# Hyperhidrosis Priority Setting Partnership

**PROTOCOL July 2017**

## 1. Purpose of the PSP and background

The purpose of this protocol is to set out the aims, objectives and commitments of the Hyperhidrosis 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) 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.

Hyperhidrosis is a common skin condition characterised by abnormal levels of sweating, and is very common, affecting 1 -3 % of the population. It affects both sexes and all races equally. It can cause both physical problems and psychological distress, and significantly affect quality of life.

Despite its prevalence hyperhidrosis is relatively under-researched compared with other skin conditions with similar prevalence. There are only three clinical trials for hyperhidrosis recruiting worldwide, and none in the UK. In contrast, psoriasis (UK prevalence 1.5%) has 160 clinical trials, including 13 in the UK. Therefore, is it imperative that the profile of this condition is raised, and national funding bodies are made aware of the most important research questions that need to be addressed.

For the purpose of the PSP a patient is defined as someone who has been diagnosed or is self-diagnosed, and includes people of all ages, genders and ethnicities.

## 2. Aims and objectives of the Hyperhidrosis PSP

The aim of the Hyperhidrosis PSP is to identify the unanswered questions about hyperhidrosis treatment and management from patient and clinical perspectives and then prioritise those that patients and clinicians agree are the most important.

The objectives of the Hyperhidrosis PSP are to:

- work with patients and clinicians to identify uncertainties about the effects of hyperhidrosis treatment and management
- 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 Hyperhidrosis PSP will be led and managed by the following:

Academic representatives:

- De Montfort University
    - Louise Dunford (PSP Lead)
    - Andrew Clifton (Information Specialist)
- UK Dermatology Clinical Trials Network
    - Maggie McPhee

Patient representatives:

- Richard Oliver from the Hyperhidrosis Support Group UK
- PB
- HB
- RM
- KH

Clinical representative/s:

- Dr Anton Alexandroff (Consultant Dermatologist & PSP Deputy Lead)
- Dr Rodney Warner (GP)
- Kathy Radley (Nurse)
- Ms Maharukh Daruwalla (Consultant Plastic Surgeon)
- Dr Louise McDonald (Dermatology Registrar)

Administrative team:

Hana Amber Hussain (PSP co-ordinator)

Janice Miller (PSP co-ordinator)

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

- The James Lind Alliance (JLA)
    - Maryrose Tarpey

The Steering Group includes representation of patient/carer groups and clinicians[1]. 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 hyperhidrosis, e.g. Hyperhidrosis UK Support Group
- carers of people who have had hyperhidrosis
- medical doctors, nurses and professionals allied to medicine with clinical experience of hyperhidrosis e.g. British Association of Dermatologists, British Dermatology Nursing Group, British Chiropody and Podiatry Association
- wider partners who can help reach a wide population, e.g. Age UK

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.

**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,

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[1] In some cases, it has been suggested that researchers are represented at this level, 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.

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 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 Hyperhidrosis PSP.

### Step 2: 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 of hyperhidrosis. A period of 6 – 8 weeks 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.

### Step 3: 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 the Information specialist group (Lead: Andrew Clifton) 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 Louise Dunford & Anton Alexandroff 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 - i.e. 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.

Uncertainties which are not adequately addressed by previous research will be collated and recorded on a template supplied by the JLA) by the PSP Co-ordinator (Hana Hussain). 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 4: 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 hyperhidrosis. 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 50 – 70 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 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.

- Nominal group techniques will used for this prioritisation process with the advice of the JLA Adviser.

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 Hyperhidrosis PSP will be reported to funding and research agenda setting organisations such as the NIHR and the major research funding charities. In addition, dermatology related research funders will also be reported to. 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 Hyperhidrosis 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 Hyperhidrosis Priority Setting Protocol.

**Louise Dunford**

**Andrew Clifton**

**Anton Alexandroff**

**Maggie McPhee**

**Richard Oliver**

**PB**

**HB**

**RM**

**KH**

**Rodney Warner**

**Kathy Radley**

**Louise McDonald**

**Maharukh Daruwalla**

**Maryrose Tarpey, The James Lind Alliance**

**Hana Hussain**

**Janice Miller**

The protocol was formally agreed and signed off at the committee meeting on 7th September 2017.