# PARTICIPANT INFORMATION SHEET

## Analysis of the clinical workflows and decision-making processes around knee replacement surgery

### Introduction

We would like to invite you to take part in a research project. Before you decide you need to understand why the research is being done and what it will involve for you. Please take the time to read the following information carefully and ask questions about anything you do not understand. Talk to others about the study if you wish.

### What is the purpose of the study?

About 100,000 knee replacements are performed each year in the UK to help people with severe knee osteoarthritis. Although most are successful, 1 in 5 patients experience chronic pain after the surgery and 1 in 23 patients will need more surgery within 10 years, due to complications such as the replacement becoming loose. Knee replacement surgery (KRS) is commonly performed (~100,000/year in UK) in patients with severe osteoarthritis. Despite a good outcome for most patients, 20% of patients experience chronic pain afterwards and 4.4% require revision surgery within 10 years for a variety of reasons.

Radiographic knee shape has been shown to be a predictor for the outcome of KRS. Using machine learning methods (www.bone-finder.com), we are developing a software system to automatically measure the knee in pre-/post-operative radiographs, and to predict poor outcome based on the radiographic measurements, clinical and patient-reported data.

We are conducting this qualitative study to better understand the experiences and opinions of health professionals that work directly within the KRS pathway.

The outcomes will inform the design and development of our software system with regards to how the system would best fit into current clinical workflows and how to best present/integrate its findings.

### Why have I been invited to take part in the study?

You have been invited to take part in a qualitative study to help us understand the experiences and opinions of health professionals that work directly within the KRS pathway. We want to find out about:

- Your own experiences of being involved in the KRS pathway with regards to making clinical decisions and your approach to the management of service users.
- Insights into where and how a computer tool may be implemented into the clinical framework of the KRS pathway.

To be eligible to take part in the study, you must meet the following criteria:

- Age 18-75+ **AND**
- Qualified Health Professional, holding one of the following registrations: General Medical Council (GMC), Health & Care Professions Council (HCPC) or Nursing and Midwifery Council (NMC) registration **AND**
- At least two years of directly relevant clinical experience of working within the Knee Replacement Pathway in the United Kingdom **AND**
- Proficient in English

About 20-25 participants will take part in this study. We aim to identify participants that represent a range of experience, established and junior staff, mainly from an orthopaedic surgical background. We will also include other health professionals that are involved in the knee replacement pathway (such as physiotherapists and nurses).

**Do I have to take part?**

No, you do not have to participate. There will be no adverse consequences in terms of your legal rights or employment status. Even if you agree to take part, you can drop out at any time without giving a reason. If you change your mind about taking part, at any stage, you just need to let us know.

If you withdraw from the study, the following will apply in terms of your participation and data:

- With your permission, contact data and any other identifiable data already collected will be retained, if you allow us to, otherwise it will be deleted.
- Collected data that has already been anonymised will be continued to be used, because we will not be able to trace the latter information back to you.
- No further data would be collected or any other research procedures would be carried out on or in relation to you.

**What will my involvement require?**

If you agree to take part, we will ask you to sign a consent form and provide you with a copy of the information sheet to keep. There will be at least 10 days between receiving the information sheet to consent to taking part in the study.

The interview will take place virtually (e.g. via Teams, Zoom), unless the participant prefers a face-to-face interview on campus. It is therefore required that participants find a suitable location whether this be at home or workplace where they feel comfortable and able to talk about the subject matter privately and confidently.

The interview will last approximately 60-90 minutes.

The overall project is expected to run until 31st December 2027 but your involvement would only be for the duration of the interview.

**What will happen to the data that I provide?**

Anonymised research data will be stored securely on the University's central Research Data Storage system for a period of 10 years following completion of the project.

**What are the possible disadvantages or risks of taking part?**

Currently, we do not envisage any disadvantage to taking part in this study.

**What are the possible benefits of taking part?**

Outcomes of the study will inform our research on developing digital health technology to improve the KRS pathway, before and after surgery. We hope that the outcomes of the study will help us to understand the factors that are important to your decision making and what challenges health clinicians face along the KRS pathway.

You will be contributing to a large project that aims to develop technology to help clinicians and patients. Firstly, the project aims to help doctors and patients to make more informed decisions on the best pre-replacement surgery treatment pathway. Secondly, it aims to help identify patients at risk for complications. This could potentially provide a more efficient KRS pathway resulting in a more meaningful contact with patients to ensure better outcomes.

**What if there is a problem?**

If you have any complaint or concern about any aspect of the way you have been dealt with during the course of the study will be addressed, please contact Claudia Lindner, Principal Researcher via email: claudia.lindner@manchester.ac.uk in the first instance, or Dominic Cullen, Research Associate, via email: dominic.cullen@manchester.ac.uk.

To the best of our knowledge, we do not believe there will be any risk of harm by participating in this study. But if you think you might have been harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during this study then you should follow the instructions given above.

**Will my taking part in the study be kept confidential?**

Yes, your details will be held in complete confidence, and we will follow ethical and legal practice in relation to all study procedures. All data will be stored in compliance with the Data Protection Act.

Your personal data will be accessed, processed and securely destroyed by the principal investigator and/or co-investigators. To check that this research is carried out in line with the law and good practice, monitoring and auditing can be carried out by independent authorised individuals. Data collected during the study may be looked at by authorised individuals from regulatory authorities, where it is relevant to your taking part in this research. All will have a duty of confidentiality to you as a participant.

The data you provide will be anonymised. You will not be identified in any reports/publications resulting from this research. We may include anonymous verbatim quotations in reports/publications (with any potentially identifiable information being removed).

In certain exceptional circumstances where you or others may be at significant risk of harm, the researcher may need to report this to an appropriate authority, in accordance with the UK Data Protection Act. This would usually be discussed with you first.

Examples of those exceptional circumstances when confidential information may have to be disclosed are:

- The researcher believes you are at serious risk of harm, either from yourself or others.
- The researcher suspects a child may be at risk of harm.
- You pose a serious risk of harm to, or threaten or abuse others.
- As a statutory requirement e.g. reporting certain infectious diseases.
- Under a court order requiring the University to divulge information.
- We are passed information relating to an act of terrorism.

**Full contact details of study team**

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**Who is organising and funding the research?**

This study is being led by Dr Claudia Lindner and hosted at The University of Manchester. It is jointly funded by the Wellcome Trust and the Royal Society (Sir Henry Dale Fellowship: 223267/Z/21/Z).

**Who has reviewed the project?**

*This research has been reviewed by the Research Ethics Committee at The University of Manchester.*

**Thank you for taking the time to read this Information Sheet.**