

Miscarriage Priority Setting Partnership

Protocol

The purpose of this protocol is to set out the aims, objectives and commitments of the Miscarriage Priority Setting Partnership (PSP) and the basic roles and responsibilities of the partners therein. This document was discussed during the inaugural meeting of the Miscarriage PSP Steering Group. The template was then completed accordingly and finalised after the meeting, and then recirculated amongst the Steering Group for agreement and signatures.

Steering Group

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

Representatives of women, their partners and families:

- The Miscarriage Association
 - Barbara Hepworth-Jones
 - Nicola Southall
- The Royal College of Obstetricians and Gynaecologists (RCOG) Women's Network
 - Julie Orford
 - Sophie Willetts
 - Emily O'Toole
 - Lucy Easthope
- Scottish Care & Information on Miscarriage (SCIM)
 - Maureen Sharkey
- Tommy's
 - Jane Brewin

Clinical representatives:

- University of Nottingham
 - Dr Matthew Prior (PSP Coordinator)
 - Professor Jim Thornton
 - Dr Nick Raine-Fenning
- Royal College of Nursing
 - Carmel Bagness
- Royal College of Obstetricians and Gynaecologists
 - Professor Lesley Regan

- University of Warwick
 - Professor Siobhan Quenby
- University of Birmingham
 - Professor Arri Coomarasamy
- Sunderland Royal Hospital
 - Dr Kim Hinshaw

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

- The James Lind Alliance (JLA)
 - Leanne Metcalf

The Steering Group includes representation of patient¹ 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.

Background to the Miscarriage PSP

The JLA is an initiative that is overseen by the National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre (NETSCC). Its aim is to provide an infrastructure and process to help patients and clinicians work together to agree which are the most important treatment uncertainties affecting their particular interest, in order to influence the prioritisation of future research in that area. The JLA defines an uncertainty as a “known unknown” – in this case relating to the effects of treatment.

The PSP was conceived by the University of Nottingham with the Miscarriage Association acting as a patient group partner. Other key stakeholder groups and organisations were identified through a process of mind mapping and they were approached to identify suitable individuals to form a steering group.

Aims and objectives of the Miscarriage PSP

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

The objectives of the Miscarriage PSP are to:

- work with patients and clinicians to identify uncertainties about the effects of miscarriage treatments/interventions

¹ Wherever the term ‘patient’ is referred to within this Miscarriage PSP documentation, it should be interpreted as ‘women, their partners and families’. Patient is the term typically used by the James Lind Alliance within PSPs to describe those directly affected by a condition or health event.

- agree by consensus a prioritised list of those uncertainties, for research
- publicise the results of the PSP and process
- take the results to research commissioning bodies to be considered for funding

Partners

Organisations and individuals will be invited to take part in the PSP, which represent the following groups:

- people who have experienced miscarriage, directly or indirectly
- medical doctors, nurses, midwives, sonographers and other professionals allied to medicine with clinical experience of miscarriage

It is important that all organisations that can reach and advocate for these groups should be invited to become involved in the PSP. The JLA will take responsibility for ensuring the various stakeholder groups are able to contribute equally to the process.

Individuals and organisations wishing to participate in the PSP will be asked to declare any interests they have which may conflict with the aims of the Miscarriage PSP or the JLA as a whole.

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.

Methods

This section describes the stages through which the PSP will 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 (and where relevant the wider partners), guided by the PSP's aims and objectives. More details and examples can be found at www.JLAGuidebook.org.

1. Identification and invitation of potential partners

Once the Steering Group has been conceived, other potential partner organisations will be identified through a process of peer knowledge and consultation, largely through the Steering Group members' networks. Potential partners will be contacted and informed of the establishment and aims of the Miscarriage PSP and invited to take part. The Steering Group should draft the invitation, and an agreement should be reached as to the best individual/organisation to distribute it to encourage the potential partner to join.

2. Inaugural Steering Groups meeting

The inaugural Steering Group meeting has several key objectives:

- to welcome and introduce members of the Miscarriage PSP Steering Group
- 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
- to 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.

3. Identifying treatment uncertainties

The Steering Group will oversee the development of an online survey to generate questions and uncertainties of practical clinical importance relating to the treatment and management of miscarriage. Each partner will be asked to disseminate the survey to its members and promote it widely via relevant and timely communication channels. A period of c.8 weeks will be given to allow respondents to complete this survey. The steering group will ensure that the survey is distributed to a diverse range of women, their partners and families, and clinicians.

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 on-going research.

The starting point for identifying sources of uncertainties and research recommendations is NHS Evidence: www.evidence.nhs.uk.

4. Refining questions and uncertainties

The Steering Group will need to have agreed exactly who will be responsible for this stage early on to ensure the task is completed (this allocation of responsibility may need to be revised depending on the success of the initial survey) – 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 Miscarriage. These raw questions will be assembled and categorised and refined by Research Fellow Dr Matthew Prior, into “collated indicative questions” which are clear, addressable by research and understandable to all. Similar or duplicate

questions will be combined where appropriate. A face-to-face Steering Group meeting may be convened to review these.

The existing literature will be researched by Research Fellow Dr Matthew Prior 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. The Steering Group will consider how this will work and involve partner organisations where necessary.

Uncertainties which are not adequately addressed by previous research will be collated and prepared for entry into a Miscarriage section within the UK Database of Uncertainties about the Effects of Treatments (UK DUETs - www.library.nhs.uk/duets) by Research Fellow Dr Matthew Prior. This will ensure that the uncertainties have been actually checked to be uncertainties. **This is the responsibility of the Steering Group, which will need to have agreed personnel and resources to carry out this accountability.** The data should be entered into UK DUETs on completion of the priority setting exercise, in order to ensure any updates or changes to the data have been incorporated beforehand.

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 Miscarriage. This will be carried out by members of the Steering Group and the wider partnership that represents patients and clinicians.

The interim stage, to begin proceeding from a long list of uncertainties to a shorter list which can form the basis of a second survey will be carried out by the Steering Group over email and teleconference (and possibly a face-to-face meeting). Once there is a manageable list of uncertainties to be prioritised (c.50), teleconference partners will be asked to consult their membership and choose their top 10 most important uncertainties via a second online survey.

The final stage, which aims to reach 10 prioritised uncertainties, will be conducted in a face- to-face workshop, 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.

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.

Findings and research

It is anticipated that the findings of the Miscarriage PSP will be reported to funding and research agenda setting organisations such as the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), which includes the HTA Programme, and the MRC, as well as the major research funding charities. Steering Group members and partners are encouraged 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 Miscarriage PSP using both internal and external communication mechanisms. The JLA may also capture and publicise the results, through descriptive reports of the process itself. 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.

Signed by the Steering Group

The undersigned agree to follow the Miscarriage Priority Setting Protocol.

Barbara Hepworth-Jones, The Miscarriage Association

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Date:

Nicola Southall, The Miscarriage Association

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Date:

Julie Orford, The Royal College of Obstetricians and Gynaecologists (RCOG)
Women's Network

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Date:

Sophie Willetts, The Royal College of Obstetricians and Gynaecologists (RCOG)
Women's Network

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Emily O'Toole, The Royal College of Obstetricians and Gynaecologists (RCOG)
Women's Network

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Date:

Lucy Easthope, The Royal College of Obstetricians and Gynaecologists (RCOG)
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Maureen Sharkey, Scottish Care & Information on Miscarriage (SCIM)

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Professor Siobhan Quenby, University of Warwick

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Professor Arri Coomarasamy, University of Birmingham

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Date:

Dr Kim Hinshaw, Sunderland Royal Hospital

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Date:

Leanne Metcalf, The James Lind Alliance

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Date:

Protocol Appendix 1 - James Lind Alliance Miscarriage Priority Setting Partnership timeline 2014-2016

TASK	12/14	1/15	2/15	3/15	4/15	5/15	6/15	7/15	8/15	9/15	10/15	11/15	12/15	1/16	2/16	3/16	4/16	5/16	6/16	7/16	8/16	9/16	
PSP accepted & JLA Adviser allocated																							
Identify possible SG members																							
Draft SG terms of reference & protocol																							
Approach SG members																							
Inaugural SG meeting								SG F2F															
Sign off SG ToR & protocol, including scope																							
SG teleconferences									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Design & pilot survey to collect uncertainties																							
Draft website & plan publicity strategy																							
Agree website											SG F2F												
Agree final version of 1 st survey											SG F2F												
Activate & maintain publicity																							
1 st survey open																							
Start to collate																							

