

SETTING RESEARCH PRIORITIES IN DIABETES AND PREGNANCY

There is a lack of evidence-based guidance for women with, or at risk of, diabetes who are either pregnant or planning a pregnancy. A Priority Setting Partnership has addressed this issue and come up with a list of 10 research questions, taking on board a wide range of women's views and those of the healthcare professionals caring for them

Around one in 10 women will experience a pregnancy complicated by either gestational diabetes or pre-existing diabetes. And these rates are increasing along with a rise in diabetes, obesity and women becoming pregnant at a later age. While most of these women can look forward to a healthy pregnancy, with delivery of a healthy baby, diabetes can cause complications during both pregnancy and birth. Women with diabetes have a two to six times greater risk of problems like congenital abnormalities, still or pre-term birth, neonatal death and long-term cardiovascular risk for both mother and child.

Many pregnant women say there is a lack of information about the effect of diabetes or that the information is not consistent. National guidelines and reviews also show that the research into diabetes and pregnancy is of variable quality, which means that treatment guidelines are not based on hard evidence. Of course, resources are limited, so it is important to focus on research areas in diabetes and pregnancy where the findings will have most value and impact.

Healthcare research led by industry and researchers does not always prioritise those issues that matter most to those who live with a condition.

The James Lind Alliance (JLA), a UK-based initiative, was set up in 2004 to address this imbalance. In a recent exercise, the JLA used its procedure to set priorities for research into diabetes and pregnancy.

Priority Setting Partnerships

The JLA uses Priority Setting Partnerships (PSPs) to identify those research questions close to the hearts of those who have the condition involved and the healthcare professionals who look after them. When the findings of a PSP are shared with research funders, it helps align the work with the needs of those directly affected. In diabetes, there have already been PSPs in both type 1 and type 2 diabetes carried out in the UK. Two questions about pregnancy did come up in the 'long list' for the type 1 exercise but didn't make it into the top 10, meaning they went unanswered. ▶

These questions were:

- What impact do changing hormones, for example, during menstruation, pregnancy and menopause, have on blood glucose levels in women with type 1 diabetes?
- Is it safe to continue insulin analogues in preconception and pregnancy in type 1 diabetes?

In the type 2 PSP, no questions were raised on diabetes and pregnancy. There have been exercises similar to the PSPs in Canada and the USA, focusing on gestational diabetes. But women's health and pregnancy concerning diabetes have not previously been prioritised, even when identified as an area where research is needed.

A PSP was accordingly set up between the University of Oxford, Diabetes UK, Diabetes Research and Wellness Foundation, JDRF and JLA, which launched on World Diabetes Day 2018. It aimed to discover priorities for future research in any kind of diabetes and pregnancy according to women who had experience of pregnancy or were planning one, and their support networks – families, friends and healthcare professionals.

The PSP was overseen by a steering group of key stakeholders and chaired by a senior JLA advisor. Identifying the top 10 research priorities comprised a three-stage process, as follows.

Initial survey

This first stage focused on identifying questions on diabetes and pregnancy.

This was done by inviting women and healthcare professionals to put forward up to three research questions by open survey. Any questions relating to the time before, during or after pregnancy with any type of diabetes could be accepted – the scope was broad to make sure all concerns were covered. The researchers tried to reach under-represented groups, with direct approaches in diabetes and pregnancy clinics, outreach via relevant support groups, professional networks and conferences, through charities' communication channels. Ethnic minorities were targeted via organisations, support groups and community champions working on health inequalities.

Questions submitted were organised and analysed into categories. Then questions were checked to see what research on the issue already existed to establish if a knowledge gap really existed.

Interim survey

Participants were presented with the list of questions and invited to pick up to 10 that they thought were most important to answer. Each selection made by an individual respondent had equal weighting. But to account for differences in voting patterns and the number of respondents from different groups, ranking was counted separately for women and support networks, healthcare professionals, ethnic minorities and diabetes type. Within each of these groups, total points per

question were put to get a ranking. The questions ranked in the top 10 for the two main groups (women/support networks and healthcare professionals), and the top three – and at least eight of the top 10 – for each of the other subgroups were shortlisted. This gave a total of 18 questions for the final workshop.

Final workshop

The third and final stage of the PSP was a one-day online workshop dedicated to identifying the top 10 questions from the 18-question shortlist identified above. A group of 25 participants was chosen, first through phased targeted approaches to make sure there was sufficient representation from ethnic minority groups, the devolved nations and Crown dependencies, support networks and specific healthcare professionals. This was followed up by open invitation to make up the group.

The participants were then split into four breakout groups with balanced representation between women, support networks and healthcare professionals. In these groups, the attendees took part in discussions and ranking exercises to agree their top 10 most important research questions. Trained JLA advisors facilitated these sessions to make sure there was equal and open participation.

The 10 questions above were identified from an initial 466 responses – 64% from women and support networks, 32% from healthcare



Top 10 questions

The questions most needing research in diabetes and pregnancy, which we first discussed in the Spring 2021 issue of Update, were:

- 1 Diabetes technology at any stage pre- to post-pregnancy.
- 2 The best test for diabetes during pregnancy.
- 3 Diet and lifestyle interventions for diabetes management during pregnancy.
- 4 Emotional and wellbeing needs of women with diabetes pre- to post-pregnancy.
- 5 Safe birth at full term.
- 6 Postnatal care and support needs of women.
- 7 Diagnosis and management late in pregnancy.
- 8 Prevention of other types of diabetes in women with gestational diabetes.
- 9 Women's labour and birth experiences and choices.
- 10 Improving planning for pregnancy.

professionals, 4% from others – suggesting 1,161 questions. Women and support networks brought up questions about post-birth effects for themselves and their child, diabetes management during pregnancy and understanding the risks for diabetes in pregnancy. The question most frequently brought up was about the long-term effects of diabetes in pregnancy on the child – mentioned by 20.1% of this group. They also asked about breastfeeding, labour and birth and care and support. The healthcare professionals asked mainly about pre-pregnancy care and diagnosis and clinical management of diabetes in pregnancy. Both groups asked about individualised and risk-based care, optimal management and prevention of diabetes and the safety of medications.

From these questions, 142 different categories were extracted and broadly organised by stage of pregnancy, with technology, mental health and wellbeing and health services being identified as cross-cutting categories. There were a total of 934 questions within scope, of which 50 mapped to more than one category and consolidated into 60 questions, reflecting the significant overlap in priorities. All 60 were considered to have substantial uncertainty following evidence checks.

In the interim survey, there were 614

submissions – 80% women and their support network, and 20% healthcare professionals. In the rankings from this stage, there were some notable differences in the priorities of the two groups. Four of the 10 ranked questions for the healthcare professionals came below the 45th ranking for women and support networks, with the latter ranking the long-term effects of diabetes in pregnancy on the child's general health highest. Technology was a high priority for those with type 1/type 2 but low for the gestational diabetes group while testing for diabetes during pregnancy and prevention of developing diabetes was higher for women with type 2 and gestational diabetes but lower for those with type 1.

In the final workshop, there was a good balance and diversity of experience and expertise among the participants, inspiring confidence in the Top 10 choices that emerged. It was notable that questions about the long-term health of the child – whether this was about their developing diabetes or some other health condition – had ranked high in all the groups and shortlisted for the final workshop but didn't actually make the final Top 10, reaching positions 11 and 12 respectively. This issue was discussed in the final workshop. It was agreed that this was perhaps a question to be considered in the broader research agenda of child health, and including it in the Top 10 might add burden to women dealing with the responsibility of managing diabetes during pregnancy.

Feedback from the workshop was generally positive:

"It was really good having different perspectives. Moving to a second smaller group was also useful, as it showed how varied priorities can be between two groups, despite having a similar mix of people from the different backgrounds."

"Although the final top 10 was not the same as my personal top 10 that I had prepared, discussing all of the 18 questions and reflecting on them as a group, meant I was satisfied with it. It was good to hear the views of women with different forms of diabetes and look at the questions from their perspective."



In conclusion...

The final Top 10 list includes priorities that are relevant to all the stakeholders. They were generated by a robust and inclusive process which researchers and their funders can trust. Going forward, the Top 10 can be used to ensure research be directed towards filling evidence gaps in areas of most need and thus have the most impact and value for money.

The role of diabetes technology was ranked first here, and similar questions made the top three of JDRF UK's type 1 diabetes PSP Top 10. This is not surprising, as there have been significant developments – and ongoing innovation – in diabetes technology over the last few years. And since the final workshop, NICE has approved the funding of continuous glucose monitoring for pregnant women with type 1. The PSP findings back their recommendation for further research into different monitoring systems at all stages of pregnancy. And we shouldn't forget wider aspects of diabetes technology such as apps, automation, data integration and sharing in diabetes management.

There was also a strong focus on women's wellbeing and mental health. There is an ongoing lack of evidence in this area. Diabetes UK's Too Often Missing report highlights pregnancy as a time when women with diabetes may need increased emotional support.

In conclusion, further research is needed to provide evidence-based healthcare for women with, or at risk of, diabetes who are pregnant or planning a pregnancy. The findings of this PSP could help improve outcomes and the long-term health of women and their babies, as well as providing an opportunity for cost savings.

i Ayman G, Strachan JA, McLennan N, et al (2021). The top 10 research priorities in diabetes and pregnancy according to women, support networks and healthcare professionals. *Diabetic Medicine* 00:e14588. <https://doi.org/10.1111/dme.14588>