

Foot & Ankle Surgery Priority Setting Partnership

PROTOCOL 03/09/2019

1. Purpose of the PSP and background

The purpose of this protocol is to clearly set out the aims, objectives and commitments of the Foot & Ankle Surgery Priority Setting Partnership (PSP) in line with James Lind Alliance (JLA) principles. The Protocol is a JLA requirement and will be published on the PSP's page of the JLA website. The Steering Group will review the Protocol regularly and any updated version will be sent to the JLA.

The JLA is a non-profit making initiative, established in 2004. It brings patients, carers and clinicians together in PSPs. These PSPs identify and prioritise the evidence uncertainties, or 'unanswered questions', that they agree are the most important for research in their topic area. Traditionally PSPs have focused on uncertainties about the effects of treatments, but some PSPs have chosen to broaden their scope beyond that. The aim of a PSP is to help ensure that those who fund health research are aware of what really matters to patients, carers and clinicians. The National Institute for Health Research (NIHR – www.nihr.ac.uk) coordinates the infrastructure of the JLA to oversee the processes for PSPs, based at the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), University of Southampton.

The Scientific Committee of BOFAS has been interested in setting priorities in the research in Foot & Ankle for some time. As part of the BOA initiative the Scientific Committee was contacted by Head of Research at the BOA. The committee looked at the prospects of a JLA to investigate the uncertainties in foot & ankle surgery. We have also looked at other specialist societies JLA PSPs which has encouraged committee and the project lead to conduct exercise.

2. Aims, objectives and scope of the PSP

The aim of the Foot & Ankle Surgery PSP is to identify the unanswered questions Foot & Ankle Surgery from patient, carer and clinical perspectives and then prioritise those that patients, carers and clinicians agree are the most important for research to address.

The objectives of the PSP are to:

- work with patients, carers and clinicians to identify uncertainties about Foot & Ankle conditions, mainly focussing on uncertainties in surgical treatment and their outcomes.
- 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.

The scope of the Foot & Ankle Surgery PSP is defined as:

- Surgical treatments and injections for the treatment of foot & ankle conditions and injuries in adults (over 18yrs)

- Post surgical rehabilitation or injection aftercare

The PSP will exclude from its scope questions about:

- Paediatrics, age less than 18yrs
- Skin and nail conditions
- Non-UK
- Diabetic foot
- Pharmacological interventions or drug treatments (tablets/patches/capsules)
- Prehabilitation
- Genetics and predictors of outcomes
- All non-surgical non-injection treatments
- Anaesthesia
- Diagnosis of foot & ankle conditions
- Prevention of foot & ankle conditions

The Steering Group is responsible for discussing what implications the scope of the PSP will have for the evidence-checking stage of the process. Resources and expertise will be put in place to do this evidence checking.

3. The Steering Group

The Steering Group includes membership of patients and carers and clinicians¹, as individuals or representatives from a relevant group.

The Foot & Ankle Surgery PSP will be led and managed by a Steering Group involving the following:

Patient and carer representative/s:

Amanda Roberts
Steve Ingram
Lewis Cade

Clinical representative/s:

Patricia Allen – Consultant Orthopaedic Foot & Ankle Surgeon
Mark Davies – Consultant Orthopaedic Foot & Ankle Surgeon
Brigitte Scammell – Consultant Orthopaedic Foot & Ankle Surgeon
Noelene Davey – Orthopaedic Physiotherapy Practitioner
Rebecca Kearney – Clinical Associate Professor & Physiotherapist
Lyndon Mason – Consultant Orthopaedic Foot & Ankle Surgeon
Melinda Hau - T&O Specialist Registrar Trainee
Lauren Thomson - Specialty Registrar in Trauma and Orthopaedics
Douglas Grindlay – Information Specialist
Veena Patel – Consultant Rheumatologist
Stephen Lines – Surgical Podiatrist
Karen Alligan – Specialist Lead Foot & Ankle Nurse
Nick Gallogly – Consultant Orthotist

¹ In some cases, it has been suggested that researchers are represented on the Steering Group, to advise on the shaping of research questions. However, researchers cannot participate in the prioritisation exercise. This is to ensure that the final prioritised research questions are those agreed by patients, carers and clinicians only, in line with the JLA's mission.

Project coordinator:
Jitendra Mangwani – Consultant Orthopaedic Foot & Ankle Surgeon

James Lind Alliance Adviser and Chair of the Steering Group:
Katherine Cowan

Project administrator:
Jo Millard

The Steering Group will agree the resources, including time and expertise that they will be able to contribute to each stage of the process, with input and advice from the JLA.

4. Partners

Organisations and individuals will be invited to be involved with the PSP as partners *Arthritis UK, British Chiropody & Podiatry Association (BCPA)*. Partners are organisations or groups who will commit to supporting the PSP, promoting the process and encouraging their represented groups or members to participate. Organisations who can reach and advocate for these groups will be invited to become involved in the PSP. Partners represent the following groups:

- people who have had Foot & Ankle Surgery
- carers of people who have had Foot & Ankle Surgery
- health and social care professionals - with experience of Foot & Ankle Surgery.

Exclusion criteria

Some organisations may be judged by the JLA or the Steering Group to have conflicts of interest. These may be perceived to potentially cause unacceptable bias as a member of the Steering Group. 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 steps through which the PSP aims to meet its objectives. The process is iterative and dependent on the active participation and contribution of different groups. The methods used in any step will be agreed through consultation between the Steering Group members, guided by the PSP's aims and objectives. More details of the method are in the Guidebook section of the JLA website at www.jla.nihr.ac.uk where examples of the work of other JLA PSPs can 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 Foot & Ankle Surgery PSP.

Step 2: Awareness raising

PSPs will need to raise awareness of their proposed activity among their patient, carer and clinician communities, in order to secure support and participation. Depending on budget, this may be done by a face-to-face meeting, or there may be other ways in which the process can be launched, e.g. via social media. It may be carried out as part of steps 1 and/or 3. The Steering Group should advise on when to do this. Awareness raising has several key objectives:

- to present the proposed plan for the PSP
- to generate support for the process
- to encourage participation in the process
- to initiate discussion, answer questions and address concerns.

Step 3: Identifying evidence uncertainties

The Foot & Ankle Surgery PSP will carry out a consultation to gather uncertainties from patients, carers and clinicians. A period of 18 months will be given to complete this exercise (which may be revised by the Steering Group if required).

The Foot & Ankle Surgery PSP recognises that the following groups may require additional consideration. Patients from lower social economic status who may not seek timely advice and treatment for their conditions. There is some evidence in the literature that their outcomes from surgical treatment can be different to the overall outcomes.

The Steering Group will use the following methods to reach the target groups:

- Paper surveys
- Face to face work for patients who are unlikely to access the internet

Existing sources of evidence uncertainties may also be searched:

- question-answering services for patients and carers and for clinicians;
- research recommendations in systematic reviews and clinical guidelines;
- protocols for systematic reviews being prepared
- registers of ongoing research.

Step 4: Refining questions and uncertainties

The consultation process will produce 'raw' questions and comments indicating patients', carers' and clinicians' areas of uncertainty. These raw questions will be categorised and refined by Melinda Hau & Lauren Thomson in conjunction with Douglas Grindlay into summary questions which are clear, addressable by research, and understandable to all. Similar or duplicate questions will be combined where appropriate. Out-of-scope and 'answered' submissions will be compiled separately. The Steering Group will have oversight of this process to ensure that the raw data is being interpreted appropriately and that the summary questions are being worded in a way that is understandable to all audiences. The JLA Adviser will observe to ensure accountability and transparency.

This will result in a long list of in-scope summary questions. These are not research questions and to try and word them as such may make them too technical for a non-research audience. They will be framed as researchable questions that capture the themes and topics that people have suggested.

The summary questions will then be checked against evidence to determine whether they have already been answered by research. This will be done by Douglas Grindlay. The PSP will complete the JLA Question

Verification Form, which clearly describes the process used to verify the uncertainty of the questions, before starting prioritisation. The Question Verification Form includes details of the types and sources of evidence used to check uncertainty. The Question Verification Form should be published on the JLA website as soon as it has been agreed to enable researchers and other stakeholders to understand how the PSP has decided that its questions are unanswered, and any limitations of this.

Questions that are not adequately addressed by previous research will be collated and recorded on a standard JLA template by Jit Mangwani/Katherine Cowan. This will show the checking undertaken to make sure that the uncertainties have not already been answered. 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.

The Steering Group will also consider how it will deal with submitted questions that have been answered, and questions that are out of scope.

Step 5: Prioritisation – interim and final stages

The aim of the final stage of the priority setting process is to prioritise through consensus the identified uncertainties about Foot & Ankle Surgery. This will involve input from patients, carers and clinicians. The JLA encourages PSPs to involve as wide a range of people as possible, including those who did and did not contribute to the first consultation. There are usually two stages of prioritisation.

1. Interim prioritisation is the stage where the long list of questions is reduced to a shorter list that can be taken to the final priority setting workshop. This is aimed at a wide audience, and is done using similar methods to the first consultation. With the JLA's guidance, the Steering Group will agree the method and consider how best to reach and engage patients, carers and clinicians in the process. The most highly ranked questions (around 25) will be taken to a final priority setting workshop. Where the interim prioritisation does not produce a clear ranking or cut off point, the Steering Group will decide which questions are taken forwards to the final prioritisation.

2. The final priority setting stage is generally a one-day workshop facilitated by the JLA. With guidance from the JLA and input from the Steering Group, up to 30 patients, carers and clinicians will be recruited to participate in a day of discussion and ranking, to determine the top 10 questions for research. All participants will declare their interests. The Steering Group will advise on any adaptations needed to ensure that the process is inclusive and accessible.

6. Dissemination of results

The Steering Group will identify audiences with which it wants to engage when disseminating the results of the priority setting process, such as researchers, funders and the patient and clinical communities. They will need to determine how best to communicate the results and who will take responsibility for this. Previous PSPs' outputs have included academic papers, lay reports, infographics, conference presentations and videos for social media.

It should be noted that the priorities are not worded as research questions. The Steering Group should discuss how they will work with researchers and funders to establish how to address the priorities and to work out what the research questions are that will address the issues that people have prioritised. The dissemination of the results of the PSP will be led by Jit Mangwani .

The JLA encourages PSPs to report back about any activities that have come about because of the PSP, including funded research. Please send any details to jla@soton.ac.uk.

7. Agreement of the Steering Group

The Foot & Ankle Surgery PSP Steering Group agreed the content and direction of this Protocol on 11th July 2019.