

## **Epilepsy Priority Setting Partnership**

### **PROTOCOL June 2019 Version 2**

## **1. Purpose of the PSP and background**

The purpose of this protocol is to clearly set out the aims, objectives and commitments of the epilepsy 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](http://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.

Epilepsy is a brain disorder that affects 1 in 100 people worldwide and is characterized by repeated, unprovoked seizures. Epilepsy can develop at any point during the lifespan, and in most cases the cause is unknown. 1 in 3 people with epilepsy has seizures that cannot be controlled with medication and will require more innovative treatment options. Seizures can range from full-body convulsions to blank stares, and in some circumstances can be life-threatening. Uncontrolled seizures can significantly diminish quality of life due to the presence of stigma, social isolation, the inability to drive and/or to work and live independently. Epilepsy is associated with a number of physical and psychiatric comorbidities, including depression, anxiety, migraines, osteoporosis, developmental delays and cognitive impairment. Even in those with well-controlled seizures, the side effects of anti-seizure medications can be substantial and may include memory loss, fatigue, and emotional disturbance.

A considerable number of unanswered questions exist related to the diagnosis and treatment of epilepsy. This PSP will be the first such initiative to address epilepsy in Canada, and we hope that the results of this PSP will re-shape the research agenda for epilepsy, giving a stronger voice to the patients, carers and clinicians who live and work with epilepsy every day.

## **2. Aims, objectives and scope of the PSP**

The aim of this PSP is to identify the unanswered questions about epilepsy 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 the diagnosis, treatment and care of epilepsy

- 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 epilepsy PSP is defined as:

- Diagnosis and cause
- Treatment options
- Care and management (includes social, emotional and psychological well-being)
- Co-existing conditions

The PSP will exclude from its scope questions about:

- Access to services
- Treatment of epilepsy outside of Canada

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 clinicians<sup>1</sup>, as individuals or representatives from a relevant group.

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

Patient and carer representative/s:

Terry Boyd, parent/caregiver

Deirdre Floyd, Canadian Epilepsy Alliance/Epilepsy Maritimes

Joanna Kapusta, Epilepsy Toronto

Donovan McKenzie, Epilepsy Toronto

Cheryl Mendes, Epilepsy Toronto

Kristi Nysten-Burns, parent/caregiver

Mary Secco, Secretary General, International Bureau for Epilepsy

Clinical representative/s:

James Deutsch, Child Psychiatrist, University of Toronto

Paolo Federico, Neurologist, University of Calgary

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<sup>1</sup> 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.

Evan Lewis, Neurologist, Neurology Centre of Toronto

Marcus Ng, Neurologist/Epileptologist, University of Manitoba

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Project coordinators (Project Team):

Rebecca Woelfle, Communications Lead, EpLink

Amaya Singh, Program Manager, EpLink

Carla Southward, Senior Lead, Knowledge Translation

James Lind Alliance Adviser and Chair of the Steering Group:

Katherine Cowan, JLA Adviser

Jorge Burneo, Epileptologist, Chair of the Steering Group

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 [*this section should be updated as partners are confirmed*]. 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 epilepsy
- carers of people who have had or do have epilepsy
- health and social care professionals - with experience in treating people with epilepsy

### 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](http://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 epilepsy 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 epilepsy PSP will carry out a consultation to gather uncertainties from patients, carers and clinicians. A period of three months will be given to complete this exercise (which may be revised by the Steering Group if required).

The epilepsy PSP recognises that the following groups may require additional consideration:

- Populations living in remote communities
- Marginalized populations
- Caregivers
- People living with epilepsy as a result of another disease or disorder, such as Rett Syndrome, cerebral palsy, vascular disease, etc.

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

- Our steering committee includes a clinician with experience working in remote areas on Ontario, who also runs a telemedicine practice
- Partner organizations
- A communication strategy developed by the project team and steering group

Existing sources of evidence uncertainties may also be searched. These can include question/answering services for patients and caregivers and for clinicians; research recommendations in systematic reviews and clinical guidelines; protocols for systematic reviews being prepared, and 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 the information specialist 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 the information specialist and verified by members of the steering group. 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 the Project Team. 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 epilepsy. 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 the Project Team].

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](mailto:jla@soton.ac.uk).

## 7. Agreement of the Steering Group

The Epilepsy PSP Steering Group agreed the content and direction of this Protocol on June 27, 2019.