James Lind Alliance
Priority Setting Partnerships

Venous Thromboembolism JLA Priority Setting Partnership
PROTOCOL 30April2019 Version 1.1

1. Purpose of the PSP and James Lind Alliance

The purpose of this protocol is to clearly set out the aims, objectives and commitments of the Venous Thromboembolism (VTE) 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.

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.

Further details about the JLA and PSPs are at http://www.jla.nihr.ac.uk/. The JLA Guide and useful templates and examples are available on the website for viewing and downloading.

The VTE PSP is an initiative of the Canadian Venous Thromboembolism Clinical Trials and Outcomes Research (canVECTOR) network. CanVECTOR is a Canadian Institute of Health Research (CIHR) funded community development program centred on VTE related research, training, and knowledge translation. The mission statement of CanVECTOR is: "To decrease the health, social and economic burden of VTE on affected individuals, their families, and on Canadians as a whole." The VTE PSP represents a joint initiative between CanVECTOR Patient Partner members, researchers, and clinicians to establish a list of unanswered research questions related to the prevention, diagnosis, management and long term impact of VTE and its associated treatments on patients, carers, and their families.

2. Aims, objectives and scope of the PSP

The aim of the PSP is to identify the unanswered questions about venous thromboembolism (pulmonary embolism, PE, deep vein thrombosis, DVT) 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 PSP will help ensure that those who fund health research are aware of what really matters to patients, carers and clinicians.

The objectives of the PSP are to:

- work with patients, carers and clinicians to identify uncertainties about the prevention, diagnosis, management and long term impact of VTE and its associated treatments on patients, carers, and their families.
- to agree by consensus a prioritised list of those uncertainties, for research
- to publicise the results of the PSP and process
- to use the results to prioritize research created and supported by CanVECTOR and the strategic priorities of the network
- to take the results to research commissioning bodies to be considered for funding

The scope of the PSP is defined as:

- the prevention, diagnosis, management and long term impact of VTE and its associated treatments on patients, carers, and their families.

The scope of the PSP excludes:

- cardiac conditions such as coronary artery disease, atrial fibrillation and ischemic stroke
- peripheral arterial vascular disease
- thrombotic conditions specific only to children (pediatrics)
- provincial access to care and administration of services

The Steering Group is responsible for considering what implications the scope of the PSP will have for the data analysis and evidence-checking stage of the process, mindful that time and expertise needs to be available for this work.

3. The Steering Group

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

The PSP will be led and managed by a Steering Group involving the following:

Patient and carer representative/s:

Carol West, patient partner, Ottawa

Jacqueline Russell, patient partner, Ottawa

Suzanne Dubois, patient partner, Brantford

Margaret Ostrowski, patient partner, Vancouver

Danielle Morneault, patient partner, Ottawa

Jessica Zambito, patient partner, Toronto

Clinical representative/s:

Lisa Duffett, physician, thrombosis, The Ottawa Hospital

Jessica Emed, nurse specialist, Jewish General Hospital

Leslie Skeith, physician, thrombosis, Alberta Health Services

Kristin De Wit, physician, emergency medicine, Hamilton Health Sciences

Lori Ann Linkins, physician, thrombosis, Juravinski Hospital Hamilton

Nancy MacDonald, nurse practitioner, Cornwall Community Hospital

Project coordinator:

Debbie Witham, clinical research nurse coordinator, Ottawa

Charlotte Guzman, CanVECTOR network manager (Maryam Ebrahimi parental leave replacement)

James Lind Alliance Adviser and Chair of the Steering Group:

Toto Gronlund, JLA advisor

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 [eg. Thrombosis Canada, CanVECTOR, Heart and Stroke Foundation of Canada, National Blood Clot Alliance, Clots Matter.

May-Thurner Syndrome Resource Network]. 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 which 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 venous thromboembolic conditions, DVT or PE
- carers of people who have had venous thromboembolic conditions, DVT or PE
- health and social care professionals - with experience of venous thromboembolic conditions, DVT or PE

Exclusions

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 by the Steering Group, 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 .

Step 1: Identification and invitation of potential partners

Potential partner organisations will be identified through a process of peer knowledge and consultation, and through the Steering Group members' networks. Potential partners will be contacted and informed of the establishment and aims of the PSP, and invited to participate. As partners, they are expected to support the PSP in communications and dissemination, and may benefit from having their logo displayed on official PSP documents and websites.

Step 2: Awareness raising

PSPs will raise awareness of their proposed activity among their patient, carer and clinician communities, in order to secure support and participation. This will include a description of the VTE PSP in the CanVECTOR newsletter and through CanVECTOR social media campaign (twitter). The @CanVECTOR Twitter handle will be used to send updates on the project with reference to a hashtag specific to the VTE PSP (#ClotTop10) will be promoted.

Awareness raising has several 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 PSP will carry out a consultation to gather uncertainties from patients, carers and clinicians. A period of approximately 75 days will be given to complete this exercise (which may be revised by the Steering Group if required).

The Steering Group will use the following methods to reach the target groups. The aim is to be inclusive.

- Online survey distributed through partner organizations, created using Survey Monkey software and hosted on the CanVECTOR web server.
- Paper survey and/or paper promotional cards linked to online survey distributed within clinics throughout Canada caring for patients with VTE (targeting patient, carers and clinicians within each clinic)
- Social media campaign distributed through CanVECTOR

Existing sources of evidence uncertainties:

- searching clinical practice guidelines with moderate to weak quality of evidence supporting recommendations and where recommendations for future research identified.
- Research recommendations identified in Cochrane systematic reviews
- Previous CanVECTOR clinician survey

The time allocated to collate, analyse and categorise responses will be approximately 45 days.

Step 4: Refining questions and uncertainties

The consultation process will gather 'raw' questions and comments from patients, carers and clinicians. These raw questions will be analysed and refined by PSP information specialist and steering committee members 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' 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 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. Evidence checking will be done by systematic literature searching for published systematic reviews and clinical practice guidelines. The literature search will be lead by an experienced research librarian. If a treatment uncertainty is identified through the PSP that cannot be verified using evidence checking with existing systematic reviews or guidelines, then the project lead and steering committee will review and discuss and make a consensus decision on a way of proceeding, such as conducting a new systematic review. This process will be led by the PSP information specialist and project leads, Lisa Duffett and Jessica Emed. This will be reviewed and finalized by the steering committee.

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 verified unanswered questions will be recorded on a standard JLA template by the PSP information specialist. This will show the verification undertaken for each question to make sure that the question has not already been answered by research.

The data will 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, along with the the Question Verification Form. This will enable researchers and other stakeholders to understand how the PSP has decided that its questions are unanswered, and any limitations of this.

The Steering Group will also consider how it will deal with submitted questions that have been answered, and questions that are out of scope. This may include publication of such lists through CanVECTOR network.

Step 5: Prioritisation – interim and final stages

Prioritisation of the summary questions will involve input from a wide range of patients, carers and clinicians. There will be two stages of prioritisation.

1. Interim prioritisation is the stage where the long list of summary questions is reduced to a shorter list that can be taken to the final priority setting workshop. With the JLA's guidance, the Steering Group will engage additional individuals, such as patients, clinicians and clinician researchers selected to ensure balanced perspectives represented. The most highly ranked questions (around 20-25) 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 will be 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 from the short

list of 20-25. All participants will be asked to make a Declaration of Interests, to support transparency. The Steering Group will advise on any adaptations needed to ensure that the process is inclusive and accessible.

6. Dissemination of results

The findings of the VTE PSP will be reported to funding and research agenda setting organizations such as Canadian Institutes for Health Research, Social Sciences and Humanities Research Council, Heart and Stroke Foundation of Canada, Canadian Venous Thromboembolism Clinical Trials and Outcomes Research Network, International Network of Venous Thromboembolism Clinical Research Networks, International Society of Thrombosis and Haemostasis.

The findings will be submitted to relevant peer reviewed scientific journals in the field and to international scientific meetings.

The findings will be promoted through distributions of partnering organizations and their associated communication channels (email, newsletters, websites and social media).

Promotion targeting the general population will be through press release to national and local media outlets and through patient groups identified during the PSP process.

It should be noted that the priorities are not worded as research questions. The Steering Group 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 questions that people have prioritised. The dissemination of the results of the PSP will be led by the PSP project leads Lisa Duffett and Jessica Emed.

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 VTE PSP Steering Group agreed the content and direction of this Protocol on [insert date].