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*SHE defined as number of hypoglycaemic events requiring third-party assistance (with or without medical assistance). 1. Puhr S *et al.* Diabetes Technol Ther. 2019;21(4):155-158. 2. Puhr S *et al.* J Diabetes Sci Technol. 2020;14(1):83-86. 3 Heinemann L, *et al.* Lancet 2018;391:1367–1377. Dexcom, Dexcom G6, Dexcom Follow, Dexcom Share, and Dexcom CLARITY are registered trademarks of Dexcom, Inc. in the U.S. and may be in other countries. www.dexcom.com | +1.858.200.0200 | Dexcom, Inc. 6340 Sequence Drive San Diego, CA 92121 USA | MDSS GmbH Schiffgraben 41 30175 Hannover, Germany. LBL021139 Rev001.

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DIABETIC Medicine

RESEARCH ARTICLE

The top 10 research priorities in diabetes and pregnancy according to women, support networks and healthcare professionals

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Abstract

Aims: To undertake a Priority Setting Partnership (PSP) to establish priorities for future research in diabetes and pregnancy, according to women with experience of pregnancy, and planning pregnancy, with any type of diabetes, their support networks and healthcare professionals.

Marian Knight and Katherine Cowan should be considered joint senior authors.

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Methods: The PSP used established James Lind Alliance (JLA) methodology working with women and their support networks and healthcare professionals UK-wide. Unanswered questions about the time before, during or after pregnancy with any type of diabetes were identified using an online survey and broad-level literature search. A second survey identified a shortlist of questions for final prioritisation at an online consensus development workshop.

Results: There were 466 responses (32% healthcare professionals) to the initial survey, with 1161 questions, which were aggregated into 60 unanswered questions. There were 614 responses (20% healthcare professionals) to the second survey and 18 questions shortlisted for ranking at the workshop. The top 10 questions were: diabetes technology, the best test for diabetes during pregnancy, diet and lifestyle interventions for diabetes management during pregnancy, emotional and well-being needs of women with diabetes pre- to post-pregnancy, safe full-term birth, post-natal care and support needs of women, diagnosis and management late in pregnancy, prevention of other types of diabetes in women with gestational diabetes, women's labour and birth experiences and choices and improving planning pregnancy.

Conclusions: These research priorities provide guidance for research funders and researchers to target research in diabetes and pregnancy that will achieve greatest value and impact.

KEYWORDS
diabetes mellitus, health priorities, perinatal care, post-natal care, pregnancy, prenatal care, researchNovelty statement

- Women report a lack of consistent evidence-based information to help them manage their diabetes in the period before to after pregnancy.
- The top 10 questions for research in diabetes and pregnancy according to women, their support networks and healthcare professionals were identified.
- Joint top priorities for research were diabetes technology and identifying the best test for diabetes in pregnancy.
- These questions will inform funders of research and researchers towards addressing areas of great need and impact.

1 | INTRODUCTION

Approximately one in every 10 women will experience a pregnancy complicated by either pre-existing or gestational diabetes.[1] Rates are increasing as a result of increased rates of obesity and pregnancy at a later age.[2] Although most women have healthy pregnancies and healthy babies, diabetes increases the risk of complications during pregnancy and birth, and can have long-term effects. Compared to the maternity population without diabetes, the risks are two to six times greater for adverse outcomes such as congenital anomalies, stillbirth, preterm birth, infant death within the first month of life, together with long-term risks of adverse cardiovascular outcomes in both mothers and children.[3,4]

Many pregnant women with diabetes report a lack or inconsistency of information, leaving many of their questions unanswered. National guidelines and high-quality systematic reviews highlight variable quality, heterogeneity and reliability of research. Consequently, treatment guidelines are insufficiently evidenced in line with current context and available healthcare options.[5,6] However, with limited funding and resources available for research, it is important to ensure that the research that is undertaken is of highest value and impact.

Healthcare research led by industry and researchers often does not address the issues that are most important for people living with the condition, or those who support them.[7] The James Lind Alliance (JLA), a UK-based initiative established in 2004, aims to address this mismatch.

Through Priority Setting Partnerships (PSP), the JLA supports the identification of the research questions that matter most to patients and the healthcare professionals that care for them. Sharing the outputs of PSPs with health research funders helps to align the work they fund towards addressing the areas of need prioritised by those directly affected and involved.

Previous successful PSPs have been conducted in diabetes in the UK. The type 1 diabetes PSP identified two questions in pregnancy, but both fell outside the top 10 priorities: '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?'[8] No priorities specific to pregnancy were identified in the type 2 diabetes PSP top 10.[9] There have also been prioritisation exercises using different but overlapping methodology to PSPs in Canada and the USA but focussing on gestational diabetes.[10,11] However, women's health and pregnancy, particularly in relation to diabetes, are not prioritised, despite being consistently identified as an area of much needed research.[2,12,13]

A PSP was therefore established between the University of Oxford, Diabetes UK, Diabetes Research and Wellness Foundation, JDRF the type 1 diabetes charity, and JLA, on World Diabetes Day 2018. The PSP aimed to find out the priorities for future research in diabetes and pregnancy, according to women and their support networks (families, partners, friends and carers) with experience of pregnancy, or planning pregnancy, with any type of diabetes and healthcare professionals.

2 | PARTICIPANTS AND METHODS

The PSP employed the established JLA methodology.[14]

2.1 | Establishing the PSP

The PSP was overseen by a steering group representing key stakeholders (Supplementary Table S1) and was chaired by a senior JLA advisor to ensure transparency of the process, and fair and equal involvement of all members. The group agreed the scope (Table 1) and was responsible for the completeness and appropriateness of the process, ensuring involvement of key stakeholder groups, approval of categorisation, grouping and phrasing of questions and interpretation of data. The protocol was prospectively published online at www.jla.nihr.ac.uk/priority-setting-partnerships/diabetes-and-pregnancy.

2.2 | Initial survey—identifying questions

Women and their support networks (partners, families, friends and carers) with experience of pregnancy or planning pregnancy with any type of diabetes and healthcare professionals were invited via an open survey (26 June–15 November 2019) to suggest up to three questions they felt were important to answer. These could be any questions about the time before, during or after pregnancy with any type of diabetes. The scope was intentionally broad so that the submissions reflected public need.

The survey was available, in English, online and on paper. Targeted efforts to maximise responses, particularly from underrepresented groups, included direct approaches in diabetes and pregnancy clinics, outreach through relevant support groups, professional networks and conferences, diabetes, pregnancy and birth charities' websites and communication channels and social media platforms. Concerted efforts were made to hear the voices of ethnic minorities working with organisations, support groups and community champions, which aim to address health inequalities. Representation across different ethnic minorities was monitored through broad groupings.

TABLE 1 Scope of the James Lind Alliance priority setting partnership in diabetes and pregnancy

Questions about the following were included:	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. preconception, 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 was intended to be a UK exercise with a UK focus.
Questions about the following were excluded:	Pregnancy uncertainties not specific to diabetes Care of the baby on a neonatal unit Questions or priorities without a UK focus or relevance

2.3 | Categorisation and grouping

The submitted questions were organised using NVivo qualitative data analysis software (QSR International Pty Ltd. Version 12, 2018). Initial data cleaning was manually completed with any issues about the clinical aspects or interpretation of the submitted questions resolved with the steering group. The questions were analysed using content analysis with an initial stage of open coding of the question content, followed by the grouping of codes into categories.[15] To retain the integrity of the initial submissions, some questions were mapped to two or more categories. Independent second checks were conducted with members of the steering group to ensure potential impact of individual bias, and missed or misinterpreted categorisation was minimised. The steering group further consolidated the categories into groups and summarised the initial survey submissions under an indicative question. Indicative questions were formulated to capture the issues raised by the submitted questions within each group, whether originating from single or multiple respondents.

2.4 | Evidence checking

A broad level and pragmatic evidence checking strategy was taken (January – May 2020) with the aim of ascertaining whether there was evidence of substantial uncertainty for each indicative question. The search was restricted to the Cochrane Database of Systematic Reviews (www.cochranelibrary.com), systematic reviews published since 2017 using Medline or PubMed and National Institute of Clinical Excellence (NICE) and Scottish Intercollegiate Guidelines Network (SIGN) national diabetes and pregnancy guidelines.[5,6] Expanded evidence searches, including evidence highlighted by the steering group, were applied on a question-by-question basis after finalisation of the list of indicative questions. Research underway or recently completed but not available as published was not included as evidence. Where part of the question had sufficient evidence, the question phrasing was amended to reflect the remaining uncertainty.

2.5 | Interim survey and prioritisation

The interim survey presented the long list of indicative questions in groups by phase. The order of the groups and individual questions within the groups were randomised each time the survey was entered. Participants were invited to pick up to 10 that they felt were most important to answer. Due to the Covid-19 pandemic and social distancing restrictions, the survey was offered online only. Following a pilot mid-May, the survey ran for nine weeks (29 May–31 July 2020).

2.6 | Interim ranking and shortlisting

Every selection made by an individual respondent had equal weighting and no weighting changes were made if fewer than 10 questions were selected. However, to account for the differences in observed voting patterns and the number of respondents from different groups, ranking was tallied separately for: women and support networks, healthcare professionals, ethnic minorities and diabetes type, namely type 1, type 2 and other, and gestational diabetes. Within each of the groups, the total points for each question were put into rank order. 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. In total, 18 questions were shortlisted for the final workshop, the maximum number considered feasible by the steering group for effective discussion online.

2.7 | Final workshop—agreeing the top 10

The final stage involved a 1-day workshop (2 October 2020) using the established JLA approach, which was adapted to be delivered online.[14] Twenty-five participants were identified initially through phased targeted approaches to prioritise representation from ethnic minority groups, the devolved nations and Crown dependencies, support networks and specific health professions, for example, psychologists and GPs as underrepresented groups, followed by open invitation. Contacts collated through the surveys, and special interest groups and partner communication channels were used. Participants were screened for possible conflicts of interest and whether they were highly research active in the area. The participants were split into four breakout groups balanced by representation between women, support networks and healthcare professionals, and by experience of diabetes and healthcare specialist.

In breakout groups, the attendees participated in a series of discussion and ranking exercises to jointly rank the shortlist of indicative questions and agree the top 10 most important for future research to answer. The workshop and discussions were facilitated by trained JLA advisors to ensure equal and open participation. Four steering group members joined as observers only. Technical support was made available, and a contact point for emotional support was provided should any participant be upset by the process or discussions. The participants were invited to provide anonymous feedback on the prioritised questions and the workshop generally.

2.8 | Ethics

The Medical Sciences Interdepartmental Research Ethics Committee, University of Oxford confirmed that the project did not require ethics committee approval.

3 | RESULTS

The top 10 areas of most needed research in diabetes and pregnancy identified were: diabetes technology at any stage pre- to post-pregnancy, the best test for diabetes during pregnancy, diet and lifestyle interventions for diabetes management during pregnancy, emotional and well-being needs of women with diabetes pre- to post-pregnancy, safe birth at full term, post-natal care and support needs of women, diagnosis and management late in pregnancy, prevention of other types of diabetes in women with gestational diabetes, women's labour and birth experiences and choices and improving planning for pregnancy (Table 2).

The responses at each stage of the process are summarised in Figure 1. Participant demographics at each stage of the process are in Table 3. The survey submission counts and rankings for the 60 indicative questions are available in Supplementary Table S2.

3.1 | Initial survey

Four hundred and sixty-six responses were submitted (64% women and support networks, 32% healthcare professionals and 4% other/not answered) suggesting 1161 questions covering the whole perinatal period (Supplementary Table S3).

Initial questions submitted by women and support networks were mainly in relation to post-birth effects on themselves and their child, diabetes management during pregnancy and understanding the risks for diabetes in pregnancy. The long-term effects of diabetes in pregnancy on the child (risks of the child developing diabetes and any wider health effects) being the most frequently asked question (20.1% of women and support networks' submissions). This group more specifically raised questions about breastfeeding (8.9%) and labour and birth (8.6%) in terms of informed choice, continuity/availability of care and emotional support more generally. Healthcare professionals' questions were mainly about pre-pregnancy care, and diagnosis and clinical management of diabetes in pregnancy. How to improve preconception care was most frequently asked (9.7% of healthcare professionals' submissions), closely followed by the value and methods of diagnosis and management of diabetes late in pregnancy, that is, after 34 weeks (8.5%). Modes of delivering care, improving uptake and access to services and motivational interventions were more specifically raised by this group. Common to both groups were questions about individualised and risk-based care, optimal management of diabetes, prevention of diabetes and safety of medications.

One hundred and forty-two categories were extracted and broadly organised by the phase of pregnancy: pre-pregnancy (62 questions, 6.3%), pregnancy (376, 38.2%), labour and birth (87, 8.8%) and post-birth (373, 37.9%). Technology (20, 2.0%), mental health and well-being (20, 2.0%) and health services (46, 4.7%) were identified as cross-cutting categories. A total of 934 questions were within scope, of which 50 mapped to more than one category, and consolidated into 60 indicative questions. Rarely was there a need to specify a type of diabetes within an indicative question, which reflects the significant overlap in priorities regardless of diabetes type. The main distinctions were questions relating to gestational diabetes, due to its transient nature and diagnosis in pregnancy. All 60 indicative questions were considered to have substantial uncertainty following evidence checks. The evidence check summary is provided in Supplementary Table S4.

3.2 | Interim survey

Six hundred and fourteen submissions (80% women and support networks and 20% healthcare professionals) were received in the interim survey. In the interim survey rankings, there were notable differences between women and support networks, and healthcare professionals (Figure 2a). Four of the top 10 ranked questions for healthcare professionals were below the 45th ranking for women and support networks. Women and support networks ranked the long-term effects of diabetes in pregnancy on the child's general health (non-diabetes-related) highest. Varying standards and advice across hospitals and giving birth at full term were also in the top three.

Voting patterns varied for the main groups between surveys (Figure 3) with overall movement towards labour and birth and cross-cutting categories. For example, despite being rarely asked in the initial survey, the use of technology became the highest ranked for healthcare professionals in the interim survey.

For ethnic minorities, representation was below national population figures for Black and Black British groups in both surveys (1.6% and 0.5% respectively; national 3.0%), and for Asian and Asian British groups (4.1%; national 7.0%) in the interim survey. With low numbers, the votes across 60 questions became too dispersed to discern a strong pattern. However, peaks in voting overlapped the top 10 for women and support networks, and healthcare professionals, with the eight highest voted questions already shortlisted for the final workshop.

TABLE 2 Top 10 priorities for research in diabetes and pregnancy according to women, their support networks and healthcare professionals

Final rank	Phase	Indicative question	No. initial questions	Interim survey rank by group					
				HCPs	Women & support	Ethnic minorities	T2D/ Other	T1D	GDM
=1	Cross-cutting	How can **diabetes technology** be used to improve pregnancy, birth and mother and child health outcomes?	10	1	13.5	10.5	1	1	23
=1	During pregnancy	What is the **best test** to diagnose diabetes in pregnant women?	14	7	46	13	8	43	21.5
3	During pregnancy	For women with diabetes, what is the best way to manage blood sugar levels using **diet and lifestyle** during pregnancy?	47	45	8	3	37.5	28.5	10
4	Cross-cutting	What are the **emotional and mental well-being needs** of women with diabetes before, during and after pregnancy, and how can they best be supported?	14	20	4	8.5	18.5	9	5
5	Labour and birth	When is it safe for pregnant women with diabetes to give **birth at full term** compared with early delivery via induction or elective caesarean?	16	3	3	5.5	5.5	4	4
6	After pregnancy and birth	What are the specific **post-natal care and support needs** of women with diabetes and their infants?	9	28	13.5	10.5	33	3	35.5
7	During pregnancy	What is the best way to test for and treat **diabetes in late pregnancy,** that is, after 34 weeks?	29	4	57.5	44.5	3.5	41	43.5
8	After pregnancy and birth	What is best way to reduce the risk or prevent **women with gestational diabetes developing other types of diabetes** any time after pregnancy?	64	5.5	6	2	9	52	3
9	Labour and birth	What are the **labour and birth experiences** of women with diabetes, and how can their choices and shared decision making be enhanced?	6	32	10	21	18.5	8	13
10	Before pregnancy	How can care and services be improved for women with diabetes who are **planning pregnancy**?	37	2	47	33	2	10	45

The indicative questions are presented in final rank order, with phase of pregnancy, the question concerns, the number of initial survey questions grouped within the indicative question and the interim survey ranking results by group; HCPs - Healthcare professionals; T1D – Type 1 diabetes; T2D – Type 2 diabetes; GDM – Gestational diabetes mellitus.

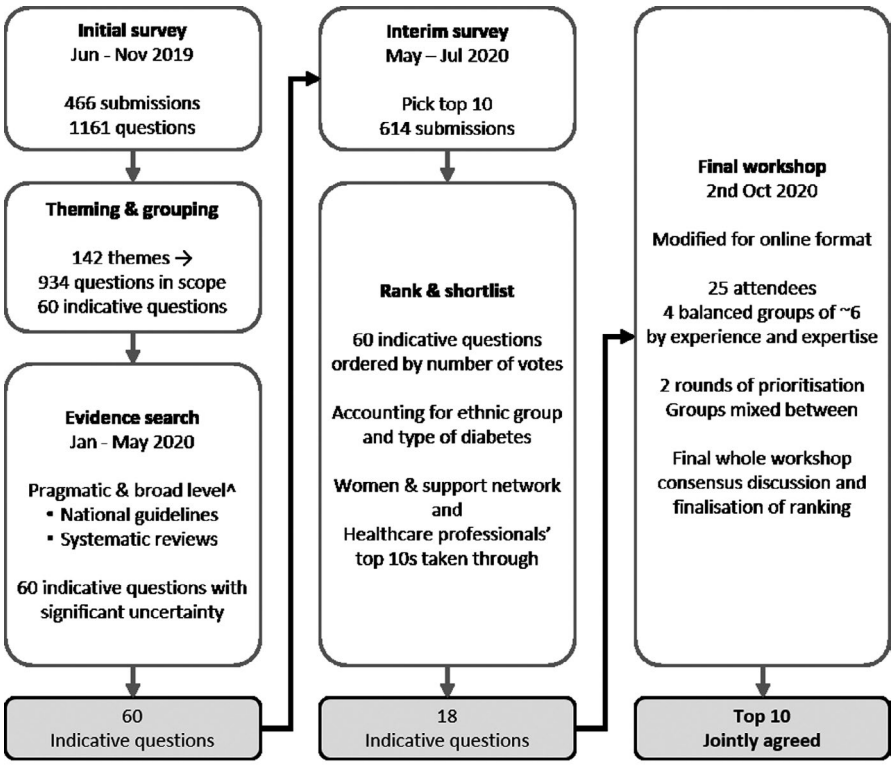

FIGURE 1 Summary of the James Lind Alliance prioritisation process showing how the top 10 questions in diabetes and pregnancy were identified. ^Ongoing studies were not included as evidence as it would not be possible to know if they answer the question

TABLE 3 Participant demographics at each stage of the priority setting process

Participant demographics / Stage n (%)	Initial survey	Interim survey	Workshop[a]
Total	466	614	25
Experience			
Women with lived experience	287 (61.6)	473 (77.0)	9 (36.0)
Support network	11 (2.4)	20 (3.3)	2 (8.0)
Healthcare professionals	149 (32.0)	121 (19.7)	14 (56.0)
Other/not answered	19 (4.0)	-	-
Living in			
England	374 (85.8)	506 (82.4)	19 (76.0)
Scotland	25 (5.7)	29 (4.7)	0 (0.0)
Wales	15 (3.4)	22 (3.6)	5 (20.0)
Northern Ireland	8 (1.8)	24 (3.9)	1 (4.0)
Crown dependency	0 (0.0)	2 (0.3)	0 (0.0)
Not in the UK	7 (1.6)	25 (4.1)	-
Not answered	7 (1.6)	6 (1.0)	-
Age			
19 years old or under	1 (0.2)	0 (0.0)	-
20 to 29 years old	79 (18.1)	92 (15.0)	-
30 to 39 years old	201 (46.1)	350 (57.0)	-
40 years old or over	144 (33.0)	166 (27.0)	-
Not answered	11 (2.5)	6 (1.0)	-
Ethnicity			
White	325 (74.5)	554 (90.2)	17 (68.0)
Asian and Asian British	59 (13.5)	25 (4.1)	5 (20.0)
Mixed and multiple ethnic groups	13 (3.0)	15 (2.4)	3 (12.0)
Black and Black British	7 (1.6)	3 (0.5)	0 (0.0)
Other	10 (2.3)	9 (1.5)	0 (0.0)
Not answered	22 (5.0)	8 (1.3)	-
Education level[b]			
School (up to GCSE or equivalent)	26 (6.0)	11 (1.8)	-
School (A-levels or equivalent)	23 (5.3)	21 (3.4)	-
Higher education (e.g. college)	60 (13.8)	76 (12.4)	-
Degree level or higher	311 (71.3)	343 (55.9)	-

(Continues)

TABLE 3 (Continued)

(Continues)

TABLE 3 (Continued)

Participant demographics / Stage n (%)	Initial survey	Interim survey	Workshop[a]
Not answered	16 (3.7)	163 (26.5)	-
Diabetes type[c] (diagnosis/ interest)			
Type 1	-	218 (27.6)	3 (25.0)
Type 2	-	88 (11.2)	3 (25.0)
Gestational	-	406 (51.5)	4 (33.3)
Other, for example, MODY, LADA	-	39 (4.9)	2 (16.7)
None/not indicated	-	38 (4.8)	-
Clinical specialism			
Consultant Nurse in Diabetes	-	-	1 (7.1)
Diabetes Specialist Nurse	-	-	2 (14.3)
Diabetes Specialist Midwife	-	-	3 (21.4)
General Practitioner (GP)	-	-	1 (7.1)
Obstetrician	-	-	3 (21.4)
Diabetes and Pregnancy Specialist Dietician	-	-	1 (7.1)
Diabetologist	-	-	3 (21.4)

[a]Unfortunately, despite purposeful outreach, no expressions of interest were received from people with Black or Black British ethnicity or people living in Crown dependencies, and three people were invited from Scotland but withdrew at a later stage before the workshop. One of the women representatives had experience of pregnancy with Maturity Onset Diabetes of the Young (MODY), and another Latent Autoimmune Diabetes of Adulthood (LADA). The support network representatives, a sister and a husband, brought experience of type 1 diabetes and type 2 diabetes respectively.

[b]Due to a technical error in the interim survey, the first 155 submissions did not have this question completed.

[c]Included in the interim survey to account for differences between priorities in relation to different types of diabetes. Multiple choice was enabled. Workshop data presented only for women and support network representatives. Some women had experience with more than one type of diabetes.

Comparing the interim survey rankings by types of diabetes, there were some clear differences (Figure 2b). Technology was ranked the top priority for type 1 and type 2/other diabetes groups, but ranked low for the gestational diabetes group. Post-birth support came in second for type 1, but ranked low for both type 2/other and gestational diabetes groups, whereas testing for diabetes during pregnancy and prevention of developing diabetes ranked high for type 2/other and gestational diabetes groups but low for the type 1 diabetes group.

3.3 | Final workshop and top 10

The diversity and balance in experiences and expertise of workshop attendees were strong (Table 3). Participants uncovered unexpected overlaps between questions, for example, technology for diabetes care was considered to include telemedicine which was subsequently ranked lower; labour and birth choices was considered to overlap with safety of giving birth at full term and the need for induction. Groups also highlighted recurring themes that linked with multiple questions. For example, technology was considered to improve understanding of diabetes management and reduce burden, linking with mental health and well-being. Therefore, with further such links highlighted, both these questions were more highly ranked as the discussions progressed.

Consistently, top ranking questions through the surveys were regarding the long-term health impact of maternal diabetes on the child. The questions submitted in the initial survey were clearly split into risk of the child developing diabetes or the risk of wider health conditions. Ranking in the top 10 of all groups, both questions were shortlisted for the final workshop. However, neither reached the final top 10 (positions 11 and 12 respectively). Workshop discussions and post-workshop feedback from participants indicated several reasons for this apparent discrepancy. Firstly, the questions were considered to be addressed within the broader research agenda of child health, and not necessarily within pregnancy or women's health. The other questions all affected or contributed to the child outcomes, so it was felt they would help address these questions too. Some participants considered that the answers to the questions about long-term child outcomes would add burden to women already concerned by many factors associated with dealing with the responsibility of a pregnancy and diabetes. For some, 'how can it be prevented' was important wording, as it balanced the concerns of adding burden of information on risks, with learning about what can be done to prevent these being realised. One of the questions did not include the specific wording about prevention and so was ranked less highly. A further possible reason for these questions receiving less priority was because the votes were split; if presented as a single question, this may have meant a higher final ranking. A final possible reason may have been that the workshop consisted of people with recent experience, that is, within the last five years.

Feedback was received from 10 women and support network representatives, and 10 healthcare professionals from the workshop:

> *'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 2 groups, despite having a similar mix of people from the different backgrounds'*

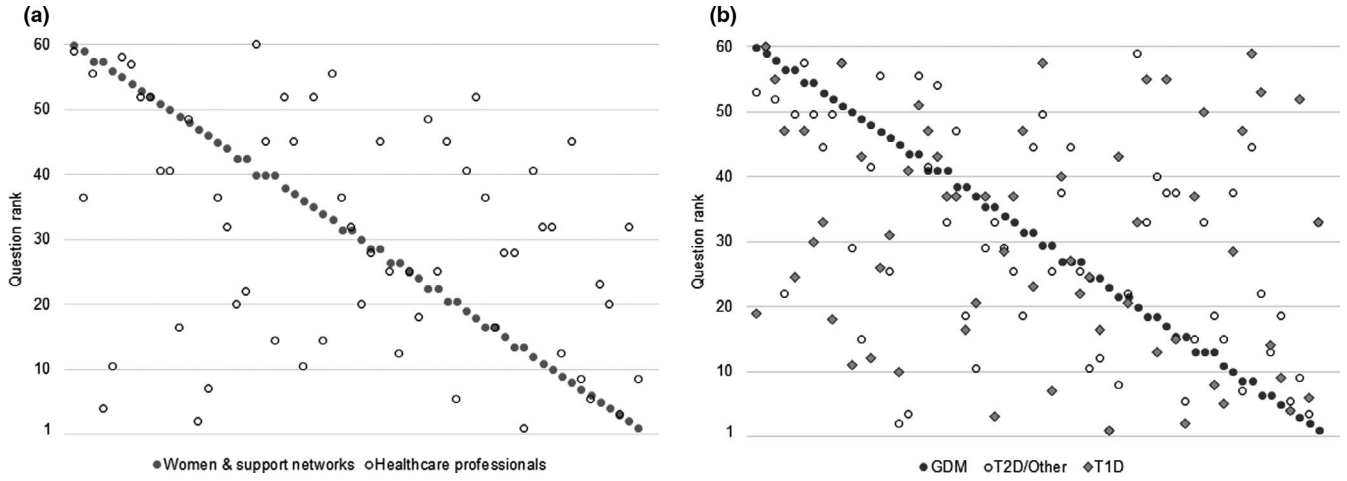

FIGURE 2 Interim survey question ranking comparisons between respondent groups. (a) Main groups: Indicative questions are ordered by rank position for women and support networks (60th to 1st place; left to right). (b) Diabetes type: Indicative questions are ordered by rank position for the group that indicated interest/experience in gestational diabetes (60th to 1st place; left to right). 'Other' types were grouped with type 2 diabetes due to low number and greatest similarity in rankings. T1D – Type 1 diabetes; T2D – Type 2 diabetes; GDM – Gestational diabetes mellitus

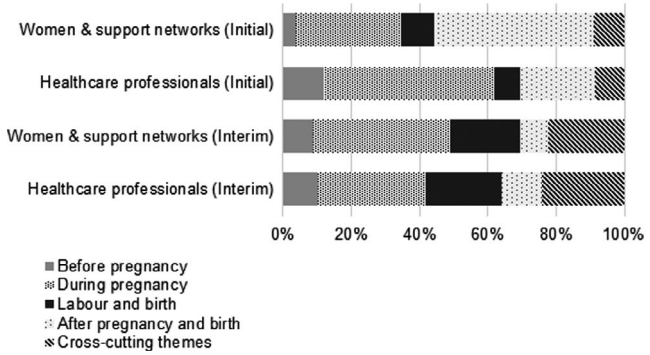

FIGURE 3 Survey submissions by main group. The initial and interim survey submissions for women and support networks, and healthcare professionals proportioned by phase of pregnancy

> *'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'.*

Further excerpts of the feedback and the JLA's review of the online format of the workshop are available at www.jla.nihr.ac.uk/development-of-online-priority-setting-workshop.htm.

4 | DISCUSSION

4.1 | Main findings

We supported women, their support networks and healthcare professionals to jointly identify the top 10 questions for research in diabetes and pregnancy. The final list includes priorities of relevance to all the stakeholders, all types of diabetes and preconception to long-term post-pregnancy. These questions were generated through a robust and inclusive process, which can be trusted and used by funders of research and researchers to inform their research activities towards addressing evidence gaps of great need and impact.

There is consistency across many areas also identified by the modified prioritisation exercises in Canada and the USA focussing on gestational diabetes, such as screening, risk factors, prevention and clinical management of diabetes in the woman.[10,11] For example, whether there is a better test for diabetes during pregnancy than the oral glucose tolerance test was ranked joint first for similar reasons of application, interpretation and practicality, with no apparent consensus on the thresholds, methods and timing to test for diabetes in pregnancy, due to small-sized studies. Our participants raised further questions such as the possible use of testing to predict gestational diabetes, the stratification of testing by risk and testing within special populations, such as those who have undergone gastric bypass surgery, and open up further opportunities for research.

There are also some clear differences in priorities including preconception care, late pregnancy diagnosis, labour and birth experiences and post-natal care needs, particularly breastfeeding. The role of diabetes technology was ranked joint first position, and while explicably not featuring in the gestational diabetes exercises, technology-specific questions formed the top three of the JDRF UK type 1 diabetes PSP final top 10. There have been significant developments in diabetes technology in the last few years with ongoing innovations.[16] In the time since the final workshop, the National Institute of Clinical Excellence has completed their review and approved the

funding of continuous glucose monitoring for pregnant women with type 1 diabetes, in line with *The NHS Long Term Plan*.[17,18] However, our results endorse their recommendations for further large-scale research in different monitoring methods and systems (i.e. insulin pumps) in women with diabetes of different types, through all stages preconception to post-pregnancy, and importantly with wider population diversity. There are also wider facets to consider such as apps, automation, data integration platforms and data sharing in supporting the management of diabetes.

Risks to the child's health was the number one priority identified by women in the Canadian exercise, and ranked highest in the USA exercise, but strikingly fell outside our top 10. However, the possible reasons for this, based on differential prioritisation of two related summary questions, made clear that the impact on the child is still considered highly important for separate study.

Important overarching issues were noted around continuity of care and support (particularly post-birth), consistency in care standards and advice, joint decision making (particularly in labour and birth) and the burden for women of being diagnosed with and managing diabetes. The consequences on women's well-being and mental health were at the core of much of the discussion at the final workshop. The initial survey submissions also raised further unanswered questions about the impact of a 'medicalised' pregnancy, withdrawal of intensive clinical involvement postpartum and support needs of women if adverse outcomes in their child linked to diabetes are realised. There is ongoing lack of evidence on the support pregnant women with diabetes may need as previously echoed by the gestational diabetes prioritisation exercises. However, the Diabetes UK *Too Often Missing* report highlights pregnancy as a time of particular high risk for emotional and psychosocial impact of diabetes requiring increased awareness and support.[19]

5 | STRENGTHS AND LIMITATIONS

This is the first priority setting exercise to focus on all different types of diabetes and at any stage before, during and after pregnancy, including long-term post-pregnancy.

The initial survey was completed in 2019 before the Covid-19 pandemic and lockdowns, but the interim prioritisation survey and final workshop took place during the pandemic over 2020. Due to the restrictions, the interim survey and final workshop could only be completed online. Despite an increased response rate in the interim survey, the online-only nature will have imposed limitations on who could take part. Reliance on online-only means of communication and participation may also have affected outreach, particularly to ethnic minority groups, which was achieved in the initial survey mainly through the support of community champions and face-to-face approaches in hospital clinics. However, despite our best efforts, representation was below what may be expected based on national population statistics, particularly Black and Black British groups.[20] Therefore, the results may not be representative of the priorities of ethnic minority groups.

Although the indicative questions were established before the 2020 Covid-19 pandemic, it is possible that the voting in the interim survey and, consequently, the shortlist of questions for the final workshop have been influenced. The final workshop participants were advised to consider the shortlisted questions thinking longer term beyond the pandemic so that this would not unduly influence the results for the future. More generally, it is not assured that if the exercise was redone that the same priorities would be identified and assigned the same rank.

6 | CONCLUSIONS

Further research is needed to provide evidence-based healthcare for women, with or at risk of diabetes complications, who are planning pregnancy or are pregnant, to ensure the best outcomes for them and their children in the short and long term.

The Covid-19 pandemic has highlighted the importance of inclusive research. Pregnant women, those planning pregnancy or breastfeeding are often actively excluded from clinical trials, perpetuating the population as a vulnerable group.[21] The addition of co-morbidities, such as diabetes, complicates matters further. As well as improved health and well-being for generations of families, interventions which improve outcomes for pregnancy with diabetes provide significant opportunity in terms of cost savings.[13]

The questions identified are areas that still have significant uncertainty and are considered to be of most importance by the beneficiaries of that research. This work presents further opportunity for funders and researchers to focus future research to address the priorities of women, support networks and health professionals.

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CONFLICT OF INTEREST

GA, FA, IB, NB, CB, SC, DC, KC, JG, MK, JLZ, FM, RM, NM, AM, JO, NR, CS, KS, AS and JAS none declared. JEH is a member of the NICE Diabetes Committee and holds a UKRI Future Leaders fellowship. HRM sits on a scientific advisory board for Medtronic (insulin pump and CGM manufacturer) and has received research support from Medtronic, Dexcom and Abbott Diabetes Care Inc. (CGM devices). MWJS has received honoraria from Astellas, AstraZeneca, Eli Lilly, Merck, Sanofi, Eisai and Bristol Myers Squibb, and has contributed to advisory boards for Novo Nordisk, Eisai and Servier.

AUTHOR CONTRIBUTIONS

GA and MK conceived the idea for the project and led the PSP. GA had full access to the data, coordinated the PSP process, drafted the surveys, analysed and led the interpretation of the data and wrote the first draft of the manuscript. GA, FA, IB, NB, CB, SC, DC, KC, MD, JG, JH, MK, AM, HM, JO, CS, KS, AS and MS are members of the Diabetes and Pregnancy Priority Setting Partnership (PSP) steering group and were responsible for the development of the protocol, and conduct, integrity and oversight of this work. All steering group members contributed to the outreach and communication activities to maximise participation and awareness. KC facilitated and chaired the PSP process, steering group and final workshop. GA, JS, NM, NR, RM, JL-Z, FM and MK completed the evidence checks. MK and KC are joint senior authors. All authors reviewed and approved the manuscript and revised it for intellectual content.

DATA AVAILABILITY STATEMENT

The top 10 and the full long-list of indicative questions will be made available on the NPEU project website www.npeu.ox.ac.uk/jla-psp and JLA website www.jla.nihr.ac.uk/priority-setting-partnerships/diabetes-and-pregnancy. For further information, please contact the team at JLAPSP@npeu.ox.ac.uk.

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REFERENCES

1. Feig DS, Hwee J, Shah BR, Booth GL, Bierman AS, Lipscombe LL. Trends in incidence of diabetes in pregnancy and serious perinatal outcomes: a large, population-based study in Ontario, Canada, 1996–2010. *Diabetes Care*. 2014;37(6):1590-1596.
2. Davies SC. *Annual Report of the Chief Medical Officer, 2014, The Health of the 51%: Women*. London: Department of Health; 2015.
3. Lowe WL Jr, Scholtens DM, Lowe LP, et al; HAPO Follow-up Study Cooperative Research Group. Association of gestational diabetes with maternal disorders of glucose metabolism and childhood adiposity. *JAMA*. 2018;320(10):1005-1016.
4. Scholtens DM, Kuang A, Lowe LP, et al; HAPO Follow-up Study Cooperative Research Group; HAPO Follow-Up Study Cooperative Research Group. Hyperglycemia and adverse pregnancy outcome follow-up study (HAPO FUS): maternal glycemia and childhood glucose metabolism. *Diabetes Care*. 2019;42(3):381-392.
5. National Institute for Health and Care Excellence. *Diabetes in pregnancy: management from preconception to the postnatal period (NG3)*. London: NICE; 2015 [cited 2020 Nov 27]. (Clinical guideline NG3). Available at: https://www.nice.org.uk/guidance/ng3.
6. Scottish Intercollegiate Guidelines Network. *Management of diabetes: A national clinical guideline (116)*. Edinburgh: SIGN; 2017 [cited 2020 Nov 27]. Clinical guideline 116. Available at: https://www.sign.ac.uk/assets/sign116.pdf.
7. Crowe S, Fenton M, Hall M, Cowan K, Chalmers I. Patient's clinicians' and the research communities' priorities for treatment research: there is an important mismatch [published correction appears. *Res Involv Engagem*. 2015;1:2.
8. Gadsby R, Snow R, Daly AC, et al. Setting research priorities for Type 1 diabetes. *Diabet Med*. 2012;29(10):1321-1326.
9. Finer S, Robb P, Cowan K, Daly A, Shah K, Farmer A. Setting the top 10 research priorities to improve the health of people with Type 2 diabetes: a Diabetes UK-James Lind Alliance Priority Setting Partnership. *Diabet Med*. 2018;35:862-870.
10. Rees SE, Chadha R, Donovan LE, et al. Engaging patients and clinicians in establishing research priorities for gestational diabetes mellitus. *Can J Diabetes*. 2017;41(2):156-163.
11. Bennett WL, Robinson KA, Saldanha IJ, Wilson LM, Nicholson WK. High priority research needs for gestational diabetes mellitus. *J Women's Health*. 2012;925-932.
12. Boddy K, Cowan K, Gibson A, Britten N. Does funded research reflect the priorities of people living with type 1 diabetes? A secondary analysis of research questions. *BMJ Open*. 2017;7:e016540.
13. Susan G, Lichten CA, Leach B, Pollard J, Parkinson S, Altenhofer M. *Pregnancy research review: Policy report*. Santa Monica, CA: RAND Corporation; 2020. [cited 2020 Nov 27]. Available from: https://www.rand.org/pubs/research_reports/RR4340.html.
14. James Lind Alliance. *James Lind Alliance Guidebook*. Southampton: JLA; 2021 [cited 2021 Mar 8]. Guideline version 10. Available from: https://www.jla.nihr.ac.uk/jla-guidebook.
15. Hsieh H-F, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res*. 2005;15(9):1277-1288.
16. Beck RW, Bergenstal RM, Laffel LM, Pickup JC. Advances in technology for management of type 1 diabetes. *The Lancet*. 2019;394(10205):1265-1273.
17. National Institute for Health and Care Excellence. *Evidence review for glucose monitoring in women with type 1 diabetes who are planning to become pregnant or who are already pregnant*. London: NICE; 2020 [cited 2021 Mar 8] (Clinical guideline NG3). Available at: https://www.nice.org.uk/guidance/ng3/evidence/a-evidence-reviews-for-continuous-glucose-monitoring-pdf-8955770797.

18. NHS. *The NHS Long Term Plan*. NHS; 2019 [cited 2021 Mar 8] Available at: https://www.longtermplan.nhs.uk.
19. Diabetes UK. *Too often missing: Making emotional and psychological support routine in diabetes care*. London: Diabetes UK; 2020 [cited 2021 Mar 8] Available at: https://www.diabetes.org.uk/get_involved/campaigning/its-missing-evidence.
20. Office for National Statistics. *Population estimates for the UK, England and Wales, Scotland and Northern Ireland: mid-2019*. . ONS; 2020. [cited 2020 Nov 27]. Available at: https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates.
21. van der Zande ISE, van der Graaf R, Oudijk MA, van Dleden JJM. Vulnerability of pregnant women in clinical research. *J Med Ethics*. 2017;43:657-663.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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