

## Diabetes and Pregnancy Priority Setting Partnership

### PROTOCOL 26/04/2019<sup>1</sup> Version 1.0<sup>2</sup>

## 1. Purpose of the PSP and background

The purpose of this protocol is to clearly set out the aims, objectives and commitments of the Diabetes and Pregnancy 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.

One in 250 pregnancies in the UK is affected by type 1 or 2 diabetes, and up to 5% of births are affected by gestational diabetes. The rate is increasing. Rates are similar in other high resource settings, and are expected to increase in Low-Middle Income Countries (LMIC), with as many as one in six pregnancies affected by hyperglycaemia. Compared to the population of women without diabetes, the risks are two to six times greater for adverse outcomes such as stillbirth, congenital anomalies, preterm birth, infant death within the first month of birth and caesarean birth, together with long-term risks of adverse cardiovascular outcomes in both mothers and children.

Further research is needed to provide evidence-based health care for women, with or at risk of diabetes complications, who are planning pregnancy or are pregnant, and their partners, to ensure the best outcomes for them and their children in the short and long-term. There is a need to align the commissioned research undertaken with the priorities of those impacted by it.

This JLA PSP, funded by the University of Oxford and the Diabetes Research and Wellness Foundation, aims to identify the research questions of priority to women (whose pregnancy or pregnancy planning has been affected by diabetes), and their support network (including families, partners, friends). By identifying the most important areas where little is known, and for which there is great need, the strategies and priorities of health

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<sup>1</sup> This protocol template should be modified with agreement from the JLA Adviser to reflect the make-up of different PSPs and the organisations driving them. This protocol template document was last updated by the JLA in November 2018.

<sup>2</sup> The Steering Group is responsible for ensuring any updates or amendments to the PSP plan are included in subsequent versions of the Protocol and sent to the JLA for publication on the website.

research funders, national policy makers and clinical studies groups will be informed and aligned to support research of high impact and value in diabetes and pregnancy.

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

The aim of the Diabetes and Pregnancy PSP is to identify the unanswered questions about diabetes and pregnancy from the perspective of women, their support networks (families, partners, friends) and healthcare professionals (HCPs) and then prioritise those that women, their support networks, and HCPs agree are the most important for research to address.

The objectives of the PSP are to:

- work with women, their support networks, and HCPs to identify uncertainties about the prevention, diagnosis, treatment, short and long-term health impacts and health care in diabetes and pregnancy.
- 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 Diabetes and Pregnancy PSP will include the following:

- women, their partners, babies, and families
- diabetes, including pre-existing diabetes of any type and subtype, and gestational diabetes
- time period in relation to pregnancy (i.e. pre-conception, antenatal, neonatal, post-natal and short to long-term health outcomes)
- management of diabetes in pregnancy (i.e. screening, causes and prevention, diagnosis and treatment)
- physical, social, cultural, economic, and psychological aspects
- co-morbidities and complications
- genetics, fertility and related aspects
- information, education and service improvement
- relevant to the UK population. This is intended to be a UK exercise with a UK focus. Questions and priorities that extend the scope outside of the UK may be considered by the steering group but will not influence the results.

The PSP will exclude from its scope questions about:

- pregnancy uncertainties not specific to diabetes
- care of the baby on the neonatal unit
- questions or priorities without a UK focus or relevance

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.

The PSP will take an iterative approach to defining the scope and the evidence checking strategy, which will be refined during the process as informed by the submitted uncertainties.

## 3. The Steering Group

The Diabetes and Pregnancy PSP will be led and managed by a Steering Group involving the following<sup>3</sup>:

Women and support network representative/s:

- Iuliana Berneantu
- Sonya Carnell
- Mariya Dzhatova
- Kate Kells
- Ankita Singal

HCP representative/s:

- Caroline Byrne, Diabetes Specialist Nurse (with specialism in pregnancy), Cambridge University Hospitals NHS Foundation Trust. (CUHFT has the largest pregnancy clinic in the country.)
- Dr David Churchill, Consultant Obstetrician, The Royal Wolverhampton NHS Trust.
- Jeannie Grisoni, Specialist Diabetes Dietician (with specialism in pregnancy), Cambridge University Hospitals NHS Foundation Trust.
- Dr Jane Hirst, Consultant Obstetrician, University of Oxford, and lead for the diabetes in pregnancy service, John Radcliffe Hospital, Oxford University Hospitals NHS Trust.
- Dr Lucy McKillop, Consultant Obstetric Physician, Oxford University Hospitals NHS Trust.
- Professor Helen Murphy, Clinical Professor in Medicine (Diabetes and Antenatal Care), University of East Anglia, National Pregnancy in Diabetes audit lead, Honorary Consultant Physician, Cambridge University NHS Foundation Trust and Norfolk & Norwich University Hospital NHS Trust.
- Professor Mark Strachan, Consultant and Honorary Professor of Diabetes and Endocrinology, Western General Hospital, Edinburgh.

The Partnership and the priority setting process will be supported and guided by the following Steering Group members:

- Professor Fiona Alderdice, Chair of Perinatal Health & Wellbeing, Director of Research at the School of Nursing & Midwifery, Queen's University Belfast and Senior Social Scientist, NPEU, University of Oxford.
- Dr Goher Ayman (PSP Co-lead), Research Facilitator, PSP Coordinator and Information Specialist.
- Professor Marian Knight, (PSP Co-lead) Honorary Consultant in Public Health with Public Health England, Professor of Maternal and Child Population Health, NPEU, University of Oxford.
- James Lind Alliance Adviser and Chair of the Steering Group: Katherine Cowan, JLA.
- Diabetes UK representatives Anna Morris, Assistant Director of Research Strategy and Partnership, and Kamini Shah, Head of Research Funding.
- JDRF representatives Caroline Schmutz, Senior Grants and Research Officer, and Rachel Connor, Director of Research Partnerships.

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.

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<sup>3</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 women, their support networks, and HCPs only, in line with the JLA's mission.

## 4. Partners

Organisations and individuals will be invited to be involved with the PSP as partners. 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 experienced diabetes and pregnancy and/or pregnancy planning
- support networks of people who have experienced diabetes and pregnancy and/or pregnancy planning
- health and social care professionals - with experience in diabetes and pregnancy
- organisations such as charities and special interest groups working in this area.

### 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

The PSP has been formed through a process of peer knowledge and consultation and further partner organisations will be identified through the Steering Group members' networks. Potential partners will be contacted and informed of the establishment and aims of the Diabetes and Pregnancy PSP.

### Step 2: Awareness raising

The PSP will raise awareness of its proposed activity among its service-user, their families and carer, and clinician communities. This will be done via appropriate and transparent methods for the relevant stakeholders e.g. a face-to-face meeting, via social media, email, postal or web-based questionnaires and message boards, focus groups and interviews, where reasonably possible and within budgetary constraints. 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 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 Diabetes and Pregnancy PSP will carry out a consultation to gather uncertainties from women, their support networks, and HCPs. A period of five months will be given to complete this exercise (which may be revised by the Steering Group if required).

The Diabetes and Pregnancy PSP recognises that the following groups may require additional consideration:

- People with more recent experiences, due to childcare and time available. It will be important to gather responses from those with more recent and current experiences, as well as those which may have been experienced more than five years ago, to ensure gaps which reflect recent and current care and treatments are captured.
- Seldom heard populations e.g. young adults, South Asian populations. There has been much research on engaging with seldom heard groups and different ethnic and cultural groups. The PSP will seek the advice of PPI champions, INVOLVE, the steering committee and their contacts. Diabetes UK completed a range of activities to enable representation of these groups for the Type 2 PSP. This includes reaching out through their community champions and attending community events.

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

- online surveys and social media platforms (including targeted adverts where funding allows) with the option of paper questionnaires
- enabling individuals to respond when convenient for them, via a clear set, easy route that does not require much time and at no cost
- actively seeking advice from experts in the target group or techniques for maximising responses and representativeness as far as reasonably possible and practicable
- where funding allows, the use of translated questionnaires and paper questionnaires
- where funding allows, the use of focus groups and interviews

Existing sources of evidence uncertainties may also be searched and included, such as the Type 2 Diabetes PSP questions. Evidence checking will be conducted across national (and where applicable, international) clinical guidelines, recommendations, national surveillance and audit findings, systematic reviews, research publication databases and trials registries. The evidence checking strategy will be informed by the submitted data. To ensure we have up-to-date information, we will engage with experts including our Steering Group members, and the Maternal Medicine CSG, who have a diabetes in pregnancy subgroup.

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

The consultation process will produce 'raw' questions and comments indicating women's, members of their support networks', and HCPs' 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. 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 Information Specialist. 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 anticipate submitted questions that have been answered, and questions that are out of scope. The group will seek to deal with these in an appropriate and considered manner outside the parameters of the partnership.

### **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 Diabetes and Pregnancy. This will involve input from women, their support networks (including families, partners, friends) and HCPs. 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 the relevant stakeholders 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 women, support network representatives and HCPs will be brought together 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 transparent, 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 public and health and social care communities. The Steering Group will 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 PSP Co-Leads Dr Goher Ayman and Professor Marian Knight, in conjunction with the Steering Group.

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 Diabetes and Pregnancy PSP Steering Group agreed the content and direction of this Protocol on 26 April 2019.