

Endometriosis Priority Setting Partnership

PROTOCOL 20 January 2016

1. Purpose of the PSP and background

The purpose of this protocol is to set out the aims, objectives and commitments of the Endometriosis 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 JLA is coordinated and overseen by the National Institute for Health Research ([NIHR](#)) Evaluation, Trials and Studies Coordinating Centre, based in Southampton ([NETSCC](#)).

Endometriosis is a chronic condition that is associated with persistent pelvic pain, pain during menstruation, pain during sexual intercourse, and infertility. It is defined by the presence of endometrial tissue implanted in ectopic sites, usually within the peritoneal cavity. Endometriosis is estimated to affect 6-10% of women of reproductive age. Endometriosis is managed surgically or medically, but symptoms recur after surgery in ~75% of women, and available medical treatments have undesirable side effects. A key barrier to treating endometriosis is that the exact aetiology of the disease is not yet well understood. In comparison to other gynaecological complications, endometriosis is significantly under-researched. One of the major issues identified as impacting on the capacity to undertake endometriosis research is the need for multidisciplinary expertise, in conjunction with sufficient funding to allow meaningful projects to be undertaken. A PSP is urgently required to identify the research priorities so that research efforts can be co-ordinated appropriately.

2. Aims and objectives of the Endometriosis PSP

The aim of the endometriosis PSP is to identify the unanswered questions about endometriosis from patient and clinical perspectives and then prioritise those that patients and clinicians agree are the most important. The scope of the endometriosis PSP will include cause, diagnostic approaches, treatment options (including lifestyle factors), prevention and awareness.

The objectives of the endometriosis PSP are to:

- work with patients and clinicians to identify uncertainties about endometriosis
- 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 Endometriosis PSP will be led and managed by the following:

- Patient representative/s:

Jane Hudson Jones, Endometriosis UK
Judy Birch, Pelvic Pain Support Network
Mary Heslin, Endometriosis Association of Ireland
Lyndsey Hogg, patient (Edinburgh)

- Clinical representative/s:

Christian Becker, Gynaecologist, Oxford
Dharani Hapangama, Gynaecologist, Liverpool
Andrew Horne, Gynaecologist, Edinburgh (lead)
Rajiv Chawla, Pain Medicine Specialist (Anaesthetist), Liverpool
Uma Marthi, GPwSI, Rochdale
Wendy Mitchell, Specialist Endometriosis Nurse, Surrey
Sarah Edwards, Clinical Psychologist, UCLH, London

- Additional (non-voting) steering group members:

Philippa Saunders, Edinburgh
Krina Zondervan, Oxford
Lone Hummelshoj, WERF
Ibtisam Abokhrais, Clinical Research Fellow, Edinburgh (PSP Coordinator)
Jackie Young, Administrator, Edinburgh (PSP Administrator)

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

- Leanne Metcalf, The James Lind Alliance (JLA)

The Steering Group includes representation of patient/carer groups and clinicians¹.

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:

- women who have/have had endometriosis

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.
James Lind Alliance: Priority Setting Partnership Protocol June 2015

- carers/partners/children/friends of women who have endometriosis
- medical doctors, nurses and professionals allied to medicine with clinical experience of caring for women with endometriosis.

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, guided by the PSP's aims and objectives. More details can be found at www.JLAguidebook.org and examples of the work of other JLA PSPs can be seen on 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, through the Steering Group members' networks. Potential partners will be contacted and informed of the establishment and aims of the endometriosis PSP and invited to join the PSP as partners, which will in turn support the delivery of the PSP's objectives.

- Partners will be written to by email to introduce the PSP and present the proposed plan for it, initiate discussion, answer questions and address concerns, and 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.

Step 2: Identifying treatment uncertainties

Each partner will help to solicit from its members questions and uncertainties of practical clinical importance relating to the scope of the Endometriosis PSP via an online survey. A period of approximately eight 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, internet message boards, social media, conferences and newsletters.

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 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 [insert name/s] 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 Ibtisam Abokhrais 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 Ibtisam Abokhrais. 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 scope of the Endometriosis PSP. 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), is likely to be carried out via an online survey, whereby partners consult their contacts and individuals 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
- 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 endometriosis 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.²

Publicity

As well as alerting funders, partners and Steering Group members are encouraged to publish the findings of the endometriosis 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

² Add further detail here about how and where the priorities will be developed and researched.
James Lind Alliance: Priority Setting Partnership Protocol June 2015