PATIENT INFORMATION SHEET, PHASE 1 #1

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 a research team from the University of Oxford, working with doctors and nurses at [INSERT SITE NAME]. We are studying the process of shared decision making for patients contemplating major surgery who may be considered 'higher risk' due to age and / or other medical conditions e.g. heart, kidney, lung problems. We don't know enough about what happens in these shared decision making discussions, which currently makes it hard to know what could be improved or how we should do this. This study is the first part of a much larger research programme, funded by the National Institute of Health Research, to develop ways of optimising shared decision making for major surgery.

Our research team aims to understand: (a) the reasons people choose or decline major surgery, including perceptions of the potential positive and negative outcomes, 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.

To achieve our research aims we are conducting a detailed study of the patient experience and patient-clinician interaction during the decision making process about surgery. We are looking to recruit 15 patients, their doctors and relevant members of their clinical team (e.g. specialist nurse) to take part.

Why have I been invited?

Your consultant has agreed to participate in the study. You have been invited because your consultant has identified you as someone who may be suitable for our study, in terms of your age and health conditions, and who might wish to take part.

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 or not taking part will not affect your current or future clinical care in any way, as the research team is separate from your medical team.

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

At this stage you have given permission for the research team to contact you. They will do so in the next 7 days and you will need to make a decision before your appointment at the hospital to discuss possible surgery. They will talk to you about the study ask if you have questions and if you are ready to make a decision about whether or not you would like to take part. If you decline to take part then we will not contact you again. If you confirm that you would like to take part in the research then we will ask you to meet with our researcher the clinic on the day of your appointment, where you will be asked to sign a consent form agreeing to take part. If you would like anyone to accompany you to your consultation we will also ask them to sign a consent form. It would be helpful if you could arrive shortly before your scheduled appointment time in order to meet with the researcher.

The researcher will video-record your consultation with the surgeon, who will also have given consent to be recorded. A small video camera or two will be positioned unobtrusively in the room to capture the consultation. The researcher will either sit in and observe the consultation taking notes or would start and stop the recordings but will leave the room during the consultation, depending on your preference. The researcher will not interrupt your consultation. At the end of the consultation the researcher will check that you are still willing for the video material to be used in the research.

The researcher will also interview you on two separate occasions. The first would be soon after the consultation with the surgeon, either immediately after or a few days later. You can choose which you prefer on the day, and where you would prefer to be interviewed. They will interview you about your illness, your experiences of the consultation and your thoughts and expectations about surgery (if this is the route you choose). The second occasion would be three to six months after you have had surgery, or if you choose not to have surgery, after the decision to decline surgery. They will check back with you that are happy to be interviewed again and, if so, interview you about how you have been since surgery and what you think about the decision to have surgery and how satisfied or not you are with the decision making process a few months later. With your permission, the researcher would like to audio record the interviews. The interviews can be held at your hospital or at your home, as you prefer. They will last no more than 1 hour each.

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 give us permission not to.

We will also interview members of your clinical team on two occasions, immediately after your consultation and again three to six months after your consultation, to understand their views on the decision-making process.

What should I consider?

The main things to consider are whether you are comfortable with researchers asking you questions, and observing and/or videoing a consultation between you and the doctor, and interviewing members of your clinical team about your care.

Are there any possible disadvantages or risks from taking part?

The main disadvantage of the interview is we are asking you to commit some time and we will ask questions about your personal medical details (to be seen by researchers). You might also find it sensitive, and potentially distressing, to discuss your decision about surgery with a researcher. For the video component of the study, the researchers will be able to see and hear you having a consultation, which you might feel should be kept private.

What are the possible benefits of taking part?

The main benefit of taking part in the research is an opportunity for you to contribute to a programme of research that focuses on improving shared decision making process for other people like yourself.

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 and give consent to the information being used for training and presentations). They will be kept on a secure part of the server at the University of Oxford and only accessible by the research team for up to six years after the end of the study, after which point all video and audio recordings will be destroyed. 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 care, or your safety, during the course of the study we would need to notify the appropriate members of the NHS organisation providing your care. 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 home, or at your hospital during a scheduled visit, 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 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.

Withdrawal from the study will NOT affect the care you receive from the NHS now or in the future.

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 this e.g. by blurring your face).. 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 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 you find something unexpected?

If anything you tell us in an interview has a direct bearing on your clinical care (for example if you disclose to us that you have a new symptom), we may inform your clinical team, as appropriate. In the unlikely event that you were to inform us of any concerns or complaints you had about your care, or if we were to notice anything untoward about your care we would advise you on the appropriate complaints processes to follow, or we would notify the appropriate managers in the organisation providing your care. We would not be able to support you in a complaint.

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.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact <insert relevant NHS site phone number and email>.

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

People like you 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?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. 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)
Nuffield Department of Primary Care Health Sciences
University of Oxford
Radcliffe Observatory Quarter
Woodstock Road
Oxford OX2 6GG

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Thank you for considering taking part.