PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Understanding decision making about major surgery: protocol for a qualitative study of shared decision making by high-risk patients and their clinical teams
AUTHORS	Shaw, Sara; Hughes, Gemma; Stephens, Tim; Pearse, Rupert; Prowle, John; Ashcroft, Richard; Avagliano, Ester; Day, James; Edsell, Mark; Edwards, Jennifer; Everest, Leslie

VERSION 1 – REVIEW

REVIEWER	Aanand Naik Baylor College of Medicine
REVIEW RETURNED	10-Sep-2019

GENERAL COMMENTS	Thank you for the opportunity to review this interesting and important study protocol. The integration of shared decision making for older, high-risk adults facing surgery is critically needed. The authors should be applauded for developing a rigorous qualitative design to understand the experiences of decision making for abdominal, orthopedic, and cardiovascular surgery. Overall the background, description of methods, and other aspects of the study protocol are appropriate and will add to our understanding of the study methodology and dissemination of results. I add the following minor comments and suggestions. 1) Add primary care providers and other referring physicians/clinicians to the list of potential subjects for the phase 2 focus groups. 2) A table or other descriptive summary of the study products/findings arising from the analyses of the phase 1 and phase 2 study results would be helpful. There are descriptive text on page 14; however, these are difficult to follow and link together. An additional/alternative method of summarizing or describing these study products would be helpful. 3) A short discussion of how these study products will improve shared decision making would be helpful. In addition, a concluding paragraph describing next steps following the completion of the study would be additive.

REVIEWER	Prof Cameron G Swift King's College London, London UK
REVIEW RETURNED	17-Oct-2019

GENERAL COMMENTS	This paper presents the protocol for the first part of a NIHR (England) funded 6-year Programme addressing the widely recognised need for an evidence-based decision-support intervention to enhance shared decision making between clinicians

	and patients at high risk of adverse outcomes in the context of elective major surgery. A qualitative methodology for this study is incorporated, comprising (1) video recordings of decision-making encounters with follow-up interviews and (2) focus groups to assess emerging findings and enable the typological identification of scenarios for subsequent work in the Programme. The research question (and justification for the study), abstract, study design, methodology and analysis (supported by a useful tabulated summary), ethical procedures, intended outcomes and background literature within the field of enquiry are clearly and coherently presented, together with an outline of the intended (OSIRIS) Programme pathway and its governance. Three categories of elective major surgical intervention have been selected – namely (1) Major joint replacement, (2) Colo-rectal surgery and (3) Cardiac surgery. Useful diagrammatic decision-making maps are provided charting the putative pathways and options envisaged in the decision-making trajectory. The following observations are offered for consideration. (1) Chronological age and the definition of “high risk”. There has been historical over-use of chronological age per se as an unjustifiable pretext (including service cost) for non-intervention in a wide range of both surgical and non-surgical interventions – the resulting denial or delay leading to unacceptable levels of subsequent premature mortality and/or protracted subsequent morbidity and dependence with enormous personal and economic cost. Evidence has increasingly emerged over recent decades that (conversely) excellent outcomes are commonly achievable even in advanced chronological age (other things being equal), given optimal pre- and post-operative management (e.g in response to early colorectal cancer diagnosis triggered by screening programmes). There are similar outcome improvements in coronary bypass surgery. Hip fracture (while not an elective scenario) is one example where the 1994 Charlson comorbidity score (Ref 42 has been at least partly superseded as a decision determinant by organised interdisciplinary assessment (including physicians as well as surgeons and anaesthetists)1, with growing cost-benefit emerging across a wide spectrum of advanced age. This cross-disciplinary approach is also evolving in other categories of surgical intervention. These concerns are in part addressed at some points (e.g.in reference to video recording and the pathway diagrams), but perhaps a push back in emphasis on chronological age per se at some points could help to avoid misunderstanding, particularly in the introduction (P5) (where even the attractiveness of cost-reduction might be seen to threaten revival of the dark days of age-related exclusion!) Having said all this, one wonders if (in today’s demographic distribution) the rather low threshold of 60+ in the purposive sample (P11) risks diluting the relevance of the findings to the contemporary population? Why not start higher?

	(2) Surgical “electiveness” It might be helpful to define a little more carefully in each category the threshold within which surgery is elective or emergency, perhaps especially in relation to cardiac surgery. (3) The place of evidence and evidence-based guidance. Given the increasing availability of national and international guidelines, is it “overly technical” for clinicians to share with patients and/or families aspects of risk-benefit ratio based on accepted evidence as an essential consideration to enable patient preference to be informed? (see Ref 10 P7). It is to be hoped that the analysis of Collaborative Deliberation and the subsequent thematic and comparative analysis of focus group data will give due emphasis and prominence to this component of information exchange. (4) Research group and focus group composition The speciality/subspeciality backgrounds of the OSIRIS Programme Group list are not specified in the Appendix provided. Given the focus on older patients at high risk, the assessment of age and “frailty”, and the points raised above, it would be reassuring if clinical gerontology expertise could be identifiable within the collaboration. The same applies to the intended focus group purposive sample. (5) Strengths and limitations (P4) It would be helpful to know to what extent consenting, recruited clinicians will be aware of the key hypotheses and content of the Programme, and perhaps modify their interaction as a result. In other words, what reassurance might be provided that the ethnographic observations are a genuine reflection of usual practice? Ref. 1. Swift C, Ftouh S, Langford P, Chesser TS, Johanssen A (Dec 2016). Interdisciplinary Management of Hip Fracture - Concise Guidance. Clinical Medicine 16 (6): 541-544

REVIEWER	Dr. Pola Hahlweg University Medical Center Hamburg-Eppendorf, Department of Medical Psychology, Hamburg, Germany
REVIEW RETURNED	04-Jan-2020

GENERAL COMMENTS	Many thanks for the opportunity to review this study protocol. The manuscript addresses the important question of shared decision-making about high-risk surgeries. The manuscript was a pleasure to read. I merely have some minor comments and suggestions to further strengthen the manuscript. General 1.You use the term “decision making scenarios” throughout the manuscript. However, I had a hard time understanding what you mean by it. It was only at the end of the manuscript that I started to understand (i.e. descriptions of how those descriptions were found to be made). Please clarify upon first mention. 2.Please add explanations of all abbreviations (e.g. MDT). Thank you!

	Introduction 3.Page 6, line 42: Please combine all references into one pair of "[…]". 4.Page 7: When reading your summary of prior studies, I was wondering if there are any studies on clinicians' perceptions/attitudes of the decision making process regarding highrisk surgeries and why (or why not) it might happen in a shared manner. In case there are, please add some information on it. 5.Page 8, lines 17-23: a.Could you please add some more specific information about what you are trying to find to your research questions? (E.g. attitudes?, conceptions?, barriers and facilitators?) b.In your research questions you mention "their families" on the same level as patients and clinical teams. However, later on it seems to me that you are mostly interested in the patients' and clinical teams' perspectives. Please clarify. Methods and analysis 6.Page 8, line 55: Are you interested in how they "reflect back on the decisions they made" or on the "decision making process"? Please re-evaluate. 7.Theoretical and conceptual framework: In my opinion your study design would benefit if you were to add a theoretical model of shared decision-making as a basis for your research. This would be a valuable addition to use during data analysis in order to have a "baseline" to compare your findings to. 8.Sampling and data collection: Please add a timeline to this section. 9.Page 10: You switch up the names for the three surgical procedures and the order in which you describe them throughout the manuscript (i.e., joint surgery, intra-abdominal, and cardiac surgery). Please pay attention to keep it consistent. 10.Are you planning to pay attention to differences in structural characteristics for each surgical procedure? 11.Phase 1: Dr. Pola Hahlweg University Medical Center Hamburg-Eppendorf Department of Medical Psychology a. Page 11, lines 24ff: Will it be possible to record more than one consultation regarding one decision to be made (e.g. two consultations in case decision will be deferred; consultations with different health care professionals)? This would be especially valuable since you wrote that decisions often entail several encounters and interactions and prolonged periods of time. b.Page 11, lines 33/34: Why did you decide for the researcher to remain in the room if possible? In my opinion this bears the unnecessary risk of consultations being altered by the presence of the researcher. c.Page 11, lines 50ff: Will the interviews be face-to-face or via telephone? Will participants be compensated? 12.Phase 2: a.Will the hospitals in phase 2 be different to the ones in phase 1? b.Why are you not planning separate focus groups with family members / caregivers? c.Are the focus groups with clinicians be attended jointly by physicians and nurses or will there be separate focus groups for

	different groups of professionals? Please elaborate on why you chose to do it the way you did. 13.Page 14, line 34: Please add a reference for “thematic and comparative analysis”. Figures 14.Please also align the order of the figures to the order within the text (cp. comment 8). 15.Please add legends to your figure explaining abbreviations. 16.Figure 2: Why do you change the wording from “patient rejects” to “patients decides against” in the right column? Also, is it always the patient who makes the decision? 17.Figure 3: This figure seems to have a different flow than the other two. There are several boxes on the left that are starting points in themselves. Also, please explain A&E.

REVIEWER	Isabelle Gaboury Universite de Sherbrooke, Canada
REVIEW RETURNED	08-Jan-2020

GENERAL COMMENTS	Very nicely written proposal. Quite clear for an audience unfamiliar with shared decision making. The rationale for doing the program/study is quite strong. The methods are well designed. I would have one minor suggestion. On page 8, second paragraph, I suggest the authors clearly state what their study would add to the findings of studies 31 and 33 (in this section or somewhere else)

VERSION 1 – AUTHOR RESPONSE

RESPONSE TO REVIEWERS COMMENTS

LITERATURE REVIEW

I was wondering if there are any studies on clinicians’ perceptions/attitudes of the decision making process regarding high-risk surgeries and why (or why not) it might happen in a shared manner. In case there are, please add some information on it.

To our knowledge, there is no published literature on this. We already summarise literature on shared decision making for high risk surgery, revealing how surgeons often regard decisions about surgery as needing to be guided by their expertise and experience, over individual and preference-sensitive choice; and the difficulties in approaching ‘shared decision making’ in the face of surgical momentum. We have now added the following on page 7: “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’.

clearly state what [the] study would add to the findings of studies 31 and 33 (in this section or somewhere else)

Studies 31 and 33 are both qualitative studies, conducted in the US and Canada exploring decision making for high risk surgery. As we say in the paper, they are the most similar in terms of study design and focus. However, they differ in three fundamental ways: (i) the primary data collection method in these studies is interviews or audio recording of pre-operative consultation, whereas our study collects video data of decision making encounters, as well as wider contextual data about the clinic/setting (from interviews and observation); (ii) both studies were conducted in health systems outside of the UK (the focus of our study), and (iii) studies focus on different clinical settings (our focus being on orthopaedics, cardiac and colorectal surgery).

Our review of the literature already points to gaps in the current literature (pps 6-8) that we aim to address in our study. Combined with restrictions on word count, we have not therefore added further detail on these two specific studies, but are happy to be guided by the editor as to whether this additional level of detail would be helpful.

RESEARCH QUESTIONS/FOCUS

Could you please add some more specific information about what you are trying to find to your research questions? (E.g. attitudes?, conceptions?, barriers and facilitators?)

We have changed the text on page 8 (preceding research questions), to "…we seek to identify perspectives on, and communicative features of, the shared decision making process for high-risk patients who are offered surgery asking…."

In your research questions you mention "their families" on the same level as patients and clinical teams. However, later on it seems to me that you are mostly interested in the patients' and clinical teams' perspectives. Please clarify.

We are primarily interested in understanding shared decision making between clinicians and patients, but recognise that families are often involved in conversations about that decision – before, during and after surgery (or a decision not to have surgery). Hence, whilst our primary focus is on patients and clinicians, we want to understand the role of families in decision making and so have not changed our research questions.

STUDY DESIGN

There has been historical over-use of chronological age per se as an unjustifiable pretext (including service cost) for non-intervention in a wide range of both surgical and non-surgical intervention….a push back in emphasis on chronological age per se at some points could help to avoid misunderstanding, particularly in the introduction (P5) (where even the attractiveness of cost-reduction might be seen to threaten revival of the dark days of age-related exclusion!)

One wonders if (in today's demographic distribution) the rather low threshold of 60+ in the purposive sample (P11) risks diluting the relevance of the findings to the contemporary population? Why not start higher?

We thank Reviewer 2 for these important points. In response we have changed the text in several places to avoid over-emphasising chronological age. E.g. p5 instead of saying that it is likely that older patients are at higher risk of poor post-surgical outcomes we say "older patients who are often (but not always) at higher risk of poor postoperative outcomes".

The choice of the threshold of 60 within the study has been informed by clinical input from the OSIRIS team and was felt to ensure a range of 'high risk' patients. As other reviewers (and indeed, the wider OSIRIS programme team) have not raised it as an issue, we have kept it at 60. We have added the following text on page 11 to qualify this:

> *"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 of ≥4, who are contemplating surgery".*

We will also be bearing this threshold in mind as we seek maximum variation in recruitment of patients and in analysing our data.

It might be helpful to define a little more carefully in each category the threshold within which surgery is elective or emergency, perhaps especially in relation to cardiac surgery.

In the section on 'sampling and data collection' (pps 10-11) we have qualified that our focus is on elective surgery. Given word count, we do not have space here to explore the distinction between elective and emergency for one or more of the selected conditions. We plan to explore this in future findings papers

given the increasing availability of national and international guidelines, is it "overly technical" for clinicians to share with patients and/or families aspects of risk-benefit ratio based on accepted evidence as an essential consideration to enable patient preference to be informed? (see Ref 10 P7). It is to be hoped that the analysis of Collaborative Deliberation and the

subsequent thematic and comparative analysis of focus group data will give due emphasis and prominence to this component of information exchange."

This is a qualitative, exploratory study. Hence, exactly as the reviewer suggests, our analytic process will enable attention to the use of evidence and evidence based guidance. We have qualified the text on page 13 to make this clear.

Will it be possible to record more than one consultation regarding one decision to be made (e.g. two consultations in case decision will be deferred; consultations with different health care professionals)?

We thank the reviewer for raising this and agree that this is important point given the nature of decision making. Our study design has some built in flexibility to enable us, where appropriate, to record or observe more than one consultation. We have added the following text at the bottom of page 11 to qualify this: "Where decision making clearly spans several encounters we will endeavour to record (or at the very least observe) more than one consultation."

METHODS

It would be helpful to know to what extent consenting, recruited clinicians will be aware of the key hypotheses and content of the Programme, and perhaps modify their interaction as a result.

We will provide basic information to all recruiting clinicians about OSIRIS, which does not include key hypotheses and content of the Programme as a whole. We provide more detailed information about the qualitative research that we are inviting them to participate in, which includes summary information about our research questions, methods and outputs. We have added the following text on page 11 to make this clear: "Working with clinical teams (who receive basic information about the study) we will recruit a maximum variation, purposive-sample of 15 high-risk patients…"

Why did you decide for the researcher to remain in the room if possible? In my opinion this bears the unnecessary risk of consultations being altered by the presence of the researcher.

This is an exploratory study, focused on gaining detailed qualitative data about decision making for surgery. With participants consent, it involves non-participant observation (i.e. unobtrusive observation, in which the researcher does not actively participate in the encounter) of the consultation and the process of decision making, thereby ensures real time appreciation of decision making and the context in which it evolves. We have qualified the text on p11 to reflect this, as follows:

> *"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)."*

This approach is usual in this kind of research. In our study it involves the researcher sitting quietly to one side in the consultation room, simply observing what's happening and switching the video recorder on and off. Follow up interviews with patients and clinicians – both immediately after and several months later – provide an opportunity to check back and reflect on this process.

Interviews

Will the interviews be face-to-face or via telephone? Will participants be compensated?

Wherever possible, interviews will be face-to-face (and by phone when not). Patients will be offered reimbursement if they incur additional expense as a result of interviews (e.g. car parking).

We have qualified the above in the text on page 12.

Focus groups:

Add primary care providers and other referring physicians/clinicians to the list of potential subjects for the phase 2 focus groups.

We appreciate interest in this element of the study. The aim of focus groups is to broaden inclusion in the study to a wider group and test out emerging findings from earlier phases (which involve a smaller group of participants). With this in mind, we have deliberately not included referring clinicians as

potential subjects (though plan to seek funding to explore this, and the wide pathway leading into surgical decision making, in a future study). We now make this clear, on page 12.

Will the hospitals in phase 2 be different to the ones in phase 1?

We have qualified the text on page 12, as follows: "We will purposively select up to 3 NHS hospitals (at least one of which will be different from phase 1)…."

Why are you not planning separate focus groups with family members / caregivers?

In the context of our study, we recognise that some patients may be extremely unwell (possibly deceased) following surgery. Family members and carers are therefore included in focus groups as a means of representing their views. We say this on page 12, as follows: "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."

Are the focus groups with clinicians be attended jointly by physicians and nurses or will there be separate focus groups for different groups of professionals? Please elaborate on why you chose to do it the way you did.

We plan different focus groups for different professional groups. However, we are also keen to understand perspectives across groups and, if possible, will seek to set up at least one group made up of different professional groups. It is likely that we will need to be guided by individual sites as to what is feasible and practical. We have added the following text at the top of page 13: "We will hold at least one focus group involving a mix of professional groups."

DECISION MAKING SCENARIOS

You use the term "decision making scenarios" throughout the manuscript….It was only at the end of the manuscript that I started to understand (i.e. descriptions of how those descriptions were found to be made). Please clarify upon first mention.

We have clarified in the abstract (page 3) and first mention in the main text (page 13). We have also taken out several mentions in the main text to aid reading.

THEORETICAL FRAMEWORK

In my opinion your study design would benefit if you were to add a theoretical model of shared decision-making as a basis for your research.

This is a qualitative study concerned with understanding how patients and clinical teams negotiate decision making for major ('high risk') surgery. As such, our intention is not to "compare" findings from our analysis with a theoretical model, but to use relevant theory (including on decision making) to understand how participants manage to make a decision about surgery.

As is usual in this kind of research, we draw on a number of theoretical and conceptual frameworks (see page 9), including Collaborative Deliberation (Elwyn et al, see reference 37). We are unsure why reviewer #3 does not feel this is sufficient – with all due respect, Collaborative Deliberation is an established model focusing on the collaborative process of decision making about health care and hence we do not feel it would be helpful to add further frameworks.

RESEARCH GROUP

The speciality/subspeciality backgrounds of the OSIRIS Programme Group list are not specified in the Appendix provided. Given the focus on older patients at high risk, the assessment of age and "frailty", and the points raised above, it would be reassuring if clinical gerontology expertise could be identifiable within the collaboration.

Thank you for pointing this out – we have now updated (and reattached) the OSIRIS Programme Group list to include affiliation/background.

In terms of the focus of the OSIRIS programme - this is indeed the impact of frailty, multi-morbidity and to a lesser extent, chronological age on the risks associated with surgery and how this might influence shared decision making. Both the Programme leads (RP and JP) are critical care doctors who have extensive expertise in frailty and multi-morbidity as part of their clinical work and have recently published epidemiological work focussed on understanding the aging surgical population

(Fowler AJ, Abbott T, Prowle J, Pearse R. Age of patients undergoing surgery. British Journal of Surgery, 2019, 10.1002/bjs.11148). We also have a perioperative physician (NM) with expertise in assessing and working with frail, multi-morbid patients in the run-up to surgery - his skill set has significant overlap with that of a gerontologist with an interest in working with surgical patients.

OUTPUTS AND IMPACT

A table or other descriptive summary of the study products/findings arising from the analyses of the phase 1 and phase 2 study results would be helpful. There are descriptive text on page 14; however, these are difficult to follow and link together. An additional/alternative method of summarizing or describing these study products would be helpful.

A short discussion of how these study products will improve shared decision making would be helpful.

a concluding paragraph describing next steps following the completion of the study would be additive.

We are unsure exactly what Reviewer 1 is looking for here, as the text on page 14 referred to data analysis. As per journal guidance, we already have a section on 'Ethics and Dissemination' at the end of the paper (pps 15-16). To aid clarity we have now added a second table (Table 2) which summarises dissemination, within and beyond the OSIRIS programme – we have edited the main text on dissemination (as detail is now in Table 2) and added additional text on next steps.

MINOR FORMATTING QUERIES

We have addressed the following minor editing queries/comments:

- Please add explanations of all abbreviations (e.g. MDT). Thank you! – *now written in full in figures*
- Page 6, line 42: Please combine all references into one pair of "[…]". *Done*
- Page 8, line 55: Are you interested in how they "reflect back on the decisions they made" or on the "decision making process"? Please re-evaluate. *We are interested in both, hence have not changed the text.*
- Sampling and data collection: Please add a timeline to this section. *Added to Table 1*
- Page 10: You switch up the names for the three surgical procedures and the order in which you describe them throughout the manuscript (i.e., joint surgery, intra-abdominal, and cardiac surgery). Please pay attention to keep it consistent.
- Are you planning to pay attention to differences in structural characteristics for each surgical procedure? *Not in this paper, but we will certainly be considering it in findings papers for this study, and the wider programme.*
- Page 14, line 34: Please add a reference for "thematic and comparative analysis".
- Please also align the order of the figures to the order within the text (cp. comment 8).
- Please add legends to your figure explaining abbreviations. *See above – now written in full*
- Figure 2: Why do you change the wording from "patient rejects" to "patients decides against" in the right column? Also, is it always the patient who makes the decision? *Patient rejects is at the point of discussion with the GP and therefore entails no referral into secondary care; the other options are in discussion with – in this case – the orthopaedic clinician/team, involving e.g. consideration of different options and potential outcomes and a change of mind. The wording is intended to capture that and we will be exploring this process in greater depth in planned findings papers.*
- Figure 3: This figure seems to have a different flow than the other two. There are several boxes on the left that are starting points in themselves. Also, please explain A&E. *We are delighted the reviewer spotted this - Figure 3 is deliberately different to the other two figures as the map for cardiac is different fro colorectal and orthopaedic – there is no way around this!*
- Please re-upload your supplementary files in PDF format – *Done*

- Figure/s should not be embedded – *Now attached separately*

VERSION 2 – REVIEW

REVIEWER	Prof Cameron G Swift King's College London, UK
REVIEW RETURNED	02-Mar-2020

GENERAL COMMENTS	1. Points (2), (3) and (5) of my review comments on Draft 1 are now addressed and satisfactorily resolved. 2. Point (1). On the matter of chronological age and the definition of "high risk": The authors have taken positive steps to redress potential misperception, but one minor wording improvement is still suggested as follows: • P 11 lines 14-16: I suggest amend to - "Our focus on high-risk linked to age and chronic co-morbidity or frailty …." 3. Point (4). On Research Group composition (details now made available by the authors) (identified as an element of "study design"): Given the focus on ageing as a risk component (and notwithstanding the obvious strengths and expertise of the research collaboration as outlined), it would still be preferable if the OSIRIS Group (and Focus Groups) incorporated at least one accredited, expert Clinical Gerontologist for the following additional reasons: • Given the now dated historical legacy of at times inappropriate chronological-age-based exclusion from otherwise timely appropriate surgical intervention, assurance is needed that the balance of age-associated issues around this is expertly incorporated into the development, observation and interpretation process. [It is still a slight concern that cost-reduction (P5 line 28) is identified as a primary component driver of the core rationale for the study]. • The specific collaborative sharing of gerontology physicians (and their teams) in surgical decision making and follow-up with the patient group in question is steadily expanding, and in some instances (e.g. in the case of hip fracture - albeit a non-elective scenario) is now incorporated into national evidence-based guidance1. Growing evidence is emerging of positive cost-benefit impact of such collaboration (in this and other surgical settings) on the otherwise negative post-surgical outcomes catalogued in the Introduction, Paragraph 2 (P5 line 26 to P6 line 6). It is accordingly arguable that by this means at least some of these historically negative outcomes are preventable going forward, and this dimension should be accurately reflected in the perspectives to be discussed. 1 https://www.nice.org.uk/guidance/CG124

REVIEWER	Dr. Pola Hahlweg Universitatsklinikum Hamburg-Eppendorf, Department of Medical Psychology
REVIEW RETURNED	26-Feb-2020

GENERAL COMMENTS	Many thanks for the opportunity to re-review this study protocol. The manuscript addresses the important question of shared decision-making about high-risk surgeries. The revision further

	strengthened the manuscript. I merely have two remaining comments: 1. I still think including e.g. Glyn Elwyn's Three-Talk Model (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3445676/; https://www.ncbi.nlm.nih.gov/pubmed/29109079) would further strengthen the study. This might be helpful to support e.g. focus group discussion or at least inform data interpretation. Without clearly defining shared decision-making for you as the study team and without knowing if participants talk about the same concept when discussing shared decisionmaking in focus groups, your results might be hard to interpret. 2. Please check again for minor typos, e.g. a. "who will receive basic study information" instead of "who will receive study basic information" on page 11 b. "as soon as possible after their consultation" instead of "as soon as practically possibly after their consultation" on page 12).

VERSION 2 – AUTHOR RESPONSE

1. **Reviewer 3 requested that we alter our study design by including Elwyn's Three-Talk model.** We are aware of this model and the classification of different types of talk. We have deliberately chosen not to use this framework precisely because it pre-specifies the types of talk perceived as inherent in shared decision making. It is also limited to talk (not other forms of interaction) and fails to fully appreciate the context in which shared decision making unfolds. We use an alternative (potentially complimentary) theoretical framework combining practice theory, collaborative deliberation (as we added in the last round of review "*an established model focusing on the collaborative process of decision making about health care")*, and ethnography of communication. We already set this out on p9 of the manuscript.
2. **Reviewer 2 requested that we change the make up of the OSIRIS Programme Group, and focus groups, to include a least one accredited, expert Clinical Gerontologist**. With all due respect, this reviewer is requesting changes to study design and governance that have already been agreed with the funder, peer reviewers and patient groups. We are not able to change these.

   We have already provided further detail on the OSIRIS Programme Group (see previous response to review), have previously offered reassurance regarding age-associated issues in an earlier round of reviews; and can confirm that cost-reduction is not a "*primary component driver of the core rationale for the study*" (indeed, the section that the reviewer points to, on page 5, refers to background literature).

   It is perhaps worth reminding that ours is a qualitative study, exploring how shared decision making unfolds in the context of high risk surgery. There is always a balance to be struck in such studies: our focus is on *depth* of understanding in a small number of clinical encounters, rather than *breadth* (e.g. of contacts with the wider clinical team, or wider social networks, that potentially support decision making). We have not set out to include Clinical Gerontologists in the core of this study, however flexibility in our approach to sampling (see p11) will enable inclusion if patient contact with a clinical gerontologist came up in the course of the study.

VERSION 3 – REVIEW

REVIEWER	

REVIEW RETURNED	

GENERAL COMMENTS	

REVIEWER	
REVIEW RETURNED	

GENERAL COMMENTS	

REVIEWER	
REVIEW RETURNED	

GENERAL COMMENTS	

REVIEWER	
REVIEW RETURNED	

GENERAL COMMENTS	

REVIEWER	
REVIEW RETURNED	

GENERAL COMMENTS	

VERSION 3 – AUTHOR RESPONSE

VERSION 4 – REVIEW

REVIEWER	
REVIEW RETURNED	

GENERAL COMMENTS	

REVIEWER	
REVIEW RETURNED	

GENERAL COMMENTS	

REVIEWER	
REVIEW RETURNED	

GENERAL COMMENTS	

REVIEWER	
REVIEW RETURNED	

GENERAL COMMENTS	

REVIEWER	
REVIEW RETURNED	

GENERAL COMMENTS	

VERSION 4 – AUTHOR RESPONSE

VERSION 5 – REVIEW

REVIEWER	
REVIEW RETURNED	

GENERAL COMMENTS	

REVIEWER	
REVIEW RETURNED	

GENERAL COMMENTS	

REVIEWER	
REVIEW RETURNED	

GENERAL COMMENTS	

REVIEWER	
REVIEW RETURNED	

GENERAL COMMENTS	

REVIEWER	
REVIEW RETURNED	

GENERAL COMMENTS	

VERSION 5 – AUTHOR RESPONSE