STAFF INFORMATION SHEET, PHASE 1 #1

Understanding shared decision making about major surgery: a qualitative study

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We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you *would like more information, please ask us.*

What is the purpose of the study?

We are a research team from the University of Oxford, working with doctors at [INSERT SITE NAME]. We are studying how clinicians like yourself, together with your patients, make decisions about whether or not major surgery is the right option for them. We are particularly interested in situations where the choice about surgery is more challenging due to a patient's age or co-morbidities. This study is part of a six-year research programme, funded by the National Institute of Health Research, designed to make it easier for patients and doctors to arrive at the best decision possible about surgery. This qualitative research forms the first phase of that programme and we are looking to recruit doctors and patients to take part.

Our research team aims to understand: (a) the reasons people choose or decline major surgery and to see how these change over time; (b) what shared decision making really means for patients, families and clinical teams; (c) the information patients and doctors exchange before and after surgery, and (d) how this shapes shared decision making.

By doing this research we are seeking to develop potentially new and better ways of ensuring patients and doctors engage in shared decision making when considering major surgery.

Why have I been invited?

We plan to interview up to 15 patients, along with their doctors and other members of the clinical team, who have been involved in the decision making process regarding cardiac, colo-rectal or major joint surgery. You have been invited to participate in the research either because you are a surgeon in one of these areas, or are an anaesthetist or clinical nurse specialist who is involved in the care of patients making decisions about surgery.

Do I have to take part?

No, taking part is entirely voluntary and you can withdraw at any time if you later change your mind, without giving a reason. Withdrawal will not affect your employment rights.

What will happen to me if I decide to take part?

You have already been approached by [INSERT NAME], your site's Principal Investigator who has told you about the study and given you this information sheet. If you are willing to take part in the study then you will need to confirm with [INSERT NAME] that you are happy for a researcher to get in touch with you. That researcher will ask you to sign a consent form agreeing to participate.

Once a patient identified by you as potentially suitable has agreed to take part in the research, we will inform you. On the day of the clinic, the researcher will confirm with you and the patient that you both agree to video-record the consultation. If everyone agrees a small video camera will be positioned unobtrusively in the consultation room to capture your interaction with the patient. The researcher will be guided by the patient as to what they prefer: video-recording with the researcher present, or video-recording with the researcher out of the room. Whichever option the patient chooses, the researcher will not interrupt your consultation. You will not need to operate the video-recorder, it will be left running during the consultation. When the consultation has finished the researcher will check that you and the patient are still willing for the video material to be used in the research.

The researcher will then interview you on two separate occasions (with the patient's consent for you to discuss their case). The first will be soon after the consultation with the patient, either immediately after (or at the end of clinic) or a few days later. You can choose which you prefer and where you would prefer to be interviewed. They will interview you about your experience of the consultation and the decision making process and your thoughts and expectations about the surgery. The second occasion would be three to six months after the surgery, or if the patient chooses not to have surgery, after the decision to decline. They will interview you about how the decision was made about surgery and, on reflection, how satisfied or not you are with the decision making process and outcome. With your permission, the researcher would like to audio-record the interview. The interviews will be held at your hospital. They will last no more than 40 minutes each. Should you have more than one patient in the study it will be possible to combine interviews should you wish (i.e. making it slightly longer but more efficient).

The video recordings will be anonymised before anyone else sees it – your name will be "bleeped" and your face and other identifying features will be anonymised – unless you ask us not to.

What should I consider?

The main thing to consider is whether you are comfortable with researchers asking you questions, and observing and/or videoing a consultation between you and your patient.

Are there any possible disadvantages or risks from taking part?

The main disadvantage of the interview is that we are asking you to commit some time.

What are the possible benefits of taking part?

The main benefit of taking part is this is an opportunity for you to contribute to improving the decision making process for clinicians like yourself and the higher-risk patients you work with.

Will my taking part in the study be kept confidential?

Yes. All data from the study (tape recordings, videos) will be made anonymous (unless you would prefer us not to blur your face). They will be kept on a secure part of the server at the University of Oxford and only accessible by the research team. In those stored data, you will be referred to only by a code name ('pseudonym'). We will keep a separate paper record in a locked cabinet of participants' real names and corresponding code names.

Audio recordings may be processed by a transcriber with a contractual agreement with the University. Transcribers are subject to the same requirements of confidentiality as researchers. They will have no other identifying information about you, and will not retain the audio recordings

Responsible members of the University of Oxford and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

In the unlikely event that there were any concerns raised about your patients care, or their safety, during the course of the study we would need to notify the appropriate members of your organisation. We would discuss this with you before doing so.

Will I be reimbursed for taking part?

No, and since the interview/recording will take place in your place of work, we do not anticipate you incurring any travel or expenses.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from interviews and observations for the study and will use the minimum personally-identifiable information possible. We will store research data (anonymised unless we have explicit consent to retain identifiers) and any research documents with personal information (such as consent forms) securely at the University of Oxford for up to six years after the end of the study. This will ensure that we have time to analyse it all, write papers and reports.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/]

You can find out more about how we use your information by contacting Sara Shaw, Chief Investigator for the study, using the contact details at the bottom of this Information Sheet.

What will happen if I don't want to carry on with the study?

You can stop at any time. Participation is voluntary and even if you originally said yes, you may change your mind at a later stage. If you withdraw from the study, unless you state otherwise, any interview or video material that has been collected whilst you have been in the study will be used for research as detailed in this participant information sheet. You are free to request that your data are destroyed at any time during or after the study.

What will happen at the end of the study?

We will analyse the data and write some papers and reports, including a 'lay summary'. We will provide you with a summary of the findings if you would like us to.

You will not be identified from any report or publication placed in the public domain as we will anonymise any quotes, images or videos (unless you specify that you do not wish us to do so). We may wish to use a short clip of your consultation in a conference presentation or in teaching (and only for that audience, not more widely e.g. we would not livestream a presentation to an external audience) as this provides a way for people to see and hear how decision making about major surgery happens in a consultation, but you do not have to agree to this. If you are happy for this to happen, tick the relevant box on the consent form.

Some of the research being undertaken may also contribute to the fulfilment of an educational requirement such as a doctoral thesis.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Professor Sara Shaw whose details are given below, or Professor Trisha Greenhalgh (Professor Shaw's line manager, same address). Alternatively, you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email ctrg@admin.ox.ac.uk.

How have patients and the public been involved in this study?

People with experience of having to make decisions about surgery were involved in helping design this study and have also checked this information sheet and consent form.

Who is organising and funding the study?

The study is funded by National Institute of Health Research (NIHR). It is part of the *Optimising Shared decision-makIng for high RIsk major Surgery* (OSIRIS) research programme. The study team is led by Professor Sara Shaw, who works at the University of Oxford; she is also custodian of the study information.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by [INSERT NAME OF RESEARCH ETHICS COMMITTEE]. The reference number is [INSERT].

Further information and contact details:

Please contact the following individual if you would like further information.

Professor Sara Shaw (Chief Investigator)
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University of Oxford
Radcliffe Observatory Quarter
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Oxford OX2 6GG

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Thank you for considering taking part.