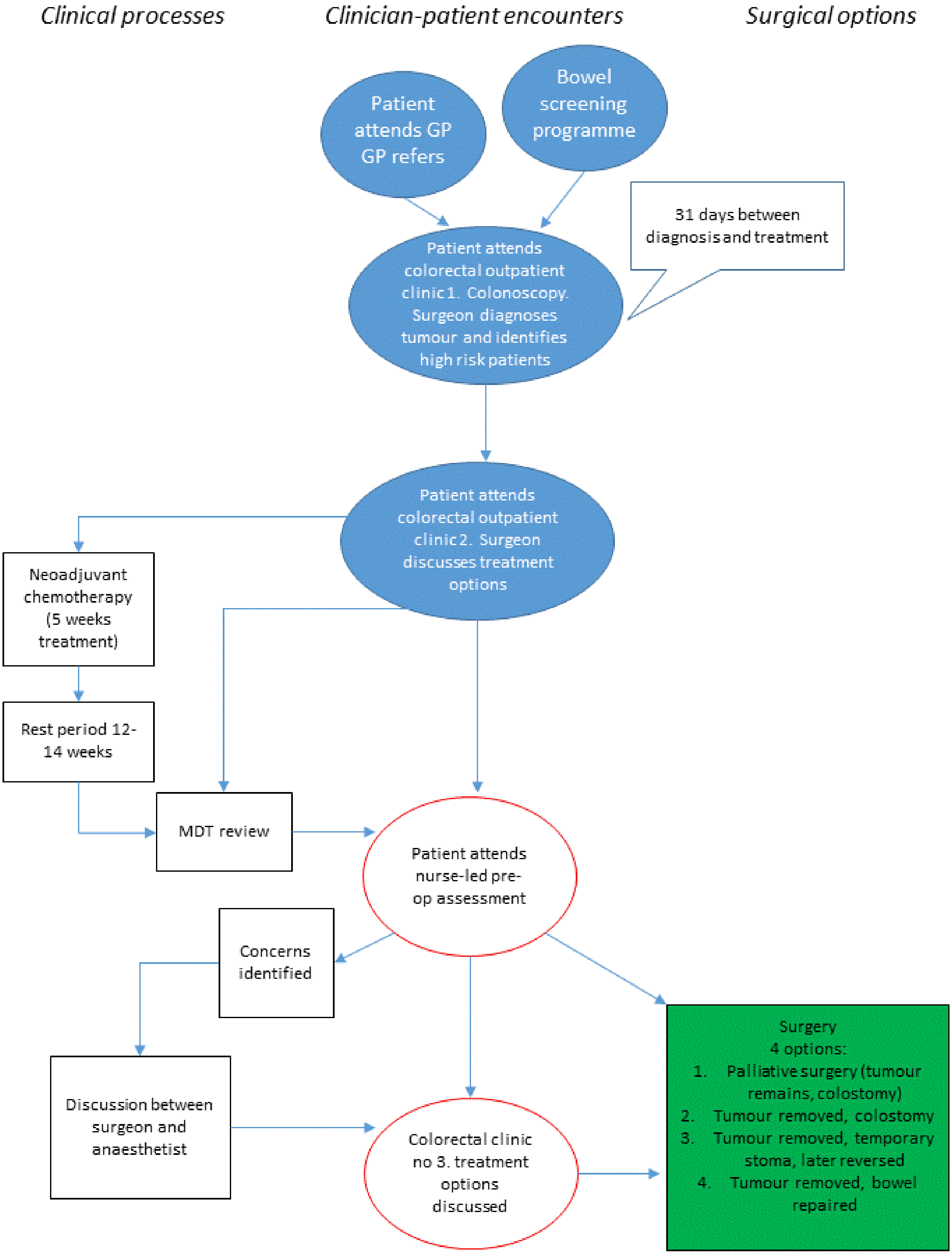
Clinical processes
Clinician-patient encounters
Surgical options
Patient attends GP GP refers
Bowel screening programme
31 days between diagnosis and treatment
Patient attends colorectal outpatient clinic 1. Colonoscopy. Surgeon diagnoses tumour and identifies high risk patients
Patient attends colorectal outpatient clinic 2. Surgeon discusses treatment options
Neoadjuvant chemotherapy (5 weeks treatment)
Rest period 12-14 weeks
MDT review
Patient attends nurse-led pre-op assessment
Concerns identified
Discussion between surgeon and anaesthetist
Colorectal clinic no 3. treatment options discussed
Surgery
4 options:
1. Palliative surgery (tumour remains, colostomy)
2. Tumour removed, colostomy
3. Tumour removed, temporary stoma, later reversed
4. Tumour removed, bowel repaired

Figure 2 - Example decision-making map for orthopaedic surgery

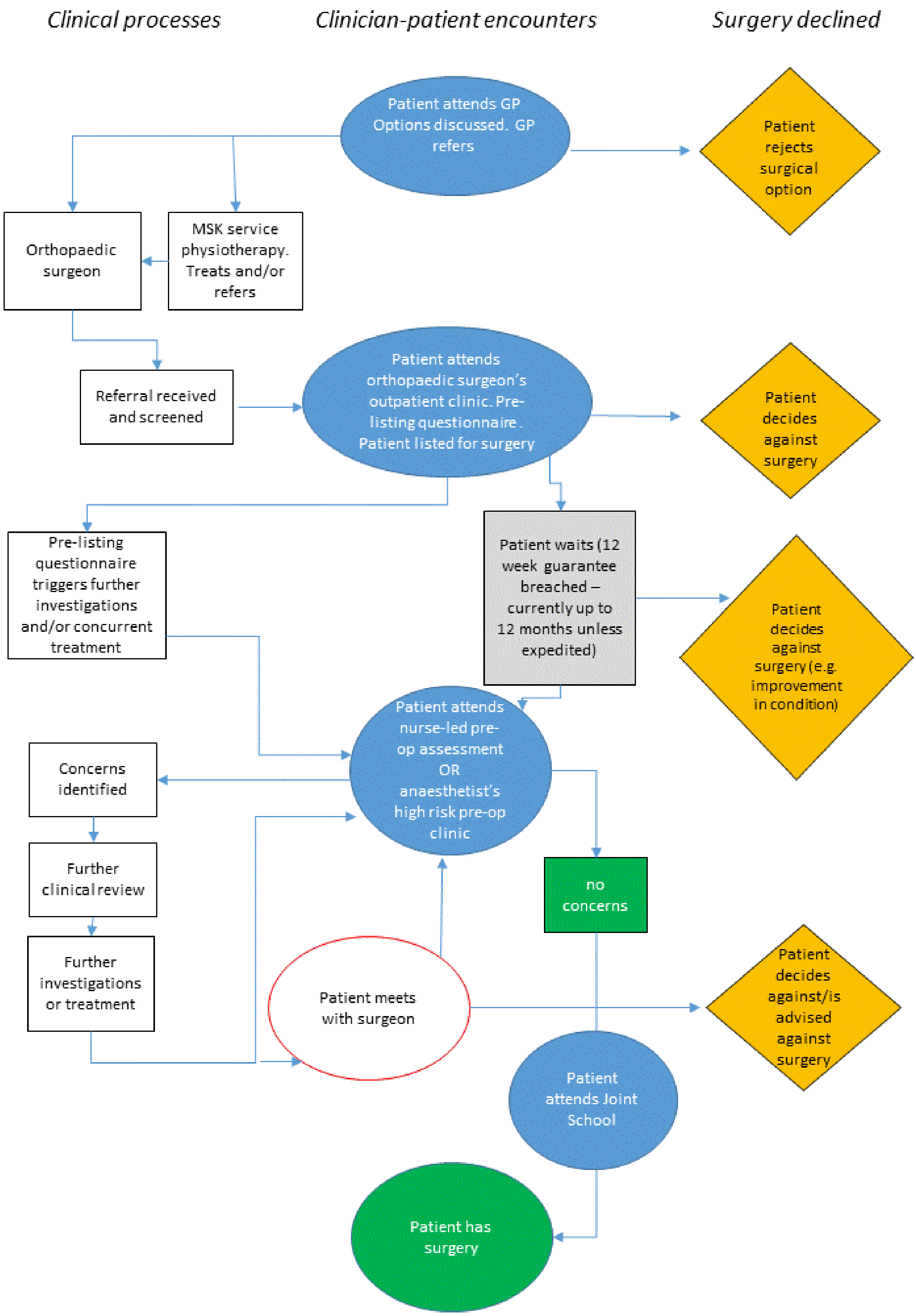

Figure 3 - Example decision-making map for cardiac bypass surgery

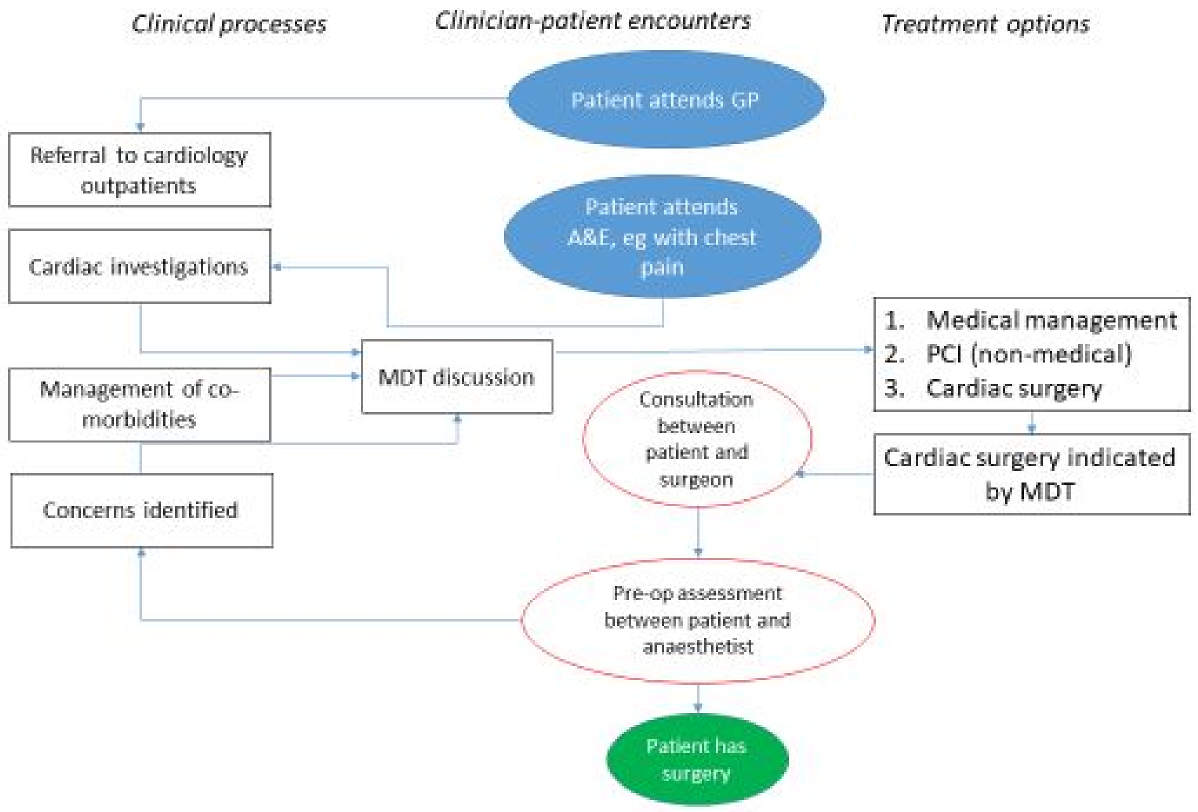

Table 1: Overview of data structure and planned analysis

Data source	Data collected	First order interpretations	Higher-order interpretations
Case studies of decision making for surgery	• Video-recordings of 15 consultations across three different surgical areas • Researcher field notes, including clinical pathways	• Key exchanges shaping decision making about surgery between clinicians, patients (and potentially carers/family members) • Unfolding interaction, and use of decision making aids/tools • Clinic workflows, 'decision points' for surgery and key interdependencies	• How patients, clinicians and carers relate; and how/when they come together to discuss – and make decisions about – surgery • 'Scripts' held by patients/clinicians about how they should behave and interact • When a meaningful decision about surgery is made, by whom and how • Organisational and clinic context to decision making
Pre-operative narratives about decision making about surgery	Follow-up interviews (up to 45) with • the same 15 consulting patients and their clinicians and, where relevant, carer/family member • other members of the clinical team (eg, anaesthetists, specialist nurses) involved in shaping decisions about surgery	• Reflections on decisions made about surgery • Perceptions on the decision making process over time, including strategies for communication and sharing information • Experiences of decision making, and expectations going forward • Key organisational and clinic strategies, and how these change over time • How participants felt	• Internal social structures (what actors 'know', how they understand and interpret about surgery, including what 'a decision' about surgery means to actors • 'Scripts' held about decision making and how they change over time, including assumptions about: - capability of users - how people interact - consent - clinical work and routines - how these all interact
Post-hoc reflections on decision making about surgery	• Follow-up interviews (up to 45) with the same 15 consulting patients and their clinicians and, where relevant, carer/family member • Focus group interviews with (up to 90) patients/carers and (up to 30) clinicians		

OSIRIS

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8th Aug 2019

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Understanding decision making about major surgery: protocol for a qualitative study of shared decision making by high-risk patients and their clinical teams

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Protocol paper for BMJ Open

Understanding decision making about major surgery: protocol for a qualitative study of shared decision making by high-risk patients and their clinical teams

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ABSTRACT (299/300)

Introduction

Surgical treatments are being offered to more patients than ever before, and increasingly to high-risk patients (typically multi-morbid and over 75). Shared decision making is seen as essential practice. However, little is currently known about what ‘good’ shared decision making involves nor how it applies in the context of surgery for high-risk patients (typically older patients with multi-morbidity). This new study aims to identify how high-risk patients, their families and clinical teams negotiate decision making for major surgery.

Methods and analysis

Focusing on major joint replacement, colo-rectal and cardiac surgery, we use qualitative methods to explore how patients, their families and clinicians negotiate decision making (including interactional, communicative and informational aspects and the extent to which these are perceived as shared) and reflect back on the decisions they made. Phase 1 involves video-recording 15 decision making encounters about major surgery between patients, their carers/families and clinicians; followed by up to 90 interviews (with the same patient, carer and clinician participants) immediately after a decision has been made and again 3-6 months later. Phase 2 involves focus groups with a wider group of (up to 90) patients and (up to 30) clinicians to test out emerging findings and inform development of shared decision making scenarios (3-5 summary descriptions of how decisions are made).

Ethics and dissemination

The study forms the first part in a six-year programme of research, *Optimising Shared decision-makIng for high RIsk Surgery* (OSIRIS). Ethical challenges around involving patients at a challenging time in their lives will be overseen by the programme steering committee, which includes strong patient representation and a lay chair. In addition to academic outputs, we will produce a typology of decision making scenarios for major surgery to feed back to patients, professionals and service providers and inform subsequent work in the OSIRIS programme.

Key words: shared decision making, distributed decision making, high risk, adult surgery, communication, qualitative research,

ARTICLE SUMMARY

Strengths and limitations of this study

- New study focused on decision making about major surgery with high-risk patients.
- Novel qualitative design, combining video-recording of decision making encounters, with individual and group interviews.
- Guided by theory, which recognises that decisions about surgery rarely occur at neat ‘decision points’, involve various stages of deliberation, and are shaped by interaction with many (clinical and non-clinical) individuals.
- Informs a programme of work, *Optimising Shared decision-makIng for high RIsk Surgery*, including development of a decision support intervention to improve shared decision making about elective major surgery.

Word count (exc title page, abstract, references, figures and tables): 3998

INTRODUCTION

Shared decision making aims to bring patient values and preferences together with clinician expertise to determine the best care package for the individual concerned. It is not new, building on influential work published since the 1980s (eg, [1-3]). The recent prominence given to shared decision making has accompanied a broader shift towards ‘patient-centred care’, along with a rise in patient advocacy and increased involvement in resource allocation [4-9]. In the UK, following a landmark legal case [10], standards in respect of the consent process have shifted away from what a body of professionals deem relevant (paternalism) to what a reasonable patient would want or need to know (shared decision making) [11-13].

In surgery, shared decision making is espoused as an essential practice on the basis that it can improve patient satisfaction, moderate use of surgery and reduce costs. It is increasingly offered to older patients who are often (but not always) at higher risk of poor postoperative outcomes. Around 1.5 million major surgical procedures are now performed each year in the UK [14], with 250,000 at high risk of post-operative complications [15]. Even when surgery and anaesthesia are straightforward, one in three high-risk patients develops serious medical complications in the days following surgery [16]. These complications delay recovery, with prolonged hospital stays and a decline in functional independence once patients return home. Critically, many high-risk patients never recover from these adverse effects, suffering significant reductions in long-term quality of life and survival [16, 17]. For some, surgery is not the successful treatment they hoped for, with feelings of guilt or regret commonplace [18]. Doctors recognise the need to help improve decision making for this patient group but often feel ill-equipped to do so [19], with surgeons and anaesthetists currently lacking the expertise to make informed judgements about the risks such patients face. The problem is becoming more frequent as more patients living with severe chronic disease are offered surgical treatments. In sum, many people are having high-risk surgery (ie, major surgery with high-risk patients) and are sometimes regretting doing so, with this problem likely to increase.

Shared decision making is perceived as a potential means of addressing this but the impact of shared decision making is currently unclear. Three systematic reviews [20-22] have shown that patients and clinicians generally value it and that it has potential to both improve the quality of decisions (largely via improved information sharing and increased knowledge [21]), and lessen conflict in decision making about preference-sensitive surgery (ie, where there is no one best available treatment). Overall reviews suggest that it is the quality of the decision making process, over the decision itself, that is key to improving outcomes. However, studies have tended to focus on a small number of clinical areas (eg, breast cancer, osteoarthritis); orient to decision making between the patient and physician alone; and assess outcomes allied to decision making rather than the process or experience *per se* (eg, of the 24 studies identified by Boss et al [21], 17 measured outcomes on the effectiveness of the decision aid without directly assessing doctor-patient interactions). Few studies have linked surgical outcomes and decision making processes, considered potentially relevant demographic characteristics (eg, age, socioeconomic status, ethnicity), or conducted follow up to consider what decisions about surgery mean in the context of peoples' lives. Recently, some authors have called for a more multi-faceted approach that further considers organisational and system-level, as well as social and temporal aspects, of shared decision making including: relevant guidelines, workflows across the clinical team (eg, involving anesthetists), the extended care pathway (eg, from pre-operative assessment through to postoperative de/prescribing), and the influence of families [4, 23-26].

Interactions between clinicians and patients prior to making a decision about surgery are important (eg, we know that good communication is associated with increased professional and patient satisfaction [27]), but rarely the focus of research. To date there has been limited research on communication between clinicians and patients in the context of shared decision making for surgery. What little there is has shown that communication practices often inadequately support preoperative shared decision making about surgery. Most (but not all) patients prefer to share in decision making but do not always have the chance to do so [8]. Surgeons rarely employ a fully collaborative decision-making process [28, 29], instead disclosing procedural risks and helping patients make choices by relying on standard practices (eg, informed consent) or communication practices such as the 'fix-it' model, describing the patient's disease as an isolated abnormality linked directly with a surgical solution [30].

Of the literature on shared decision making for surgery, only a small number of North American studies focus on high-risk patients [31-34]. 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 [31, 33]. Follow up interviews 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, over individual and preference-sensitive choice.

One study underscored the challenge for patients of incorporating their values and beliefs into shared decision making for high-risk surgery [32]. 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. Surgeons discussed the challenge of 'surgical momentum', ie, 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 potential risk of severe post-operative complications. The language used, particularly the focus on 'fixing' a problem, was found to close down discussions about the value of surgery and how it may fit with patients' overall values and goals [35]. To our knowledge, there are no published studies focused specifically on clinicians' perceptions of decision making for high-risk surgery, and why it may (or may not) be 'shared'. Research on the information needs of patients found a mis-match between what surgeons discussed in consultations and what patients wanted to know [27]. In particular, patients wanted less technical information and more discussion of long-term effects. This resonates with recent legal judgments emphasising that, "*The doctor's duty is not fulfilled by bombarding the patient with technical information*" [10].

In sum, the literature on shared decision making for surgery is in its infancy, tends to focus on information giving , and employs quantitative assessments of the outcomes of decision making over qualitative understanding of processes and experiences. Studies relevant to surgery for high-risk patients are limited in number and suggest that high-risk patients often do not realise that they have a choice about surgery and have mismatched expectations about what may happen after surgery.

Research that enables understanding of shared decision making for high-risk patients is therefore timely and necessary. In this new study we seek to identify perspectives on, and communicative features of, the shared decision making process for high-risk patients who are offered surgery asking:

1. How do patients, their families and clinical teams approach and negotiate 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?

METHODS AND ANALYSIS

Origins, design and governance of the study

The study forms part of a six-year programme of work, *Optimising Shared decision-makIng for high RIsk Surgery* (OSIRIS, https://osiris-programme.org/) funded by the National Institute for Health Research in England. OSIRIS comprises four interlinked projects leading to the development and testing of a decision support intervention, to improve shared decision making about elective major surgery between doctors and patients at high-risk of adverse long-term outcomes. The OSIRIS programme has significant governance oversight including a management group (see supplementary file), a shadow steering committee, with patient and public membership and a lay chair, which meets six-monthly and feeds into the main programme steering committee. An OSIRIS collaborators group includes stakeholders from NHS, professional bodies, academia, policy and patients.

In this study we use qualitative methods to explore in-depth how patients, their families and clinicians negotiate decision making and reflect back on the decisions they made. The study involves a multidisciplinary team with representation from medicine/nursing, sociology, social policy and bioethics. Phase 1 involves video-recording decision making encounters about major surgery, between patients, their carers/families and clinicians to understand the content and flow of decision making about surgery; followed by interviews (immediately after and 3-6 months later). Phase 2 involves focus groups with a wider group of patients and clinicians to test out emerging findings.

Theoretical and conceptual framework

Our research is framed by practice theory, recognising that decisions about surgery are distributed over time and space (ie, they rarely occur at single ‘decision points’) [36], involve varied stages of (potentially collaborative) deliberation [37], and are shaped by interaction with a range of actors and artefacts [38]. This guided us to focus on decision-making-in-action, seeing the process of decision making and the activities and events allied to it (eg, consultations, clinics, letters, family discussions), as something that happens through an on-going process of communication and collaborative articulation of what major surgery might mean for those involved. We draw on ethnography of communication (an approach that aims to produce systematic and richly contextualised descriptions of communicative genres, events and practices [39]) to understand how meanings about surgery are constructed, the influence of moral and ethical dimensions and how communication and interaction unfold.

Finally, given that healthcare is heavily institutionalised, and behaviour often ritualised (ie, we know, and play out, the roles expected of us as clinicians, patients and so on), we draw on the notion of ‘organisational routines’ [40], defined as ‘recognizable, repetitive patterns of interdependent action carried out by multiple actors’ [41]. Routines are how organisational life is patterned, hence studying these can provide key insights into how shared decision making may (or may not) be integrated in to the three surgical areas of interest.

Sampling and data collection

Surgical areas

The OSIRIS programme focuses on three different (elective) surgical procedures: major joint, intra-abdominal and cardiac surgery. We plan to examine how the context of the differing conditions influences the decisions that patients and doctors make, how these decisions are made in the light of different ways of organising treatments and resources, and the multiple points at which patients and clinicians come together to consider and make decisions about surgery.

Major joint replacement for osteoarthritis is a symptomatic treatment which will not prolong life but can improve quality of life for those with significant pain and reduced mobility. It is likely to be considered and discussed within primary care, as well as specialist musculoskeletal services, as part of a potentially long-term process of considering surgery with an orthopaedic team. Colorectal surgery for bowel cancer is essential and requires relatively rapid decisions about treatment. Following diagnosis patients, relatives and clinicians are faced with choices about the nature of the procedure (including a potential for palliative surgery) and the need for adjunct radio- or chemotherapy. Coronary artery bypass grafting may prolong life at a population level, but for the individual patient this benefit is not guaranteed, especially for frailer or multi-morbid patients. Increasingly, less invasive, percutaneous coronary interventions have created a range of options for patients with ischaemic heart disease. There are however a range of short and long term risks associated with both choices (eg, percutaneous options offer fewer short term risks to patients but have inferior long term outcomes compared to surgery for more severe ischaemic heart disease).

Preliminary work with clinicians to map out the decision making processes across conditions/sites (Figures 1-3) has highlighted variation in how services are organised (eg, variation in the anaesthetic pre-operative assessment offered) and the distributed nature of decision making (ie, taking place over time, in multiple settings, involving multiple discussions with, potentially, many people [36, 37]). This means that the process of decision making about elective surgery is likely to be different across the three surgical specialties of interest (see Figures 1-3) and across settings. Our focus on high-risk patients due to age, chronic disease, or frailty means that decision making is also likely to be influenced by past experiences (eg, prior surgery) and have a more complex combination of long-term outcomes to consider.

FIGURES 1-3 ABOUT HERE

Phase 1 –video-recording of decision making encounters, plus follow-up interviews

In phase 1 we will purposively select three NHS hospitals that are undertaking at least two of the three surgical procedures of interest. Working with clinical teams (who will receive study basic information) we will recruit a maximum variation, purposive-sample of 15 high-risk patients aged ≥60 years (to capture a range of high-risk patients, not simply those who are older) with an age-adjusted Charlson co-morbidity score [42] of ≥4, who are contemplating elective surgery (anticipating five from each surgical group including, where feasible, one patient who has declined surgery), with adequate variation in age, gender and social circumstances and including travel time to the hospital.

We will video-record up to 15 consultations that involve decision making about major surgery for those who agree to participate, seeking to capture verbal and non-verbal interaction, and enabling detailed insight into the decision making process in terms of the content of consultations (eg, information exchanged) and the interaction (eg, between clinician and patient). This will involve the researcher placing one or two video cameras in the consultation room and recording the consultation. Where the patient agrees, the researcher will remain in the room. This is usual in qualitative studies, with the researcher's presence enabling appreciation of each consultation as it unfolds in real time and the video recording facilitating detailed analysis of interaction that is not feasible through observation alone).

Pathways for major surgery vary (Figures 1-3). We will not know how decision making processes unfold – and hence exactly which consultation we will record - until we have gained access to each site and clinical team. For some participants the consultation that we record will be with their surgeon and will follow a series of contacts with the health service. For others, the consultation we record may be with another member of the clinical team (eg, anaesthetist) who has had a critical role in the decision-making process. Where decision making clearly spans several encounters we will endeavour to record (or at the very least observe) more than one consultation.

We will subsequently conduct narrative interviews with patients and clinicians (and carers where relevant) at two points (Table 1): as soon as practically possibly after their consultation, and 3-6 months later. We will adopt a narrative approach [43], encouraging interviewees to recount the details of their experiences (eg, their condition, decision making about surgery). Interviews will last up to one hour, be face-to-face (wherever possible, by phone when not) and be audio-recorded. Reimbursement will be offered for basic expenses (e.g. car parking) incurred.

Interview data will enable a detailed understanding of the relevant condition, how it has unfolded, experiences of decision making and the context within which decisions were made, and thoughts and expectations about surgery (if this is the option chosen); as well as experiences since having or declining surgery, and reflections back on the decision made.

TABLE 1 ABOUT HERE

Phase 2 – focus groups

Focus groups will allow us to test out emerging findings with a broader group of participants. We will purposively select up to 3 NHS hospitals (at least one of which will be different from phase 1) undertaking major joint surgery, intra-abdominal surgery and cardiac surgery, using the same criteria as phase 1. We will recruit a purposive maximum variation sample of up to 90 high-risk patients (up to 9 focus groups), excluding any patients recruited in phase 1, 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. Where patients with severe complications are unable to participate, we will invite them to nominate someone who can represent their views and/or have a carer attend with them.

Working with Royal Colleges, we will also recruit a purposive sample of up to 30 surgeons, doctors, anaesthetists and clinical nurse specialists (up to 3 focus groups) caring for patients having these types of surgery, ensuring a mix of age, gender, clinical position and experience, role and location. We will hold at least one focus group involving a mix of professional groups.

Focus groups with patients and carers will be held at or close by (eg, local community centre) to participating sites, involve 8-10 participants in each. Those involving clinicians will be held at central locations (eg, one of the Royal Colleges). The same topic guide will be used across groups, guiding participants to introduce themselves and say what their experience is of making decisions (or supporting others) about major surgery. We plan to ask patients, carers and clinicians to share thoughts on the draft scenarios (i.e. 3-5 summary descriptions of decision making) developed from phase 1,. Focus groups will be audio-recorded and transcribed.

Analysis and synthesis

Table 1 summarises different data sources and how these will be analysed and synthesised to provide detailed decision making scenarios and inform the wider OSIRIS programme.

In phase 1 we will develop summaries for each case (ie, patient, family/carers and clinicians), detailing 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 (including relevant national and international guidelines) 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 or of living with the condition having declined surgery; as well as post-hoc reflections on decision making in light of outcomes following surgery or the decision to decline.

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 the decision making process to examine interactions, judgements and interpretations [44], the bodily conduct of participants, and the ways in which objects (eg, consent forms) come to gain significance at particular moments [45]. Recordings will be transcribed (eg, using ELAN, a specialist programme used by linguists) to allow us to capture granular (verbal and non-verbal) detail of interaction, repeatedly view and tag data digitally (ensuring immersion in the full video and audio at the level of a sentence, comment or other linguistic feature, which is often key to analysis [45]), and produce a textual transcript meaning that we can engage indirectly with the data via transcripts of each decision making encounter.

We will then examine video data in depth to: identify key features of shared decision making encounters, examine the way ‘communicative competence’ [46] shapes shared decision making (ie, how participants deploy their tacit understanding of a particular communicative event, and competencies needed to maximise the benefits of the encounter), and attend to the contextual factors (eg, presence of carers, preceding exchange of information) that shape decision making. Analysis of interaction will be informed by ethnography of communication (see above) 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: openings (how participants initially frame the consultation); the use of questions (eg, 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 data 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 (see above) we will compare and contrast across vignettes to examine similarities and differences in 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 (ie, the key components of Collaborative Deliberation [37]). Finally we will develop 3-5 draft decision making scenarios, emerging from identification of patterns in our emerging analysis about how decision making variably unfolds amongst different groups, in different settings and for different kinds of surgery; as well as the extent to which this might be regarded as 'shared'.

We will use thematic and comparative analysis [47] to analyse focus group data, generating a detailed understanding of the choices that patients, families/carers and clinicians make about surgery, and the factors that shape decision making. We will revise 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 (or no surgery). Finally we will synthesise analyses across our datasets, seeking to extend current theory on decision making for high-risk patients offered surgery (Table 1).

Patient and public involvement

We are committed to patient and public involvement in all stages of the research. Patients with lived experience of major surgery are included in the OSIRIS programme leadership and steering committee. A patient panel has already been established, providing patients with the space to discuss the research, and feed directly into the main steering committee. Patients will be invited to participate in workshops early in the programme to refine our research design, guide the team on how best to approach sensitive topics with patients, and help to refine research tools (eg, topic guides). Later in the OSIRIS programme these patient networks will help to co-design a decision support intervention. Patient co-applicants will act as co-authors for scientific and lay reports.

ETHICS AND DISSEMINATION

The research has received ethical approval from South Central Oxford C Research Ethics Committee (19/SC/0043). At the time of writing we have recruited all three sites and gained local governance approval.

An important ethical issue relates to the involvement of patients (and by extension family/carers) at a time when they might be feeling emotionally and physically vulnerable and needing to make potentially life-changing decisions. We have sought to address this by ensuring that recruitment/consent is as straightforward as possible, framing questions about care and experiences of surgery sensitively, and inviting patients (should they wish) to involve family members or other carers in interviews. Working closely with clinical teams, we will be sensitive to the different clinical pathways and the ways in which information and diagnoses are shared with patients, and have planned an observation period with each site in phase 1 to appreciate the referral and decision making process about major surgery before recruiting patients.

We plan dissemination within and outside of the OSIRIS programme (Table 2). For the former we will produce 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 of a decision support intervention to be tested in a clinical trial. For the latter, we will produce research publications and presentations for academics, including a refined theory of shared decision making relevant to high-risk patients in the context of surgery. For service providers, policymakers and regulators, we propose succinct and accessible summaries of key findings including summaries of decision making scenarios and provisional operational guidance. For patients and families/carers, we will produce a leaflet and web download summarising findings and setting out what to expect when making a decision about major surgery.

TABLE 2 ABOUT HERE

Availability of video data holds potential for further research and training about shared decision making (Table 2). In future we plan to work with colleagues in the OSIRIS programme and more widely to provide rich and detailed accounts of shared decision making in practice, and inform practice.

Author contributions:

SS conceptualised the study and wrote the first draft of the paper. GH and TS contributed to study design and will be collecting and analysing data across the study. JD, JE, EA and ME have contributed to understanding surgical pathways, developing decision making maps and approaches to recruitment. RA has contributed to theoretical approach, particularly on decision making. RP and JP are co-directors of the OSIRIS programme, of which this study is part. LE is lay chair of the OSIRIS shadow steering group and, as such, has fed into the design and conduct of the study. All authors had input to revisions of the paper and approved the final manuscript.

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Competing interests statement:

We have read and understood the BMJ Group policy on declaration of interests and declare the following interests: SES, GH, TS, JP, EA, JD, ME, JE, LE declare no interests. RP has received research grants and/or honoraria from Edwards Lifesciences, Intersurgical, BBraun and GlaxoSmithkline.

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Table 1: Overview of data structure and planned analysis

Data source	Data collected	First order interpretations	Higher-order interpretations
Case studies of decision making for surgery (Jun-19 to Feb-20)	• Video-recordings of 15 consultations across three different surgical areas • Researcher field notes, including clinical pathways	• Key exchanges shaping decision making about surgery between clinicians, patients (and potentially carers/family members) • Unfolding interaction, and use of decision making aids/tools • Clinic workflows, 'decision points' for surgery and key interdependencies	• How patients, clinicians and carers relate; and how/when they come together to discuss – and make decisions about – surgery • 'Scripts' held by patients/clinicians about how they should behave and interact • When a meaningful decision about surgery is made, by whom and how • Organisational and clinic context to decision making
Pre-operative narratives about decision making about surgery (Sep-19 to Feb-20)	Follow-up interviews (up to 45) with • the same 15 consulting patients and their clinicians and, where relevant, carer/family member • other members of the clinical team (eg, anaesthetists, specialist nurses) involved in shaping decisions about surgery	• Reflections on decisions made about surgery • Perceptions on the decision making process over time, including strategies for communication and sharing information • Experiences of decision making, and expectations going forward • Key organisational and clinic strategies, and how these change over time • How participants felt	• Internal social structures (what actors 'know', how they understand and interpret about surgery, including what 'a decision' about surgery means to actors • 'Scripts' held about decision making and how they change over time, including assumptions about: - capability of users - how people interact - consent - clinical work and routines - how these all interact
Post-hoc reflections on decision making about surgery (Dec-19 to Jun-20)	• Follow-up interviews (up to 45) with the same 15 consulting patients and their clinicians and, where relevant, carer/family member • Focus group interviews with (up to 90) patients/carers and (up to 30) clinicians		

Table 2: Anticipated outputs and impact

	Planned outputs	**Anticipated impact**
Phase 1 Video recording of consultations, plus interviews	15 detailed vignettes of decision making for high risk surgery 3-5 draft decision making scenarios, summarising patient pathways and decision making	Increased understanding (within and beyond OSIRIS) of the process of decision making. Identification of the long-term outcomes that matter most to patients contemplating major surgery
Phase 2 Focus groups with patients, carers and clinicians	Typology of decision making scenarios Exemplar vignettes and videos (with consent) providing insights into decision making for high risk surgery Research publications and presentations, plus accessible summaries of key findings Leaflet and web download for patients and families.	Inform co-design, with patients and doctors, of a decision support intervention to be tested in a clinical trial Refined theory of shared decision making relevant to high-risk surgical patients Improved guidance for clinicians, patients and providers Increased understanding of what to expect when making a decision about major surgery.

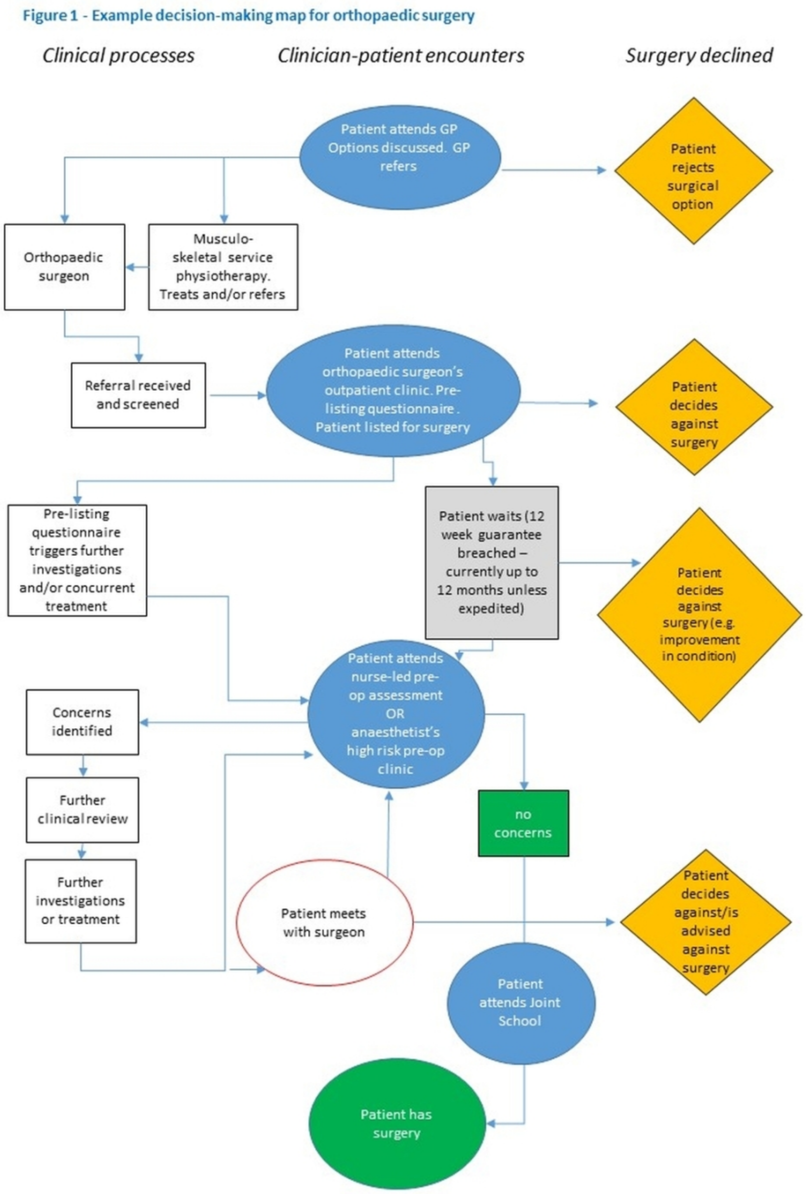

Figure 1: Example decision-making map for orthopaedic surgery

90x129mm (300 x 300 DPI)

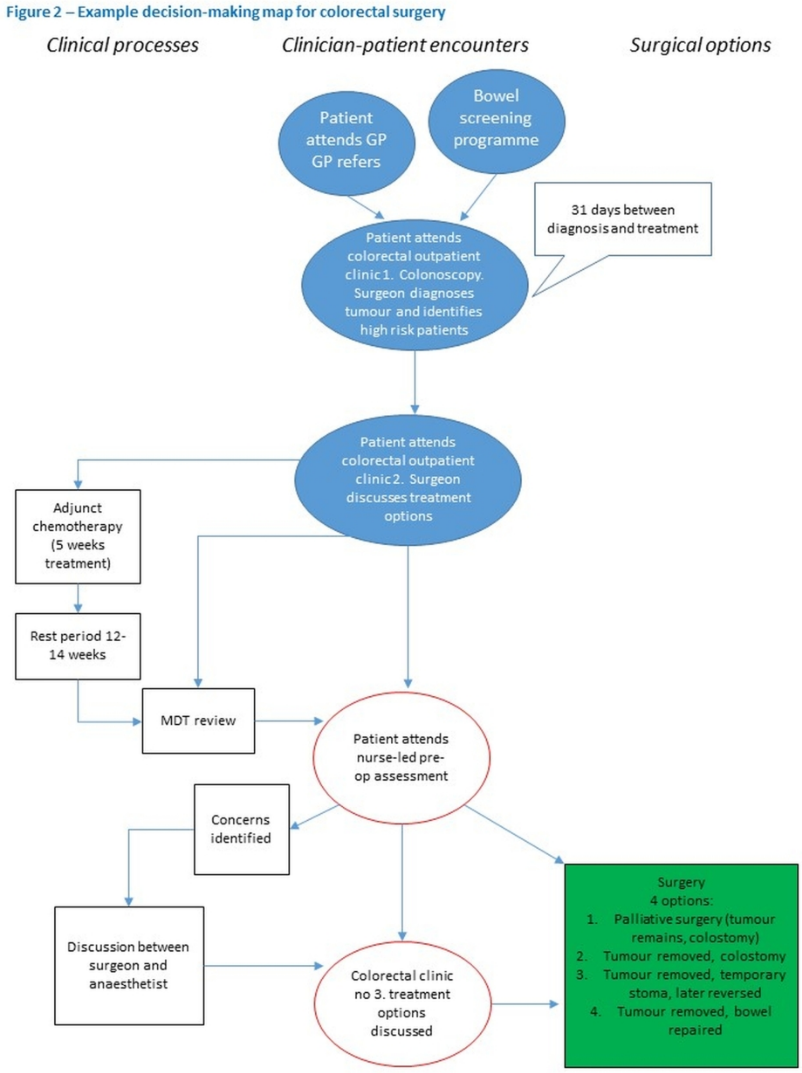

Figure 2: Example decision-making map for colorectal surgery

190x275mm (300 x 300 DPI)

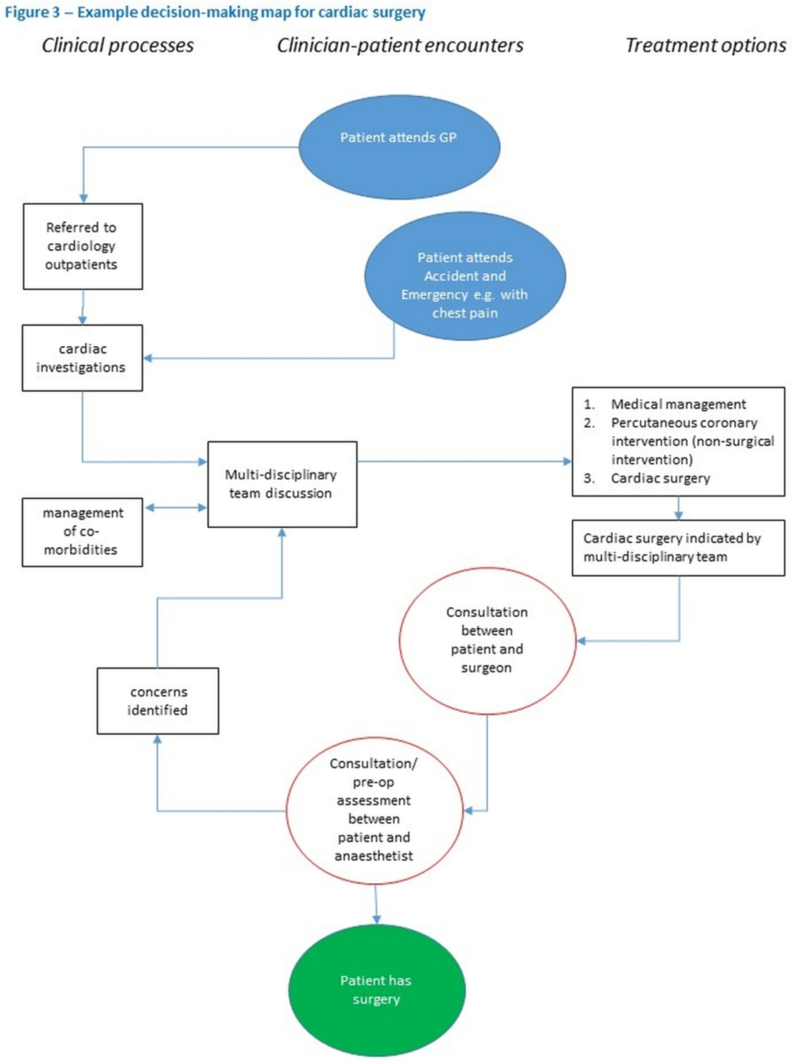

Figure 3: Example decision-making map for cardiac surgery

190x275mm (300 x 300 DPI)

OSIRIS

Queen Mary
University of London

OSIRIS

Programme group list

3rd February 2020

Important note: ‘bartshealth.nhs.uk’ are liable to change to ‘nhs.net’ email addresses in the near future. Update these when possible, as peoples emails might change.

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Project 1: Phase 1: Interviews and video recordings of shared decision making encounters between doctors and patients considering major surgery, & Phase 2: Qualitative focus group discussions with patients and doctors after surgery:

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<u>Project 1.3: Comparison of patient and doctor decision making frameworks</u>

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<u>Project 1.4: Discrete choice surgical decision making experiments</u>

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Project 2.1: Long-term surgical outcomes in the UK population

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Project 2.2: Burden of primary and secondary care for high-risk patients before and after major

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Project 2.3: Collation of quality of life dataset

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Project 3.1: Modelling outcomes for high-risk patients contemplating major surgery

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Project 3.2: Co-design of the decision support intervention and implementation planning

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Project 4.1: Testing the feasibility of the decision support intervention

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Project 4.2: Cluster randomised trial

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Project 4.3: Mixed method process evaluation of the OSIRIS cluster trial

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Project 4.4: Health economic analyses

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Standards for Reporting Qualitative Research (SRQR)

O'Brien B.C., Harris, I.B., Beckman, T.J., Reed, D.A., & Cook, D.A. (2014). Standards for reporting qualitative research: a synthesis of recommendations. *Academic Medicine, 89(9)*, 1245-1251.

No. Topic	**Item**	**Page/Line**
Title and abstract		
S1 Title	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	Page 1
S2 Abstract	Summary of key elements of the study using the abstract format of the intended publication; typically includes objective, methods, results, and conclusions	Page 3
Introduction		
S3 Problem formulation	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	Pps 5-7 Page 9
S4 Purpose or research question	Purpose of the study and specific objectives or questions	Page 8
Methods		
S5 Qualitative approach and research paradigm	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., positivist, constructivist/interpretivist) is also recommended	Pps 8-9
S6 Researcher characteristics and reflexivity	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, or transferability	Page 8
S7 Context	Setting/site and salient contextual factors; rationale[a]	Page 9-10
S8 Sampling strategy	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale[a]	Pps 10-12, Table 1, p21
S9 Ethical issues pertaining to human subjects	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	Page 15
S10 Data collection methods	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale[a]	Pps 10-12
S11 Data collection instruments and technologies	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Pps 11-12
S12 Units of study	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	Table 1, p21

S13 Data processing	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/deidentification of excerpts	Page 13 Table 2, p22
S14 Data analysis	Process by which inferences, themes, etc., were identified and developed, including researchers involved in data analysis; usually references a specific paradigm or approach; rationale[a]	Pps 12-14
S15 Techniques to enhance trustworthiness	Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale[a]	Page 12 Table 2, p22
Results/Findings		
S16 Synthesis and interpretation	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	N/a – protocol paper
S17 Links to empirical data	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	N/a protocol paper
Discussion		
S18 Integration with prior work, implications, transferability, and contribution(s) to the field	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	N/a – protocol paper
S19 Limitations	Trustworthiness and limitations of findings	N/a – protocol paper
Other		
S20 Conflicts of interest	Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	Page 17
S21 Funding	Sources of funding and other support; role of funders in data collection, interpretation, and reporting	Page 17

[a] The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

BMJ Open

Understanding decision making about major surgery: protocol for a qualitative study of shared decision making by high-risk patients and their clinical teams

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Protocol paper for BMJ Open

Understanding decision making about major surgery: protocol for a qualitative study of shared decision making by high-risk patients and their clinical teams

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ABSTRACT (299/300)

Introduction

Surgical treatments are being offered to more patients than ever before, and increasingly to high-risk patients (typically multi-morbid and over 75). Shared decision making is seen as essential practice. However, little is currently known about what ‘good’ shared decision making involves nor how it applies in the context of surgery for high-risk patients (typically older patients with multi-morbidity). This new study aims to identify how high-risk patients, their families and clinical teams negotiate decision making for major surgery.

Methods and analysis

Focusing on major joint replacement, colo-rectal and cardiac surgery, we use qualitative methods to explore how patients, their families and clinicians negotiate decision making (including interactional, communicative and informational aspects and the extent to which these are perceived as shared) and reflect back on the decisions they made. Phase 1 involves video-recording 15 decision making encounters about major surgery between patients, their carers/families and clinicians; followed by up to 90 interviews (with the same patient, carer and clinician participants) immediately after a decision has been made and again 3-6 months later. Phase 2 involves focus groups with a wider group of (up to 90) patients and (up to 30) clinicians to test out emerging findings and inform development of shared decision making scenarios (3-5 summary descriptions of how decisions are made).

Ethics and dissemination

The study forms the first part in a six-year programme of research, *Optimising Shared decision-makIng for high RIsk Surgery* (OSIRIS). Ethical challenges around involving patients at a challenging time in their lives will be overseen by the programme steering committee, which includes strong patient representation and a lay chair. In addition to academic outputs, we will produce a typology of decision making scenarios for major surgery to feed back to patients, professionals and service providers and inform subsequent work in the OSIRIS programme.

Key words: shared decision making, distributed decision making, high risk, adult surgery, communication, qualitative research,

ARTICLE SUMMARY

Strengths and limitations of this study

- New study focused on decision making about major surgery with high-risk patients.
- Novel qualitative design, combining video-recording of decision making encounters, with individual and group interviews.
- Guided by theory, which recognises that decisions about surgery rarely occur at neat ‘decision points’, involve various stages of deliberation, and are shaped by interaction with many (clinical and non-clinical) individuals.
- Informs a programme of work, *Optimising Shared decision-makIng for high RIsk Surgery*, including development of a decision support intervention to improve shared decision making about elective major surgery.

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INTRODUCTION

Shared decision making aims to bring patient values and preferences together with clinician expertise to determine the best care package for the individual concerned. It is not new, building on influential work published since the 1980s (eg, [1-3]). The recent prominence given to shared decision making has accompanied a broader shift towards 'patient-centred care', along with a rise in patient advocacy and increased involvement in resource allocation [4-9]. In the UK, following a landmark legal case [10], standards in respect of the consent process have shifted away from what a body of professionals deem relevant (paternalism) to what a reasonable patient would want or need to know (shared decision making) [11-13].

In surgery, shared decision making is espoused as an essential practice on the basis that it can improve patient satisfaction, moderate use of surgery and reduce costs. It is increasingly offered to older patients who are often (but not always) at higher risk of poor postoperative outcomes. Around 1.5 million major surgical procedures are now performed each year in the UK [14], with 250,000 at high risk of post-operative complications [15]. Even when surgery and anaesthesia are straightforward, one in three high-risk patients develops serious medical complications in the days following surgery [16]. These complications delay recovery, with prolonged hospital stays and a decline in functional independence once patients return home. Critically, many high-risk patients never recover from these adverse effects, suffering significant reductions in long-term quality of life and survival [16, 17]. For some, surgery is not the successful treatment they hoped for, with feelings of guilt or regret commonplace [18]. Doctors recognise the need to help improve decision making for this patient group but often feel ill-equipped to do so [19], with surgeons and anaesthetists currently lacking the expertise to make informed judgements about the risks such patients face. The problem is becoming more frequent as more patients living with severe chronic disease are offered surgical treatments. In sum, many people are having high-risk surgery (ie, major surgery with high-risk patients) and are sometimes regretting doing so, with this problem likely to increase.

Shared decision making is perceived as a potential means of addressing this but the impact of shared decision making is currently unclear. Three systematic reviews [20-22] have shown that patients and clinicians generally value it and that it has potential to both improve the quality of decisions (largely via improved information sharing and increased knowledge [21]), and lessen conflict in decision making about preference-sensitive surgery (ie, where there is no one best available treatment). Overall reviews suggest that it is the quality of the decision making process, over the decision itself, that is key to improving outcomes. However, studies have tended to focus on a small number of clinical areas (eg, breast cancer, osteoarthritis); orient to decision making between the patient and physician alone; and assess outcomes allied to decision making rather than the process or experience *per se* (eg, of the 24 studies identified by Boss et al [21], 17 measured outcomes on the effectiveness of the decision aid without directly assessing doctor-patient interactions). Few studies have linked surgical outcomes and decision making processes, considered potentially relevant demographic characteristics (eg, age, socioeconomic status, ethnicity), or conducted follow up to consider what decisions about surgery mean in the context of peoples' lives. Recently, some authors have called for a more multi-faceted approach that further considers organisational and system-level, as well as social and temporal aspects, of shared decision making including: relevant guidelines, workflows across the clinical team (eg, involving anesthetists), the extended care pathway (eg, from pre-operative assessment through to postoperative de/prescribing), and the influence of families [4, 23-26].

Interactions between clinicians and patients prior to making a decision about surgery are important (eg, we know that good communication is associated with increased professional and patient satisfaction [27]), but rarely the focus of research. To date there has been limited research on communication between clinicians and patients in the context of shared decision making for surgery. What little there is has shown that communication practices often inadequately support preoperative shared decision making about surgery. Most (but not all) patients prefer to share in decision making but do not always have the chance to do so [8]. Surgeons rarely employ a fully collaborative decision-making process [28, 29], instead disclosing procedural risks and helping patients make choices by relying on standard practices (eg, informed consent) or communication practices such as the 'fix-it' model, describing the patient's disease as an isolated abnormality linked directly with a surgical solution [30].

Of the literature on shared decision making for surgery, only a small number of North American studies focus on high-risk patients [31-34]. 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 [31, 33]. Follow up interviews 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, over individual and preference-sensitive choice.

One study underscored the challenge for patients of incorporating their values and beliefs into shared decision making for high-risk surgery [32]. 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. Surgeons discussed the challenge of 'surgical momentum', ie, 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 potential risk of severe post-operative complications. The language used, particularly the focus on 'fixing' a problem, was found to close down discussions about the value of surgery and how it may fit with patients' overall values and goals [35]. To our knowledge, there are no published studies focused specifically on clinicians' perceptions of decision making for high-risk surgery, and why it may (or may not) be 'shared'. Research on the information needs of patients found a mis-match between what surgeons discussed in consultations and what patients wanted to know [27]. In particular, patients wanted less technical information and more discussion of long-term effects. This resonates with recent legal judgments emphasising that, "*The doctor's duty is not fulfilled by bombarding the patient with technical information*" [10].

In sum, the literature on shared decision making for surgery is in its infancy, tends to focus on information giving , and employs quantitative assessments of the outcomes of decision making over qualitative understanding of processes and experiences. Studies relevant to surgery for high-risk patients are limited in number and suggest that high-risk patients often do not realise that they have a choice about surgery and have mismatched expectations about what may happen after surgery.

Research that enables understanding of shared decision making for high-risk patients is therefore timely and necessary. In this new study we seek to identify perspectives on, and communicative features of, the shared decision making process for high-risk patients who are offered surgery asking:

1. How do patients, their families and clinical teams approach and negotiate 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?

METHODS AND ANALYSIS

Origins, design and governance of the study

The study forms part of a six-year programme of work, *Optimising Shared decision-makIng for high RIsk Surgery* (OSIRIS, https://osiris-programme.org/) funded by the National Institute for Health Research in England. OSIRIS comprises four interlinked projects leading to the development and testing of a decision support intervention, to improve shared decision making about elective major surgery between doctors and patients at high-risk of adverse long-term outcomes. The OSIRIS programme has significant governance oversight including a management group (see supplementary file), a shadow steering committee, with patient and public membership and a lay chair, which meets six-monthly and feeds into the main programme steering committee. An OSIRIS collaborators group includes stakeholders from NHS, professional bodies, academia, policy and patients.

In this study we use qualitative methods to explore in-depth how patients, their families and clinicians negotiate decision making and reflect back on the decisions they made. The study involves a multidisciplinary team with representation from medicine/nursing, sociology, social policy and bioethics. Phase 1 involves video-recording decision making encounters about major surgery, between patients, their carers/families and clinicians to understand the content and flow of decision making about surgery; followed by interviews (immediately after and 3-6 months later). Phase 2 involves focus groups with a wider group of patients and clinicians to test out emerging findings.

Theoretical and conceptual framework

Our research is framed by practice theory, recognising that decisions about surgery are distributed over time and space (ie, they rarely occur at single ‘decision points’) [36], involve varied stages of (potentially collaborative) deliberation [37], and are shaped by interaction with a range of actors and artefacts [38]. This guided us to focus on decision-making-in-action, seeing the process of decision making and the activities and events allied to it (eg, consultations, clinics, letters, family discussions), as something that happens through an on-going process of communication and collaborative articulation of what major surgery might mean for those involved. We draw on ethnography of communication (an approach that aims to produce systematic and richly contextualised descriptions of communicative genres, events and practices [39]) to understand how meanings about surgery are constructed, the influence of moral and ethical dimensions and how communication and interaction unfold.

Finally, given that healthcare is heavily institutionalised, and behaviour often ritualised (ie, we know, and play out, the roles expected of us as clinicians, patients and so on), we draw on the notion of ‘organisational routines’ [40], defined as ‘recognizable, repetitive patterns of interdependent action carried out by multiple actors’ [41]. Routines are how organisational life is patterned, hence studying these can provide key insights into how shared decision making may (or may not) be integrated in to the three surgical areas of interest.

Sampling and data collection

Surgical areas

The OSIRIS programme focuses on three different (elective) surgical procedures: major joint, intra-abdominal and cardiac surgery. We plan to examine how the context of the differing conditions influences the decisions that patients and doctors make, how these decisions are made in the light of different ways of organising treatments and resources, and the multiple points at which patients and clinicians come together to consider and make decisions about surgery.

Major joint replacement for osteoarthritis is a symptomatic treatment which will not prolong life but can improve quality of life for those with significant pain and reduced mobility. It is likely to be considered and discussed within primary care, as well as specialist musculoskeletal services, as part of a potentially long-term process of considering surgery with an orthopaedic team. Colorectal surgery for bowel cancer is essential and requires relatively rapid decisions about treatment. Following diagnosis patients, relatives and clinicians are faced with choices about the nature of the procedure (including a potential for palliative surgery) and the need for adjunct radio- or chemotherapy. Coronary artery bypass grafting may prolong life at a population level, but for the individual patient this benefit is not guaranteed, especially for frailer or multi-morbid patients. Increasingly, less invasive, percutaneous coronary interventions have created a range of options for patients with ischaemic heart disease. There are however a range of short and long term risks associated with both choices (eg, percutaneous options offer fewer short term risks to patients but have inferior long term outcomes compared to surgery for more severe ischaemic heart disease).

Preliminary work with clinicians to map out the decision making processes across conditions/sites (Figures 1-3) has highlighted variation in how services are organised (eg, variation in the anaesthetic pre-operative assessment offered) and the distributed nature of decision making (ie, taking place over time, in multiple settings, involving multiple discussions with, potentially, many people [36, 37]). This means that the process of decision making about elective surgery is likely to be different across the three surgical specialties of interest (see Figures 1-3) and across settings. Our focus on high-risk patients due to age, chronic comorbidity, or frailty means that decision making is also likely to be influenced by past experiences (eg, prior surgery) and have a more complex combination of long-term outcomes to consider.

FIGURES 1-3 ABOUT HERE

Phase 1 –video-recording of decision making encounters, plus follow-up interviews

In phase 1 we will purposively select three NHS hospitals that are undertaking at least two of the three surgical procedures of interest. Working with clinical teams (who will receive basic study information) we will recruit a maximum variation, purposive-sample of 15 high-risk patients aged ≥60 years (to capture a range of high-risk patients, not simply those who are older) with an age-adjusted Charlson co-morbidity score [42] of ≥4, who are contemplating elective surgery (anticipating five from each surgical group including, where feasible, one patient who has declined surgery), with adequate variation in age, gender and social circumstances and including travel time to the hospital.

We will video-record up to 15 consultations that involve decision making about major surgery for those who agree to participate, seeking to capture verbal and non-verbal interaction, and enabling detailed insight into the decision making process in terms of the content of consultations (eg, information exchanged) and the interaction (eg, between clinician and patient). This will involve the researcher placing one or two video cameras in the consultation room and recording the consultation. Where the patient agrees, the researcher will remain in the room. This is usual in qualitative studies, with the researcher's presence enabling appreciation of each consultation as it unfolds in real time and the video recording facilitating detailed analysis of interaction that is not feasible through observation alone).

Pathways for major surgery vary (Figures 1-3). We will not know how decision making processes unfold – and hence exactly which consultation we will record - until we have gained access to each site and clinical team. For some participants the consultation that we record will be with their surgeon and will follow a series of contacts with the health service. For others, the consultation we record may be with another member of the clinical team (eg, anaesthetist) who has had a critical role in the decision-making process. Where decision making clearly spans several encounters we will endeavour to record (or at the very least observe) more than one consultation.

We will subsequently conduct narrative interviews with patients and clinicians (and carers where relevant) at two points (Table 1): as soon as practically possible after their consultation, and 3-6 months later. We will adopt a narrative approach [43], encouraging interviewees to recount the details of their experiences (eg, their condition, decision making about surgery). Interviews will last up to one hour, be face-to-face (wherever possible, by phone when not) and be audio-recorded. Reimbursement will be offered for basic expenses (e.g. car parking) incurred.

Interview data will enable a detailed understanding of the relevant condition, how it has unfolded, experiences of decision making and the context within which decisions were made, and thoughts and expectations about surgery (if this is the option chosen); as well as experiences since having or declining surgery, and reflections back on the decision made.

TABLE 1 ABOUT HERE

Phase 2 – focus groups

Focus groups will allow us to test out emerging findings with a broader group of participants. We will purposively select up to 3 NHS hospitals (at least one of which will be different from phase 1) undertaking major joint surgery, intra-abdominal surgery and cardiac surgery, using the same criteria as phase 1. We will recruit a purposive maximum variation sample of up to 90 high-risk patients (up to 9 focus groups), excluding any patients recruited in phase 1, 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. Where patients with severe complications are unable to participate, we will invite them to nominate someone who can represent their views and/or have a carer attend with them.

Working with Royal Colleges, we will also recruit a purposive sample of up to 30 surgeons, doctors, anaesthetists and clinical nurse specialists (up to 3 focus groups) caring for patients having these types of surgery, ensuring a mix of age, gender, clinical position and experience, role and location. We will hold at least one focus group involving a mix of professional groups.

Focus groups with patients and carers will be held at or close by (eg, local community centre) to participating sites, involve 8-10 participants in each. Those involving clinicians will be held at central locations (eg, one of the Royal Colleges). The same topic guide will be used across groups, guiding participants to introduce themselves and say what their experience is of making decisions (or supporting others) about major surgery. We plan to ask patients, carers and clinicians to share thoughts on the draft scenarios (i.e. 3-5 summary descriptions of decision making) developed from phase 1,. Focus groups will be audio-recorded and transcribed.

Analysis and synthesis

Table 1 summarises different data sources and how these will be analysed and synthesised to provide detailed decision making scenarios and inform the wider OSIRIS programme.

In phase 1 we will develop summaries for each case (ie, patient, family/carers and clinicians), detailing 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 (including relevant national and international guidelines) 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 or of living with the condition having declined surgery; as well as post-hoc reflections on decision making in light of outcomes following surgery or the decision to decline.

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 the decision making process to examine interactions, judgements and interpretations [44], the bodily conduct of participants, and the ways in which objects (eg, consent forms) come to gain significance at particular moments [45]. Recordings will be transcribed (eg, using ELAN, a specialist programme used by linguists) to allow us to capture granular (verbal and non-verbal) detail of interaction, repeatedly view and tag data digitally (ensuring immersion in the full video and audio at the level of a sentence, comment or other linguistic feature, which is often key to analysis [45]), and produce a textual transcript meaning that we can engage indirectly with the data via transcripts of each decision making encounter.

We will then examine video data in depth to: identify key features of shared decision making encounters, examine the way ‘communicative competence’ [46] shapes shared decision making (ie, how participants deploy their tacit understanding of a particular communicative event, and competencies needed to maximise the benefits of the encounter), and attend to the contextual factors (eg, presence of carers, preceding exchange of information) that shape decision making. Analysis of interaction will be informed by ethnography of communication (see above) 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: openings (how participants initially frame the consultation); the use of questions (eg, 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 data 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 (see above) we will compare and contrast across vignettes to examine similarities and differences in 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 (ie, the key components of Collaborative Deliberation [37]). Finally we will develop 3-5 draft decision making scenarios, emerging from identification of patterns in our emerging analysis about how decision making variably unfolds amongst different groups, in different settings and for different kinds of surgery; as well as the extent to which this might be regarded as 'shared'.

We will use thematic and comparative analysis [47] to analyse focus group data, generating a detailed understanding of the choices that patients, families/carers and clinicians make about surgery, and the factors that shape decision making. We will revise 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 (or no surgery). Finally we will synthesise analyses across our datasets, seeking to extend current theory on decision making for high-risk patients offered surgery (Table 1).

Patient and public involvement

We are committed to patient and public involvement in all stages of the research. Patients with lived experience of major surgery are included in the OSIRIS programme leadership and steering committee. A patient panel has already been established, providing patients with the space to discuss the research, and feed directly into the main steering committee. Patients will be invited to participate in workshops early in the programme to refine our research design, guide the team on how best to approach sensitive topics with patients, and help to refine research tools (eg, topic guides). Later in the OSIRIS programme these patient networks will help to co-design a decision support intervention. Patient co-applicants will act as co-authors for scientific and lay reports.

ETHICS AND DISSEMINATION

The research has received ethical approval from South Central Oxford C Research Ethics Committee (19/SC/0043). At the time of writing we have recruited all three sites and gained local governance approval.

An important ethical issue relates to the involvement of patients (and by extension family/carers) at a time when they might be feeling emotionally and physically vulnerable and needing to make potentially life-changing decisions. We have sought to address this by ensuring that recruitment/consent is as straightforward as possible, framing questions about care and experiences of surgery sensitively, and inviting patients (should they wish) to involve family members or other carers in interviews. Working closely with clinical teams, we will be sensitive to the different clinical pathways and the ways in which information and diagnoses are shared with patients, and have planned an observation period with each site in phase 1 to appreciate the referral and decision making process about major surgery before recruiting patients.

We plan dissemination within and outside of the OSIRIS programme (Table 2). For the former we will produce 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 of a decision support intervention to be tested in a clinical trial. For the latter, we will produce research publications and presentations for academics, including a refined theory of shared decision making relevant to high-risk patients in the context of surgery. For service providers, policymakers and regulators, we propose succinct and accessible summaries of key findings including summaries of decision making scenarios and provisional operational guidance. For patients and families/carers, we will produce a leaflet and web download summarising findings and setting out what to expect when making a decision about major surgery.

TABLE 2 ABOUT HERE

Availability of video data holds potential for further research and training about shared decision making (Table 2). In future we plan to work with colleagues in the OSIRIS programme and more widely to provide rich and detailed accounts of shared decision making in practice, and inform practice.

Author contributions:

SS conceptualised the study and wrote the first draft of the paper. GH and TS contributed to study design and will be collecting and analysing data across the study. JD, JE, EA and ME have contributed to understanding surgical pathways, developing decision making maps (Figures 1-3) and approaches to recruitment into the study. RA has contributed to theoretical approach, particularly on decision making. RP and JP are co-directors of the OSIRIS programme, of which this study is part and which the OSIRIS Programme Group oversees. LE is lay chair of the OSIRIS shadow steering group. Both the OSIRIS Programme Group and shadow steering group have fed into the design and conduct of the study. All authors had input to revisions of the paper and approved the final manuscript.

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Competing interests statement:

We have read and understood the BMJ Group policy on declaration of interests and declare the following interests: SES, GH, TS, JP, EA, JD, ME, JE, LE declare no interests. RP has received research grants and/or honoraria from Edwards Lifesciences, Intersurgical, BBraun and GlaxoSmithkline.

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Table 1: Overview of data structure and planned analysis

Data source	Data collected	First order interpretations	Higher-order interpretations
Case studies of decision making for surgery (Jun-19 to Feb-20)	• Video-recordings of 15 consultations across three different surgical areas • Researcher field notes, including clinical pathways	• Key exchanges shaping decision making about surgery between clinicians, patients (and potentially carers/family members) • Unfolding interaction, and use of decision making aids/tools • Clinic workflows, 'decision points' for surgery and key interdependencies	• How patients, clinicians and carers relate; and how/when they come together to discuss – and make decisions about – surgery • 'Scripts' held by patients/clinicians about how they should behave and interact • When a meaningful decision about surgery is made, by whom and how • Organisational and clinic context to decision making
Pre-operative narratives about decision making about surgery (Sep-19 to Feb-20)	Follow-up interviews (up to 45) with • the same 15 consulting patients and their clinicians and, where relevant, carer/family member • other members of the clinical team (eg, anaesthetists, specialist nurses) involved in shaping decisions about surgery	• Reflections on decisions made about surgery • Perceptions on the decision making process over time, including strategies for communication and sharing information • Experiences of decision making, and expectations going forward • Key organisational and clinic strategies, and how these change over time • How participants felt	• Internal social structures (what actors 'know', how they understand and interpret about surgery, including what 'a decision' about surgery means to actors • 'Scripts' held about decision making and how they change over time, including assumptions about: - capability of users - how people interact - consent - clinical work and routines - how these all interact
Post-hoc reflections on decision making about surgery (Dec-19 to Jun-20)	• Follow-up interviews (up to 45) with the same 15 consulting patients and their clinicians and, where relevant, carer/family member • Focus group interviews with (up to 90) patients/carers and (up to 30) clinicians		

Table 2: Anticipated outputs and impact

	Planned outputs	**Anticipated impact**
Phase 1 Video recording of consultations, plus interviews	15 detailed vignettes of decision making for high risk surgery 3-5 draft decision making scenarios, summarising patient pathways and decision making	Increased understanding (within and beyond OSIRIS) of the process of decision making. Identification of the long-term outcomes that matter most to patients contemplating major surgery
Phase 2 Focus groups with patients, carers and clinicians	Typology of decision making scenarios Exemplar vignettes and videos (with consent) providing insights into decision making for high risk surgery Research publications and presentations, plus accessible summaries of key findings Leaflet and web download for patients and families.	Inform co-design, with patients and doctors, of a decision support intervention to be tested in a clinical trial Refined theory of shared decision making relevant to high-risk surgical patients Improved guidance for clinicians, patients and providers Increased understanding of what to expect when making a decision about major surgery.

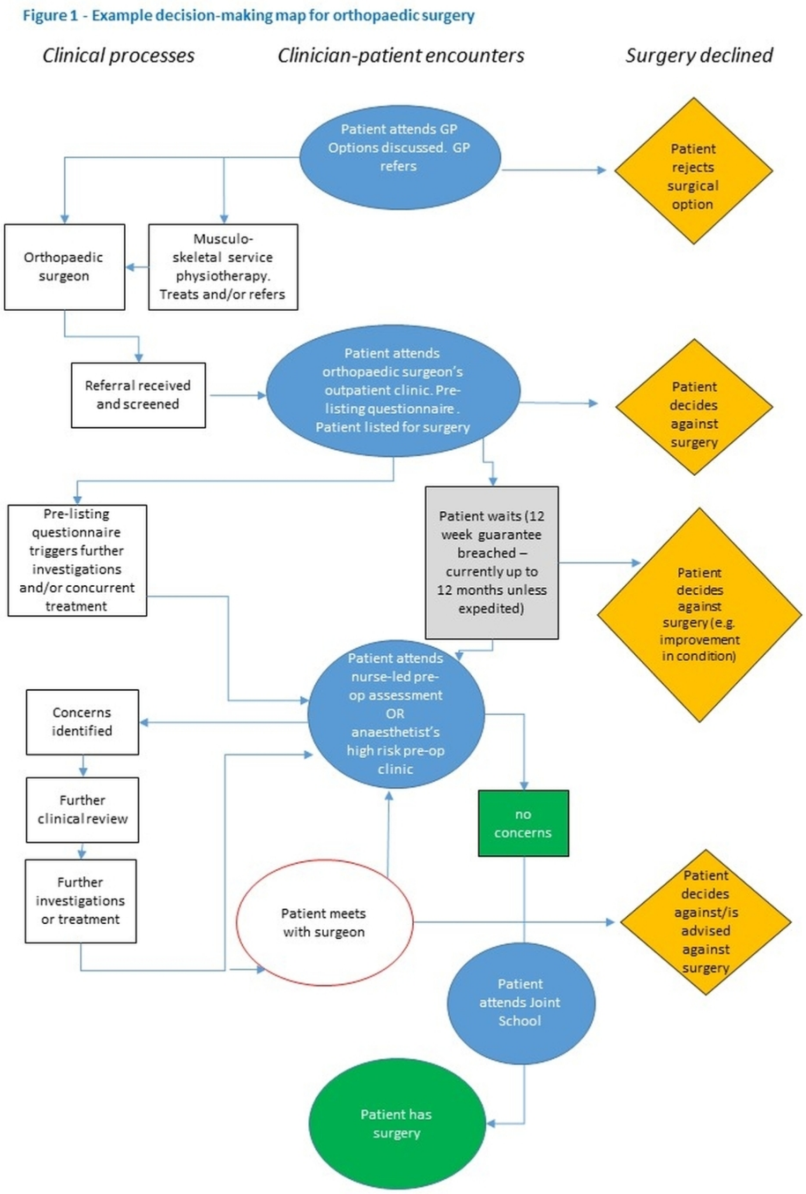

Figure 1: Example decision-making map for orthopaedic surgery

90x129mm (300 x 300 DPI)

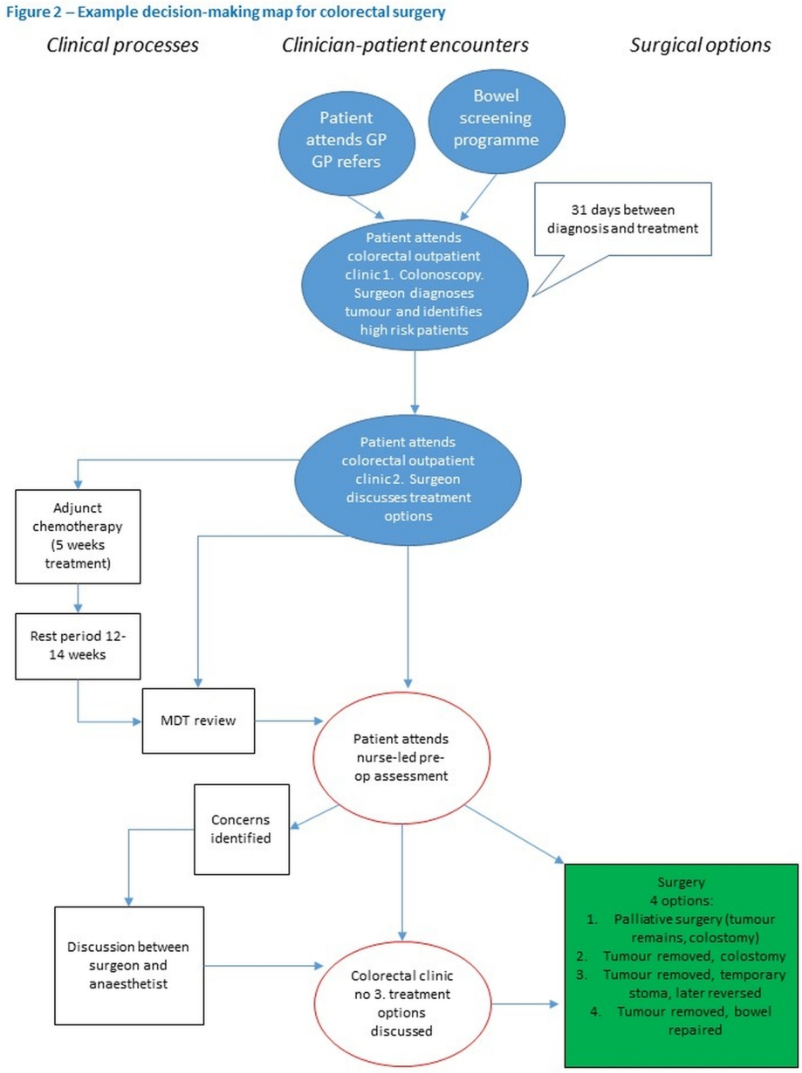

Figure 2: Example decision-making map for colorectal surgery

190x275mm (300 x 300 DPI)

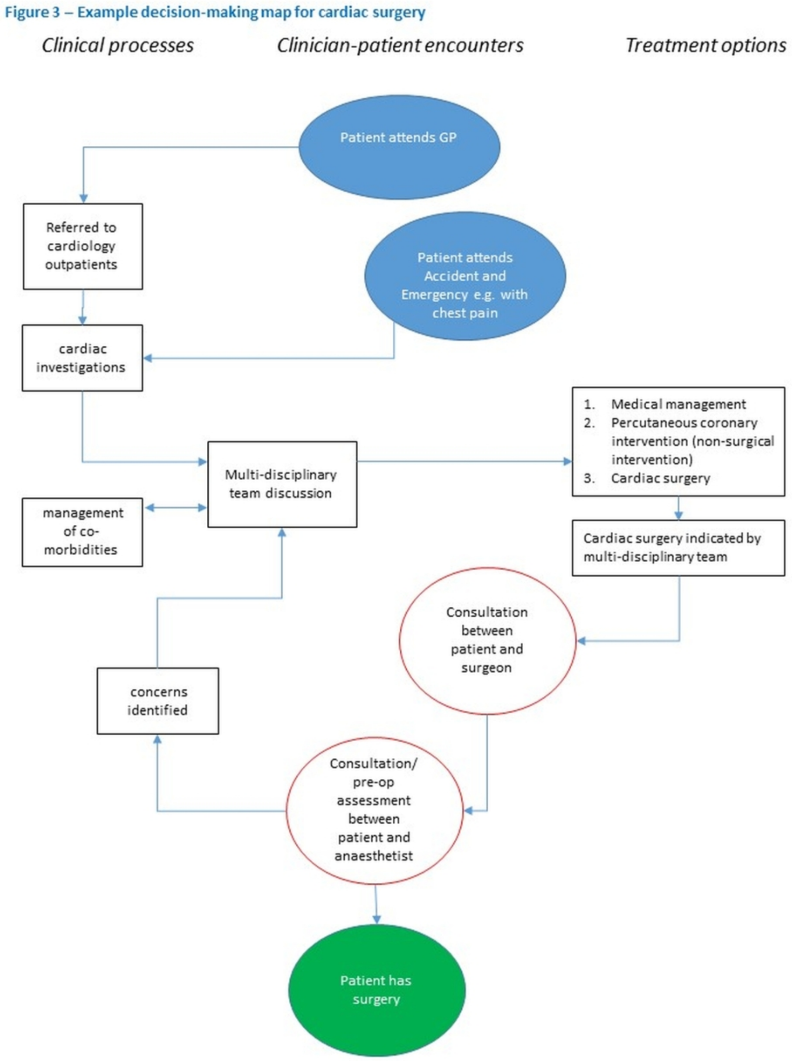

Figure 3: Example decision-making map for cardiac surgery

190x275mm (300 x 300 DPI)

OSIRIS

Programme group list

3rd February 2020

Important note: ‘bartshealth.nhs.uk’ are liable to change to ‘nhs.net’ email addresses in the near future. Update these when possible, as peoples emails might change.

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Project 1: Phase 1: Interviews and video recordings of shared decision making encounters between doctors and patients considering major surgery, & Phase 2: Qualitative focus group discussions with patients and doctors after surgery:

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Project 1.3: Comparison of patient and doctor decision making frameworks

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Project 1.4: Discrete choice surgical decision making experiments

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Project 2.1: Long-term surgical outcomes in the UK population

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Project 2.2: Burden of primary and secondary care for high-risk patients before and after major

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Project 2.3: Collation of quality of life dataset

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Project 3.1: Modelling outcomes for high-risk patients contemplating major surgery

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Project 3.2: Co-design of the decision support intervention and implementation planning

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Project 4.1: Testing the feasibility of the decision support intervention

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Project 4.2: Cluster randomised trial

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Project 4.3: Mixed method process evaluation of the OSIRIS cluster trial

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Standards for Reporting Qualitative Research (SRQR)

O'Brien B.C., Harris, I.B., Beckman, T.J., Reed, D.A., & Cook, D.A. (2014). Standards for reporting qualitative research: a synthesis of recommendations. *Academic Medicine, 89(9)*, 1245-1251.

No. Topic	Item	Page/Line
Title and abstract		
S1 Title	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	Page 1
S2 Abstract	Summary of key elements of the study using the abstract format of the intended publication; typically includes objective, methods, results, and conclusions	Page 3
Introduction		
S3 Problem formulation	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	Pps 5-7 Page 9
S4 Purpose or research question	Purpose of the study and specific objectives or questions	Page 8
Methods		
S5 Qualitative approach and research paradigm	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., positivist, constructivist/interpretivist) is also recommended	Pps 8-9
S6 Researcher characteristics and reflexivity	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, or transferability	Page 8
S7 Context	Setting/site and salient contextual factors; rationale[a]	Page 9-10
S8 Sampling strategy	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale[a]	Pps 10-12, Table 1, p21
S9 Ethical issues pertaining to human subjects	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	Page 15
S10 Data collection methods	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale[a]	Pps 10-12
S11 Data collection instruments and technologies	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Pps 11-12
S12 Units of study	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	Table 1, p21

S13 Data processing	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/deidentification of excerpts	Page 13 Table 2, p22
S14 Data analysis	Process by which inferences, themes, etc., were identified and developed, including researchers involved in data analysis; usually references a specific paradigm or approach; rationale[a]	Pps 12-14
S15 Techniques to enhance trustworthiness	Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale[a]	Page 12 Table 2, p22
Results/Findings		
S16 Synthesis and interpretation	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	N/a – protocol paper
S17 Links to empirical data	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	N/a protocol paper
Discussion		
S18 Integration with prior work, implications, transferability, and contribution(s) to the field	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	N/a – protocol paper
S19 Limitations	Trustworthiness and limitations of findings	N/a – protocol paper
Other		
S20 Conflicts of interest	Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	Page 17
S21 Funding	Sources of funding and other support; role of funders in data collection, interpretation, and reporting	Page 17

[a] The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.