

Vascular Condition Priority Setting Partnership

Protocol April 2019¹ Version 1²

1. Purpose of the PSP and background

The purpose of this protocol is to openly and transparently set out the aims, objectives and commitments of the Vascular Condition JLA Priority Setting Partnership (PSP). The Protocol is a JLA requirement and will be published on the PSP's page of the JLA website. The Protocol will be regularly reviewed by the Steering Group and any updated version will be sent to the JLA.

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 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 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.

The PSP will cover key areas of vascular conditions in which there is currently a lack of complete evidence to guide practice.

A clinician led DELPHI process has been completed, which incorporated a total of 45 potential areas of vascular practice into which research might be needed. This process has narrowed this total down to 9 key areas in which there is current clinical equipoise, which we would like to take forward into the PSP.

These include the following:

- | | |
|-------------------------------|---|
| ▪ Amputation | ▪ Vascular Access |
| ▪ Aorta | ▪ Venous |
| ▪ Carotid | ▪ Wound Management |
| ▪ Diabetic Foot | ▪ Service Organisation, Access and Delivery |
| ▪ Peripheral Arterial Disease | |

Other categories may emerge from the PSP consultation with patients and carers.

¹ This is a generic protocol which should be updated to include the names and details of the Steering Group members. The document may be modified with agreement from the JLA to reflect the make-up of different PSPs and the organisations driving them.

² The Steering Group is responsible for ensuring any updates or amendments to the PSP plan are included in subsequent versions of the Protocol and sent to the JLA for publication on the website.

2. Aims, objectives and scope of the (health problem) PSP

The aim of the PSP is to identify the unanswered questions about vascular conditions from patient, carer and clinical perspectives, and then prioritise those questions that patients, carers and clinicians agree are the most important for research to address. We aim for this PSP to begin a priority setting process to guide vascular research into the future.

The objectives of the PSP are to:

- work together with patients, carers and clinicians
- to use the JLA approach for prioritisation
- to publicise the results of the PSP and process
- to take the results to research commissioning bodies to be considered for funding.

The Vascular Condition PSP will include in its **scope** questions that are:

- relevant to the clinical areas listed in section 1
- within the UK health care systems
- relate to adult care (age above 18)
- about the diagnosis, management and outcomes of vascular conditions

The PSP will exclude from its **scope** questions about:

- Paediatric care
- Non-UK care

The Steering Group is responsible for discussing what implications the scope of the PSP will have for the evidence-checking stage of the process, with adequate resource and expertise available.

Phase 1: Launch & the Steering Group

Steering group

The PSP will be led by the Steering Group, which includes a balanced number of patients and carers, and professionals, as individuals or representatives from a relevant group.

The Vascular Condition PSP is led and managed by the following:

Clinical Leads: Professor Ian Chetter, Mr George Smith, Mr Tom Wallace
PSP co-ordinator: Judith Long
PSP Information scientist: Judith Long
James Lind Alliance Chair: Toto Anne Gronlund

Patient and carer representative/s from:

The Circulation Foundation
British Heart Foundation
Diabetes UK
PPI groups

Clinical and other professional representative/s:

Venous Forum
Stroke UK
National Association of Assistants in Surgical Practice (NAASP)

The Steering Group agrees the resources, including time and expertise that they are able to contribute to each stage of the process.

Researchers may advise on the Steering Group, but will not participate in prioritisation activities. Clinician scientists may participate in their clinical capacity.

Partners

Our Partners are organisations or groups who are committed to supporting the PSP, promoting the process and encouraging their represented groups or members to participate. Research funders may be partners as long as there is no influence on the Steering Group or process.

Partner organisations will be identified through a process of peer knowledge and consultation, including the Steering Group members' networks.

Partners can represent the following groups:

- People with vascular conditions or who have had vascular surgery
- Carers of people who have vascular conditions or who have had vascular surgery
- Clinicians and other professionals - with experience of vascular conditions or who have had vascular 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.

Launch and Awareness raising

- The PSP will launch at the Vascular Society Conference in Glasgow on 28-30 November 2018. This event will be used to: raise awareness and generate support for the process
- initiate discussion and encourage participation in the process
- present the proposed plan for the PSP.

Phase 2: Identifying uncertainties

This phase of the PSP will carry out a consultation to gather uncertainties from patients, and carers.

A period of three months will be given to the consultation. This timescale may be revised by the Steering Group if required.

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

- online survey
- paper surveys in outpatient clinics
- focus groups (face to face work)

Existing sources of information about evidence uncertainties may also be searched. The starting point for identifying sources of uncertainties and research recommendations is

NHS Evidence: www.evidence.nhs.uk.

Phase 3: Refining questions and uncertainties

The consultation process will produce “raw” questions and comments. These raw questions will be categorised and refined. Similar or duplicate questions will be combined where appropriate into summary questions which are clear and understandable to all, while reflecting the intent of the original raw questions.

Out-of-scope questions 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 accessibly. It should be noted that these are not formatted as research questions. They are framed as researchable questions that capture the themes and questions that people have suggested.

The results of an earlier Delphi survey of clinicians in 2017-2018 (conducted broadly in line with JLA principles), will be incorporated here. The summary questions generated through the patient and carer consultation will be combined with those derived from the clinician Delphi process, again eliminating any duplicates, and reviewing how questions fit in the existing and emergent categories. The Steering Group will confirm the final choice of Categories. This will result in a long list of in-scope summary questions for each Category.

The summary questions will then be checked against evidence to determine whether or not they have already been answered by research. The PSP will complete the JLA Question Verification Protocol which clearly describes the process employed to verify the uncertainty of the questions, before commencing prioritisation. The Question Verification Protocol includes the details of the types and sources of evidence used to ascertain uncertainty.

In the interest of transparency, all summary questions will need to have a complete audit trail of which raw questions contributed to the summary questions, and how they were verified as being unanswered. This information will be submitted to the JLA for publication on its website on completion of the PSP, taking into account any changes made at the final workshop, in order to ensure that PSP results are publicly available. The Question Verification Protocol will be submitted at this point, to be published alongside the questions to enable researchers and other stakeholders to understand how the PSP has decided that its questions are unanswered, and any limitations therein.

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

Phase 4: Interim prioritisation

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.

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 also 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.

Each category, if it has more than 25 summary questions, will undergo interim prioritisation. Professionals and patients/carers may choose to complete prioritisation for either one or more categories of which they have personal experience.

The most highly ranked questions (around 20-25) will be taken to a final priority setting workshop. If 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.

Phase 5: Final prioritisation

The final priority setting stage is generally a one day consensus workshop facilitated by the JLA. With guidance from the JLA and input from the Steering Group, up to 30 patients/carers and professionals 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 required to ensure that the process is inclusive and accessible.

The PSP plans to ensure there is a final prioritisation for each category, as it would not be practicable to rank across the categories. With guidance from the JLA, the Steering Group will consider options for a cost effective and practical way of achieving this, including holding several final consensus workshops.

Phase 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 also 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 JLA encourages PSPs to report back about any activities which have come about as a result of the PSP, including funded research. Please send any details to jl@oton.ac.uk.

7. Agreement of the Steering Group

The Vascular Condition PSP Steering Group agreed the content and direction of this Protocol on 23.04.19.