**Revision Knee Replacement ( Problematic Knee Replacement) Priority Setting Partnership**

**PROTOCOL version 3**

## 1. Purpose of the PSP and background

The purpose of this protocol is to set out the aims, objectives and commitments of the Revision Knee Replacement Priority Setting Partnership (PSP) and the basic roles and responsibilities of the partners therein. It is recommended that the Protocol is reviewed by the Steering Group and updated on at least a quarterly basis.

The James Lind Alliance (JLA) is a non-profit making initiative, established in 2004. It brings patients, carers and clinicians together in Priority Setting Partnerships (PSPs). These partnerships identify and prioritise uncertainties, or 'unanswered questions', about the effects of treatments that they agree are the most important. The aim of this is to help ensure that those who fund health research are aware of what really matters to both patients and clinicians. The National Institute for Health Research (NIHR – www.nihr.ac.uk) funds the infrastructure of the JLA to oversee the processes for priority setting partnerships, based at the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), University of Southampton.

Over recent years there have been increasing numbers of knee replacements performed in the UK. In the majority of cases these are successful procedures which allow patients to lead more active lives and greatly improve their joint symptoms. Over time such replacements may become problematic for a variety of reasons causing patients to experience further pain, swelling, stiffness or instability. This can, in turn, limit patients by reducing their ability to perform desired activities.

This PSP is focussed on such patients who have undergone knee replacements (partial or total), which have subsequently gone on to become problematic. Patients experiencing problems after knee replacement may present to their GP or hospital for assessment. Further management may involve surgery or not - these options are often described as 'operative' or 'non-operative'.

Non-operative treatments include medications (e.g pain relief), injections and rehabilitation (involving physiotherapy and/or occupational therapy). Surgical procedures may involve removing part or all of the original implants and replacing them with new ones. There are around 6000 such revision knee replacement procedures performed in the UK each year.

For some situations, there is a lack of high quality evidence (such as well-designed trials) regarding the assessment, management and rehabilitation of this group of patients. This insufficient up-to date information can leave patients, carers and clinicians faced with uncertainties regarding the best way to move forward. We will identify key research questions to help address these uncertainties.

## 2. Aims and objectives of the Revision Knee Replacement PSP

The aim of the Revision Knee Replacement PSP is **to identify the unanswered questions about the assessment, management or rehabilitation of patients with problematic knee replacements**, from patient and clinical perspectives and then prioritise those that patients and clinicians agree are the most important.

The objectives of the Revision Knee Replacement PSP are to:

- work with patients and clinicians to identify uncertainties about the assessment, management and rehabilitation of patients with problematic knee replacements
- to agree by consensus a prioritised list of those uncertainties, for research
- to publicise the results of the PSP and process
- to take the results to research commissioning bodies to be considered for funding.

**SCOPE:**

The scope of this PSP will cover patients who have a problematic primary (partial or total) knee replacement from the point they experience problems with that joint, through the management stage (which encompasses operative or non-operative therapies), and during the rehabilitation stage up until 2 years post operatively.

## 3. The Steering Group

The Revision Knee Replacement PSP will be led and managed by the following:

Project Lead

- Andrew Toms, Consultant Knee Surgeon & Honorary Clinical Professor – Exeter

Project Co-ordinator

- Johnny Mathews, BRC Doctoral Fellow and Specialist Registrar, Trauma & Orthopaedics - Bristol

Patient representative/s:

- John Brooks
- David Hillebrandt *
- Bill Rowles
- Ian Tanner
- Polly Tarrant *

Clinical representative/s:

- Simon Abram, NIHR Doctoral Fellow and Specialist Registrar, Trauma & Orthopaedics - Oxford
- Abtin Alvand, Honorary Senior Clinical Lecturer in Trauma & Orthopaedics – Oxford

- Neil Artz, Chartered Physiotherapist, Bristol
- Rachel Bray, Senior Research Nurse, Bristol
- David Hillebrandt, *Patient and semi-retired General Practitioner - Devon
- Beverley Hopwood, Associate Specialist Anaesthetics and Pain Management - Exeter
- Nicholas Howells, Consultant Knee Surgeon – Bristol
- James Murray, Consultant Knee Surgeon – Bristol
- Jonathan Phillips, Consultant Knee Surgeon – Exeter
- Andrew Porteous, Consultant Knee Surgeon - Bristol
- Andrew Price, Consultant Knee Surgeon & Professor of Orthopaedic Surgery – Oxford
- David Searle, Surgical Care Practitioner - Exeter
- Rowenna Stroud, Extended Scope Physiotherapist –Exeter
- Polly Tarrant * patient and retired Lead Research Nurse
- Ben Waterson, Clinical Lecturer Trauma & Orthopaedics, Exeter
- Vikki Wylde, Senior Lecturer in Musculoskeletal Health Services Research - Bristol

**indicates experience as patient and healthcare professional*

The Partnership and the priority setting process will be supported and guided by:

Patricia Ellis, Adviser – The James Lind Alliance (JLA)
Kristina Staley – Independent Information Specialist
Nick Kalson – Recruitment and evidence checking

The Steering Group will agree the resources, including time and expertise that they will be able to contribute to each stage of the process. The JLA will advise on this.

## 4. The wider Partners

Organisations and individuals will be invited to be involved with the PSP as partners. Partners are groups or individuals who will commit to supporting the PSP by disseminating the PSP survey and helping the PSP to gather questions and uncertainties of practical clinical importance relating to the treatment and management of the health problem in question. Partners represent the following groups:

- people who have had problematic knee replacements
- carers of people who have had problematic knee replacements
- medical doctors, nurses and professionals allied to medicine with clinical experience of problematic knee replacements
- It is important that all organisations which can reach and advocate for these groups should be invited to become involved in the PSP. The JLA Adviser will take responsibility for ensuring the various stakeholder groups are able to contribute equally to the process.

**Exclusion criteria**
Some organisations may be judged by the JLA or the Steering Group to have conflicts of interest. These may be perceived to adversely affect those organisations' views, causing unacceptable bias. As this is likely to affect the ultimate findings of the PSP, those organisations will not be invited to participate. It is possible, however, that interested parties may participate in a purely observational capacity when the Steering Group considers it may be helpful

## 5. The methods the PSP will use

This section describes a schedule of proposed stages through which the PSP aims to fulfil its objectives. The process is iterative and dependent on the active participation and contribution of different groups. The methods adopted in any stage will be agreed through consultation between the Steering Group members, guided by the PSP's aims and objectives. More details can be found in the Guidebook section of the JLA website at www.jla.nihr.ac.uk where examples of the work of other JLA PSPs can also be seen.

### Step 1: Identification and invitation of potential partners

Potential partner organisations will be identified through a process of peer knowledge and consultation, through the Steering Group members' networks. Potential partners will be contacted and informed of the establishment and aims of the Revision Knee Replacement PSP and may be invited to attend and participate in an initial stakeholder meeting if this is being arranged.

### Step 2: Identifying treatment uncertainties

Each partner will identify a method for soliciting from its members questions and uncertainties of practical clinical importance relating to the treatment and management of problematic knee replacements. A period of 3 months will be given to complete this exercise.

The methods may be designed according to the nature and membership of each organisation, but must be as transparent, inclusive and representative as practicable. Methods may include membership meetings, email consultation, postal or web-based questionnaires, internet message boards and focus group work.

Existing sources of information about treatment uncertainties for patients and clinicians will be searched. In due course, these existing sources of information will be named in later versions of the protocol. These can include question-answering services for patients and carers and for clinicians; research recommendations in systematic reviews and clinical guidelines; protocols for systematic reviews being prepared and registers of ongoing research.

The starting point for identifying sources of uncertainties and research recommendations is NHS Evidence: www.evidence.nhs.uk.

### Step 3: Refining questions and uncertainties

The consultation process will produce "raw" unanswered questions about diagnosis and the effects of treatments. These raw questions will be assembled and categorised and refined by Kristina Staley into "collated indicative questions" which are clear, addressable by research and understandable to all. Similar or duplicate questions will be combined where appropriate.

Systematic reviews and guidelines will be identified and checked by Simon Abram / Abtin Alvand (Oxford) to see to what extent these refined questions have, or have not, been answered by previous research. This process will involve double screening/ reviewing by other members of the group (including Johnny Mathews, Vikki Wylde, Polly Tarrant) depending on number of results. A search specialist from the University of Oxford wil aid the development of a search strategy to identify:

- Relevant systematic reviews, randomised controlled trials (RCTs) and guidelines
- from databases- Medline, Embase ,Cochrane and CINAHL.

Expert advice will also be taken to check if any of the long list summary questions have been answered by any published research that is lower level than systematic review or randomised controlled trial. This will involve consultation of members of the UK Revision Knee Expert Group, ATOCP and the Trauma and Orthopaedic Society of Nursing.

Uncertainties which are not adequately addressed by previous research will be collated and recorded on a template (supplied by the JLA) by Simon Abram (Oxford), and brought to the May meeting. This will demonstrate the checking undertaken to make sure that the uncertainties have not already been answered. This is the responsibility of the Steering Group, which will need to have agreed personnel and resources to carry this accountability. The data should be submitted to the JLA for publication on its website on completion of the priority setting exercise, taking into account any changes made at the final workshop, in order to ensure that PSP results are publicly available.

**Step 4: Prioritisation – interim and final stages**

The aim of the final stage of the priority setting process is to prioritise through consensus the identified uncertainties relating to the treatment or management of Revision Knee Replacement. This will be carried out by members of the Steering Group and the wider partnership that represents patients and clinicians.

- The interim stage, to proceed from a long list of uncertainties to a shorter list to be discussed at the final priority setting workshop (e.g. up to 30), may be carried out over email or online, whereby organisations consult their membership and choose and rank their top 10 most important uncertainties. Each ranked uncertainty will be given a score ( 1st rank to be given 10 points, 2nd rank to be given 9 points and so on) – cumulative points for each submission will be calculated, thus giving an overall interim ranking.

- The final stage, to reach, for example, 10 prioritised uncertainties, is to be conducted in a face-to-face workship, using group discussions and plenary sessions.

- The JLA will facilitate this process and ensure transparency, accountability and fairness. Participants will be expected to declare their interests in advance of this meeting.

- To recruit for these stages, all steering groups will approach their contacts locally and nationally. In addition, Johnny Mathews will email out to all respondents from the initial survey who expressed an interest in being involved in latter stages of the project. He will also contact the wider partners including:

AfPP, ACPA, ATOCP BASK, BOA, BOTA, Royal College of Anaesthesia, Royal College of General Practitioners

Royal College of Nursing Society of T&O, PPI groups (Oxford/ Exeter/ Bristol), INVOLVE, National Voices, Pain Concern

## 6. Dissemination of findings and research

**Findings and research**
It is anticipated that the findings of the Revision Knee Replacement PSP will be reported to funding and research agenda setting organisations such as the NIHR and the major research funding charities. Steering Group members and partners are expected to develop the prioritised uncertainties into research questions, and to work to establish the research needs of those unanswered questions to use when approaching potential funders, or when allocating funding for research themselves, if applicable.

**Publicity**
As well as alerting funders, partners and Steering Group members are encouraged to publish the findings of Revision Knee Replacement PSP using both internal and external communication mechanisms. The Steering Group may capture and publicise the results through descriptive reports of the process itself in Plain English. This exercise will be distinct from the production of an academic paper, which the partners are also encouraged to do. However, production of an academic paper should not take precedence over publicising of the final results.

## 7. Agreement of the Steering Group

- Agreed by the Revision Knee Replacement PSP Steering group members on