

## **Idiopathic Intracranial Hypertension (IIH) Priority Setting Partnership**

**PROTOCOL JANUARY 2017<sup>1</sup>**

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

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

IIH is currently under-researched and there are currently no national clinical guidelines for the diagnosis and treatment of IIH, which varies widely across the country. In the last decade, an estimated 24,000 people have been diagnosed with IIH in the UK, which is predicted to rise with the increasing global prevalence of obesity.

IIH predominantly affects overweight women of childbearing age and up to 25% of patients can lose vision permanently. In those with severely affected vision, surgery may be indicated. For the majority, it can be a chronic condition with increased healthcare costs, impacting quality of life and the ability to work.

The current Cochrane review highlighted only two clinical trials in IIH and although they showed modest benefits for acetazolamide for some outcomes, there is insufficient evidence to recommend or reject the efficacy of this intervention, or any other treatments currently available, for treating people with IIH.

By bringing patients, carers and clinicians together in this JLA partnership, we hope that this will ensure that shared priorities for research and treatment of IIH are identified.

### **2. Aims and objectives of the IIH PSP**

The aim of the IIH PSP is to identify the unanswered questions about IIH diagnosis, pathogenesis, treatment and care provision (acute and chronic management) from patient and clinical perspectives and then prioritise those that patients and clinicians agree are the most important.

The objectives of the IIH PSP are to:

- work with patients and clinicians to identify uncertainties about diagnosis, pathogenesis, treatment and care provision (acute and chronic management) in adult (16+) IIH.

- 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.

### 3. The Steering Group

The IIH PSP will be led and managed by the following:

Patient representative/s:

- Lead: Krystal Hemmings
- Project Co-ordinator: Michelle Williamson
- Rachel Bennett
- Martin Plowright
- Tracey Ritson
- Norma-Ann Dann
- Amanda Denton

Clinical representative/s:

- Clinical lead: Dr Alex Sinclair (Consultant Neurologist and Clinical Scientist, University Hospitals Birmingham)
- Dr Anita Krishnan (Consultant Neurologist, The Walton Centre)
- Miss Susan Mollan (Consultant Neuro-ophthalmologist, University Hospitals Birmingham)
- Miss Jayne Best (Consultant Ophthalmologist, Royal Victoria Hospital Belfast)
- Dr Arun Chandran (Consultant Neuroradiologist, The Walton Centre)
- Mr Ahmed Toma (Consultant Neurosurgeon, National Hospital for Neurology & Neurosurgery)
- Mr Kamal Mahawar (Consultant General and Bariatric Surgeon, City Hospitals Sunderland NHS Foundation Trust)
- Sister Julie Edwards (Clinical Nurse Specialist for Headache, University Hospitals Birmingham)
- Dr Caroline Rick (Neuroscience Team Leader, University of Birmingham)
- Dr Kamal Mahawar, (Consultant Surgeon, Sunderland Royal Hospital)

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

- The James Lind Alliance (JLA)

JLA adviser: Maryrose Tarpey

The Steering Group includes representation of patient/carer groups and clinicians.

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 IHH
- Carers of people who have had IHH
- Medical doctors, nurses and professionals allied to medicine with clinical experience of IHH.

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.

Confirmed Partners: Shine, Neurological Alliance, SBNS CSF Subgroup - The Society of British Neurological Surgeons, ABN - Association of British Neurologists, BASH - British Association for the Study of Headache, BIOS - British and Irish Orthoptic Society, UKNOSIG - The United Kingdom Neuro-Ophthalmology Special Interest Group, RCO - Royal College of Ophthalmologists, Fight for Sight.

### 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](http://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 IHH PSP and may be invited to attend and participate in an initial stakeholder meeting if this is being arranged.

### Step 2: Initial stakeholder meeting / awareness raising

The initial stakeholder meeting / awareness raising will have several key objectives:

- To welcome and introduce potential members of the IHH PSP
- To present the proposed plan for the PSP

- To initiate discussion, answer questions and address concerns
- To identify those potential partner organisations which will commit to the PSP and identify individuals who will be those organisations' representatives and the PSP's principal contacts
- To establish principles upon which an open, inclusive and transparent mechanism can be based for contributing to, reporting and recording the work and progress of the PSP.

### **Step 3: 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 IIH. 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. 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](http://www.evidence.nhs.uk).

### **Step 4: Refining questions and uncertainties**

The Steering Group will need to have agreed exactly who will be responsible for this stage – the JLA can advise on the amount of time likely to be required for its execution. The JLA will participate in this process as an observer, to ensure accountability and transparency.

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 an information specialist 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 experts in the field to see to what extent these refined questions have, or have not, been answered by previous research. Sometimes, uncertainties are expressed that can in fact be resolved with reference to existing research evidence - ie they are "unrecognised knowns" and not uncertainties. If a question about treatment effects can be answered with existing information but this is not known, it suggests that information is not being communicated effectively to those who need it. Accordingly, the JLA recommends strongly that PSPs keep a record of these 'answerable questions' and deal with them separately from the 'true uncertainties' considered during the research priority setting process.<sup>2</sup>

Uncertainties which are not adequately addressed by previous research will be collated and recorded on a template supplied by the JLA) by the PSP leads. 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 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 relating to the treatment or management of IIH. 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. There are examples of how other PSPs have achieved this at [www.jla.nihr.ac.uk](http://www.jla.nihr.ac.uk) in the Key Documents of the [Anaesthesia and Perioperative Care PSP](#) section and the [Childhood Disability PSP](#) section.
- The final stage, to reach, for example, 10 prioritised uncertainties, is likely to be conducted in a face-to-face meeting, using group discussions and plenary sessions.
- The methods used for this prioritisation process will be determined by consultation with the partner organisations and with the advice of the JLA Adviser. Methods which have been identified as potentially useful in this process include: adapted Delphi techniques; expert panels or nominal group techniques; consensus development conference; electronic nominal group and online voting; interactive research agenda setting and focus groups.

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.

## 6. Dissemination of findings and research

### Findings and research

It is anticipated that the findings of the IIH 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 the IIH 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

### Signed by the Steering Group

The undersigned agree to follow the IIH Priority Setting Protocol on behalf of the steering group.

Krystal Hemmings  
Date: 08/03/2017

Michelle Williamson  
Date: 08/03/2017

Alex Sinclair  
Date: 08/03/2017

Maryrose Tarpey  
Date: 08/03/2017