STAFF INFORMATION SHEET, PHASE 1 #2

Understanding shared decision making about major surgery: a qualitative study

Version 1.2, 13 December 2018

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 the same research team that you spoke to before from the University of Oxford. We are working with doctors at [INSERT SITE NAME] and 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?

You have been invited because we previously interviewed you as part of the study and recorded a consultation between you and up to 5 of your patients about the decision to undergo surgery or not. We are getting in touch three to six months after the decision was made to have (or not to have) surgery, because we would like to talk to you one final time.

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?

Our researcher will interview you about the decision 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.

What should I consider?

The main thing to consider is whether you are comfortable with researchers asking you questions, and audio recording the discussion.

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 to contribute to improving decision making 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 the care of your patients, 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 for the study and will use the minimum personally-identifiable information possible. We will store de-identified research data, audio recordings 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 from interviews. 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
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Thank you for considering taking part.