Glycaemic control in labour with Diabetes

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Version control table

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
Minor 1	1.1	28 February	Natalie Wakefield	Study consensus meeting to occur prior to study design

SYNOPSIS

Title	Glycaemic control in Labour with Diabetes
Acronym	GILD
Short title	N/A
Chief Investigator	Dr Nia Wyn Jones
Objectives	**PRIMARY OBJECTIVE** To determine current practices in intrapartum glucose control and decide on how best to conduct a future trial for all forms of diabetes in pregnancy. **SECONDARY OBJECTIVES** • To assess common themes and variation in current UK clinical guidelines in intrapartum glycaemic care in women with all forms of diabetes and neonatal hypoglycaemia in the babies • To determine current practice, training and experience of midwifery staff in intrapartum glycaemic control in the UK • Record the views of women with diabetes in a current or recent pregnancy on acceptability of participating in research in intrapartum glucose control and ascertain the views of women on important outcomes for any future trial(s) • Assess adherence to local clinical guidelines in intrapartum glycaemic care in diabetes. • Determine the incidence of important outcomes e.g. number of women with diabetes whose term babies had hypoglycaemia or were admitted to the neonatal unit within 24 hours of birth. • Compare maternal and fetal outcomes in mothers who had intensive glycaemic control in labour and mothers who maintained a more permissive / relaxed control. • Determine presence of other risk factors (size of the baby/macrosomia/growth restriction, presence of infection/sepsis, hypothermia, third trimester control) associated with neonatal hypoglycaemia (potential confounders) • To reach consensus on the most important clinical components of a future trial of permissive versus intensive intrapartum glycaemic control (types of diabetes to be included, glucose levels, frequency of monitoring, outcomes), in pregnancies complicated by diabetes • To establish if a trial of intensive versus permissive intrapartum glycaemic control is feasible to conduct and determine the trial design • Understand facilitators or barriers (feasibility) of conducting a trial comparing permissive to intensive glycaemic control for women with diabetes • Evaluation of what the health economic assessment in the definitive trial might be or whether such an assessment is unnecessary.
Study Configuration	Mixed method scoping study with four linked work packages.

Setting	Maternity care in the NHS
Sample size estimate	This is a scoping study and a power calculation is not required.
Number of participants	Work package 1a: 132 guidelines Work package 1b: ~300 respondents Work package 1c: ~200 respondents Work package 1d: 36 units Work package 2: minimum of 30 participants Work package 3: 30 attendees Work package 4: interview sample size will be guided by data saturation but is expected to be around 30 women and 30 health care professionals.
Eligibility criteria	These are described in the individual work packages below but participants in work packages 1b, 1c, 2 and 4 should be – Aged 16 years or older (no upper age limit) – Employed as a midwife, obstetrician or endocrinologist, delivering care to women with diabetes in pregnancy in the NHS OR be a woman who has diabetes and has given birth in the past 3 years or is currently pregnant – Must speak adequate English – Ability to give informed consent
Description of interventions	Work package 1a: National audit of UK clinical guidelines Work package 1b: Online survey of midwifery staff and other health care professionals Work package 1c: Online survey of women who have diabetes and have given birth in the past 3 years or are currently pregnant Work package 1d: National prospective service evaluation of adherence to clinical guidelines for maternal glycaemic control taking place in secondary care via UKARCOG Work package 2: Delphi consensus building survey of relevant stakeholders Work package 3: Trial design with a consensus workshop of relevant stakeholders Work package 4: Qualitative telephone interviews with women and health care professionals. There will be no control group in this study.
Duration of study	The study will run over a 24-month period and funding is due to commence in December 2020. Survey participants (WP1b and WP1c) will be required to complete an online survey taking around 15 minutes. Delphi survey participants will be requested to complete three online survey rounds. Participants will be invited to a trial design consensus meeting which will be one day in duration. Participants will be included in a single telephone interview in WP4.
Methods of analysis	Data will be summarised using descriptive statistics for quantitative data and content analysis for qualitative free text data. Statistical analysis will depend on distribution of data. Framework analysis will be used for the qualitative interviews.

ABBREVIATIONS

ABCD Association of British Clinical Diabetologists

BAPM British Association of Perinatal Medicine

BICS British Intrapartum Care Society

BAME Black, Asian and minority ethnicities

CI Chief Investigator

CRF Case Report Form

GCP Good Clinical Practice

GDM Gestational Diabetes Mellitus

NCT National Childbirth Trust

NHS National Health Service

PIS Participant Information Sheet

RCM Royal College of Midwives

RCT Randomised controlled trial

REC Research Ethics Committee

R&D Research and Development department

T1DM Type 1 Diabetes Mellitus

T2DM Type 2 Diabetes Mellitus

UKARCOG UK Audit and Research Collaborative in Obstetrics and Gynaecology

UoN University of Nottingham

WP Work package

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STUDY BACKGROUND INFORMATION AND RATIONALE

Diabetes in pregnancy affects at least 5% of pregnant women or 40,000 women every year and is on the increase in the UK. For most women this is gestational diabetes (GDM) developing during pregnancy (87.5%), but some women have pre-existing diabetes (12.5%) which can be Type 1 (T1DM: 7.5%) or Type 2 (T2DM: 5%) (1). There is evidence that intensive or 'tight' glycaemic control in pregnancy reduces the risk of adverse outcomes for the mother (pre-eclampsia, diabetes complications, preterm delivery and operative birth) and the baby (congenital anomalies, macrosomia, birth injury, neonatal hypoglycaemia, neonatal unit admission and death) (1).

Traditionally, intensive glucose control (target 4-7 mmol/L) (1, 2) is recommended in labour. Treatment with intravenous insulin during labour to maintain intensive control, however, increases the risk of maternal hypoglycaemia in labour, which carries a risk to the mother. Hypoglycaemia in labour is reported to happen in up to 50% of mothers (3) and is more likely if the target range is narrow and low. It is much more likely to be required with T1DM and T2DM, with only 15% of women with GDM requiring intravenous insulin to maintain a target of <7.2 mmol/L in one study (4). Whilst trained endocrinologists and diabetes specialist nurses supervise antenatal control, midwives, using variable rate intravenous insulin infusion (a 'sliding scale'), adjust intrapartum glucose levels. Knowledge and ongoing training is recommended by the Joint British Diabetes Societies (JBDS), although it is unclear if this is happening routinely in practice. The JBDS also acknowledges that patients undergoing regional analgesia are particularly vulnerable to maternal hypoglycaemia and a more permissive target may be more appropriate for them.

However, accepting more permissive glucose levels in the mother may be detrimental to the baby. Maternal hyperglycaemia results in increased fetal insulin production because of excess placental transfer of glucose. Theoretically, avoidance of maternal hyperglycaemia in labour could reduce the risk of neonatal hypoglycaemia by preventing the acute rise in fetal insulin prior to birth.

Prevention of neonatal hypoglycaemia is a priority for women with diabetes. It is common within the first 24 hours of birth occurring in up to 50% of babies born to women with T1DM or T2DM (5) and 7 – 20% of women with GDM (6-7). It can range from mild and asymptomatic to more prolonged and severe, potentially causing long-term neuro-developmental problems for the baby. Although rare, litigation from such cases are a financial burden to the NHS. Between 2002 and 2011, 25 such claims had a total cost of £162 million (8). Neonatal hypoglycaemia is a leading cause of neonatal unit admission in early term neonates (37-38 week's gestation) (9). Currently within the UK there is a focus on providing safer care to term babies (≥37 weeks) whilst reducing the number of neonatal admissions. One of the focuses of this ATAIN programme has been neonatal hypoglycaemia, which accounted for 12% of all term admissions (>13000 over a 3-year period), represented over 76,000 care days and imposed a financial burden of over £25 million to the NHS (10). Many mothers of these babies requiring neonatal care for hypoglycaemia had diabetes (25% estimated from similar studies (11)). In babies of diabetic mothers, the majority (86%) were admitted to the neonatal unit within 4 hours of birth, a period known to be associated with a physiological transient fall in neonatal blood glucose amenable to feeding interventions (10). Appropriate management of mother during labour and baby in the postnatal ward may prevent such admissions by reducing the risk of hypoglycaemia or enabling its management with increased feeding in the postnatal ward.

As stated earlier, traditionally intensive intrapartum glucose control (target 4-7 mmol/L) (1, 2) is recommended. However, there is no consensus that this target is ideal, how well or how quickly these targets should be achieved, or whether clinicians are better at controlling targets

than women self-managing their diabetes. It is unclear if an identical approach is optimal in differing scenarios: type of diabetes (T1DM, T2DM or GDM), antenatal treatment (diet, metformin or insulin) and fetal risks (macrosomia, prematurity). With new technologies such as continuous glucose sensors, it is now possible to assess the percentage time in target range for glucose during labour (12). How this will affect the risk of complications in comparison to traditional hourly finger prick testing is uncertain. The traditional view that optimal antenatal control reduces complications such as macrosomia and optimal intrapartum control reduces risk of neonatal hypoglycaemia is challenged by evidence that antenatal control may be a more significant factor than intrapartum control in reducing the risk of neonatal hypoglycaemia (3). Hourly intrapartum testing is also intrusive for women and time consuming for health care practitioners.

There are no published randomised trials comparing different intrapartum glycaemic targets and the occurrence of neonatal hypoglycaemia. A systematic review included 23 cohort studies (2,835 women) and found a positive relationship between intrapartum glucose levels and the risk of neonatal hypoglycaemia in six studies, no relationship in 12 studies and a possible relationship in some analyses in five studies (3). The studies were too heterogeneous to allow meta-analyses with variations in target maternal glucose levels, definition of neonatal hypoglycaemia and the incidence of confounders including prematurity (5-30%), macrosomia (9-56%), maternal hypoglycaemia (0-56%) and third trimester control (HbA1c) with many studies failing to report these confounders. In addition, the studies were spread over a long period (1978-2016) during which the care of women with diabetes has changed dramatically and the thresholds for diagnosing gestational diabetes has been significantly lowered following the HAPO study, published in 2008 (13). This systematic review (3) and other recent studies (14-16) suggest that the optimising antenatal glycaemic control influences the risk of fetal hyperinsulinaemia more than intensive intrapartum control.

Whilst neonatal hypoglycaemia is common (one or more readings in the hypoglycaemia range recorded in 94% of infants of mothers with T1DM (12) and 12% of infants of mothers with GDM (4)), there is no universally agreed definition. A 2015 survey of all 161 neonatal units in England (17) found the majority (88%) used a value of < 2.6 mmol/L, but values ranged from 2.0 to 3.0 mmol/L. Similarly, the method for testing glucose levels and duration of monitoring differed widely; management practices were not assessed.

In addition, the safety of intensive control has recently been questioned, with some researchers advocating more permissive targets e.g. 8 mmol/L (18) citing evidence in other disciplines in medicine that intensive control is associated with increased morbidity and mortality. Due to the uncertainty on optimal glucose targets, it is therefore important to conduct this feasibility work to explore current practice, determine the best trial design and ascertain willingness of patients and acceptability to clinicians to participate in this clinical trial.

STUDY OBJECTIVES AND PURPOSE

PURPOSE

To determine the feasibility of a randomised clinical trial for assessing the clinical and cost-effectiveness of permissive versus intensive intrapartum glycaemic control in women with pregnancies complicated by diabetes.

PRIMARY OBJECTIVE

To determine current practices in intrapartum glucose control and decide on how best to conduct a future trial for all forms of diabetes in pregnancy.

SECONDARY OBJECTIVES

Work package 1a: To assess common themes and variation in current UK clinical guidelines in intrapartum glycaemic care in women with all forms of diabetes and neonatal hypoglycaemia in the babies

Work package 1b: To determine current practice, training and experience of midwifery staff in intrapartum glycaemic control in the UK

Work package 1c: Record the views of women with diabetes in a current or recent pregnancy on acceptability of participating in research in intrapartum glucose control and ascertain the views of women on important outcomes for any future trial(s)

Work package 1d:

- Assess adherence to local clinical guidelines in intrapartum glycaemic care in diabetes.
- Determine the incidence of important outcomes e.g. number of women with diabetes whose term babies had hypoglycaemia or were admitted to the neonatal unit within 24 hours of birth.
- Compare maternal and fetal outcomes in mothers who had intensive glycaemic control in labour and mothers who maintained a more permissive / relaxed control.
- Determine presence of other risk factors (size of the baby/macrosomia/growth restriction, presence of infection/sepsis, hypothermia, third trimester control) associated with neonatal hypoglycaemia (potential confounders).

Work package 2: To reach consensus on the most important clinical components of a future trial of permissive versus intensive intrapartum glycaemic control (types of diabetes to be included, glucose levels, frequency of monitoring, outcomes), in pregnancies complicated by diabetes.

Work package 3:

- Through assimilation of information collected in work packages 1 -2, establish if a trial of intensive versus permissive intrapartum glycaemic control is feasible to conduct and determine the trial design.
- Evaluation of what the health economic assessment in the definitive trial might be or whether such an assessment is unnecessary

Work package 4: Understand facilitators or barriers (feasibility) of conducting a trial comparing permissive to intensive glycaemic control for women with diabetes.

STUDY DESIGN

STUDY CONFIGURATION

This scoping study will determine the feasibility of a randomised clinical trial and the way in which a trial should be designed for glycaemic control in labour with diabetes. Work package 1 aims to determine current practice and womens' views of research in this area. Work package 2-4 aims to determine the most appropriate and acceptable design for a future RCT.

This study is a mixed-methods study with several work packages, as described below:

Work package 1a: National audit of UK clinical guidelines
Work package 1b: Online survey of midwifery staff and other health care professionals
Work package 1c: Online survey of women who have diabetes and have given birth in the past 3 years or are currently pregnant
Work package 1d: National prospective service evaluation of adherence to clinical guidelines for maternal glycaemic control taking place in secondary care via UKARCOG
Work package 2: Delphi consensus building survey
Work package 3: Trial design with a consensus workshop
Work package 4: Qualitative telephone or online interviews with women and health care professionals.

STUDY MANAGEMENT

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

The data custodian will be the Chief Investigator.

A Study Management Group (SMG) will be responsible for day-to-day management of the project. Membership of this group will include the Chief Investigator (Jones), Assistant Professor (Mitchell) and study coordinator, with other members of the wider study team invited to attend as necessary. This group will meet monthly for the duration of the project. Day-to-day management of individual work packages will be the responsibility of work package lead/co-leads, supported by the SMG.

Oversight will be by an independent Study Steering Committee consisting of independent members approved by the funding body. This Steering Committee will meet (either in person or by video conferencing) soon after commencement of the project and then at a minimum of once yearly (to be decided by the Committee according to NIHR guidelines and outlined in the Charter), to ensure maximum integration of the work, problem solving of any issues, and timely delivery of outputs. The SMG will report to the Steering Committee.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration: 24 Months

Participant Duration: Survey participants (WP1b and WP1c) will be required to complete an online survey, which is expected to take around 15 minutes. Delphi survey participants will be requested to complete three online survey rounds with intervals in between; it is expected all three surveys will take place over a 12 week period. Participants will be invited to a trial design consensus meeting which will be one day in duration. Participants will be included in a single telephone or online interview in WP4.

End of the Study

When all data for all work packages is collected or end of funding.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

Work package 1a: No participants are involved directly in this work package. Local clinical guidelines will be collected from all Delivery Suites across the UK. Where possible, guidelines

which are easily accessible online will not have to be collected from Delivery Suites. Those which are not available online will be requested via the British Intrapartum Care Society. If no response is received after an initial request and a one-week reminder, the guidelines will be requested via the Directors and Heads of Midwifery network.

Work package 1b: Midwives will be invited to complete the online survey via social media and the Royal College of Midwives (RCM). RCM Directors and Heads of Midwifery network and RCM consultant midwives will highlight the study. Midwives will be encouraged to distribute amongst their peers utilising a snowball sampling technique to further disseminate. This online survey will also be available for completion to other health care professionals including diabetes specialist nurses, endocrinologists, consultant and trainee obstetricians and neonatologists. Recruitment of these groups will be facilitated by social media and/or email information from ABCD, BICS, UKARCOG and BAPM. The National Pregnancy in Diabetes Audit (NPID) newsletter have also agreed to include information about the surveys. Midwives and other Healthcare professionals (as above) who complete the survey will be invited to take part in the Delphi survey (WP2) if they wish.

Work package 1c: Women will be invited to complete the online survey via social media and website advertisement from appropriate networks, which include, but are not limited to; NCTU's Bump2Baby online PPI group, NCT, Positive Birth Movement, National Maternity Voices, Gestational Diabetes UK and Diabetes UK. The study PPI advisory group will disseminate the survey with their peers and local network groups. The PPI advisory group will also recruit women from BAME and seldom-heard groups by attending local existing groups and completing surveys. Women who complete the survey will be invited to take part in the Delphi survey (WP2) if they wish.

Work Package 1d: Units will be recruited to take part in the service evaluation via UKARCOG. Regional leads will cascade the service evaluation to local data collectors within individual hospital trusts.

Work Package 2: Participants will be recruited to take part in the Delphi survey from several stakeholder groups. Women with diabetes and midwives who have agreed to take part in the Delphi survey when completing online surveys in WP1, will be invited by email (having previously provided an email address in work packages 1b and 1c). Midwives will also be invited to take part in the Delphi through the RCM Directors and Heads of Midwifery and Consultant Midwives Networks, and via social media. Obstetricians will be invited through social media and/or emails via BICS and UKARCOG, neonatologists will be invited via BAPM and endocrinologists via ABCD. The National Pregnancy in Diabetes Audit (NPID) newsletter will also publicise the survey. Participants who complete the Delphi survey will be asked for their willingness to attend the consensus workshop (WP3).

Work package 3: Stakeholders will be invited to attend the consensus workshops from the following groups: obstetricians, endocrinologists, neonatologists, midwives, trialists/ methodologists, PPI groups and women who have experienced labour with diabetes. Stakeholders will be invited via email if they have expressed a willingness to attend via the Delphi survey or previous survey responses.

Work package 4: Women will be recruited to participate in the qualitative interviews via social media, posters and website advertisements from appropriate networks, which include but aren't limited to; NCT, Positive Birth Movement, National Maternity Voices, RCOG Women's Voices, Gestational Diabetes UK and Diabetes UK. The study PPI advisory group will disseminate the survey with their peers and local network groups. Women will also be recruited through community and third sector organisations such as children's centres. Targeted recruitment, using a sampling matrix, will be used to ensure specific groups are represented

where there is evidence the characteristics of these groups might influence the acceptability of different intrapartum tests or techniques and where groups are typically under-represented in perinatal research e.g. women from minority groups. Targeted recruitment will also be used to ensure women with all forms of diabetes are interviewed. If these attempts at obtaining a representative sample are unsuccessful we will also approach women from under-represented backgrounds in groups local to the study team and give a presentation on the study and a personal invite to the qualitative interviews.

Healthcare professionals employed as an obstetrician, endocrinologist or midwife will also be invited to take part. They will be identified via national publicity from BICS, UKARCOG, RCM and ABCD, and include individuals from the different disciplinary backgrounds and with differing levels of experience. Invites will be by social media and/or email.

Women and clinicians who express an interest to participate in the study will be sent a letter of invitation and participant information sheet (PIS) by post or electronically. If they are interested in taking part, they will return a pre-paid postal card or email response and consent form to the research team indicating their interest and providing contact details. A written paper consent form or online consent form will be completed depending upon participant preference. The researcher will then contact them to arrange a suitable time to interview after asking a few brief screening questions. Consent will be verbally reconfirmed at the beginning of the interview.

It will be explained to the potential participant that entry into the study is entirely voluntary and, for patients, that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

Eligibility criteria

Inclusion criteria

WP1a: Consultant led delivery unit within the UK

WP1d: Maternity units within the UK

WP4: Aged 16 years or older (no upper age limit)
Women who are currently pregnant or experienced the birth of a baby involving active labour in the past three years with T1DM, T2DM or GDM OR
Employed as an obstetrician, endocrinologist, or midwife
Must speak adequate English
Ability to give informed consent

Exclusion criteria

None

Expected duration of participant participation

Study participants will be participating in the study for:
1. online surveys (WP1b, WP1c) will be one-off surveys, which are expected to take around 15 minutes to complete. There will be three rounds of the Delphi survey (WP2) over a three month period; each is expected to take around 15 minutes to complete.

2. qualitative interviews (WP4) which will take around 45 minutes of their time over a six month duration.
The participants may be involved on one or both of these study modalities.

Participant Withdrawal

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future care. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

Informed consent

Participants taking part in the online surveys (WP1b, WP1c and WP2) will not provide written informed consent, completion and submission of the survey will be taken as implied consent.

All participants taking part in the qualitative interviews (WP4) will provide informed consent. Consent will be recorded via a written paper consent form or online consent form, depending on the participant preference. The informed Consent Form will be signed and dated by the participant before they enter the study. The qualitative researcher will explain the details of the study and provide a Participant Information Sheet regardless of the type of consent being recorded, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation.

The process of obtaining consent will be conducted before the qualitative interviews (WP4). As interviews will be conducted via telephone or online software, written informed consent will be posted or emailed to the Investigator prior to the interview or an online consent form will be completed.

STUDY REGIMEN

Work package 1a. **Lead: Jones (supported by Gazis, Ojha)**
National audit of UK clinical guidelines. No participant involvement. Focusing on intrapartum diabetes care, the study team will review each clinical guideline with data extraction in line with JBDS (2) and BAPM (19) recommendations to establish what monitoring is undertaken, with what technology, how often, when and how insulin is given, what are considered acceptable blood glucose levels for the mother and baby, which require treatment, and any differences in care for women with different forms of diabetes (T1DM, T2DM, GDM on treatment or diet) and their babies. With respect to neonatal hypoglycaemia, the guideline will be reviewed focusing on risk factors for routine monitoring, diagnostic criteria including functional threshold for hypoglycaemia, practices for monitoring and recommended management.

Work package 1b. **Lead: Jones (supported by Pallotti)**
Online survey of midwifery staff and other health care professionals that should take around 15 minutes or less to complete. One response is required.
The survey will ask about practice, training and experience in intrapartum diabetes care at their current hospital (region and whether teaching or district general hospital), including forms of intrapartum glucose monitoring (e.g. capillary sampling, Libre device) and insulin administration (e.g. intravenous insulin, sub-cutaneous insulin, pump device). We will ask how useful their hospital intrapartum guideline for glucose control is for delivering care and what information they feel is lacking/required at their unit. We will ask about their level of confidence in caring for women using the various approaches to establish what training would be necessary prior to a clinical trial. Similarly, questions will be asked on confidence in diagnosis

and treatment of neonatal hypoglycaemia. The survey will involve a set of closed questions, room for free text responses when 'other' is chosen, some open-ended questions and Likert scales for usefulness or confidence. The survey will be tested for clarity and face validity on a group of midwives and any necessary adjustments made prior to dissemination.

Work package 1c. **Lead: Mitchell (supported by Plachcinski)**

Online survey of women who have diabetes and have given birth in the past 3 years or are currently pregnant that should take 15 minutes or less to complete. One response is required. Women will be surveyed about their views on intrapartum testing, their (hypothetical) willingness to participate in a future clinical trial of intrapartum glucose control and their opinions of important outcomes for both mother and baby. The survey will involve a set of closed questions, room for free text responses when 'other' is chosen and some open-ended questions. Likert scales will be included where appropriate.

Work package 1d. **Lead: Rimmer (supported by Jones)**

A national prospective service evaluation of adherence to clinical guidelines for maternal glycaemic control taking place in secondary care via UKARCOG. No participant involvement. The service evaluation will include women with diabetes (T1DM, T2DM and GDM) who have experienced labour (elective Caesarean section births excluded) from 37 weeks onwards for an eight-week period. Intensive or 'tight' glycaemic control will be women whose glucose control has been maintained within the target range for that Maternity Unit. Permissive control will include women whose control has veered outside this target range and the duration of the time outside target. At each unit, trainees will collect numbers of women with T1DM/T2DM/GDM delivering at term and conduct a detailed service evaluation of 20 random cases, prospectively collected of women with diabetes (an average per centre of 3-4 women with T1DM and 3-4 women with T2DM with the remainder having GDM. This will result in a sample size to 108-144 women with T1DM and T2DM in the total sample size of 720. If required, to obtain the cases with T1DM/T2DM we will increase the sample duration or increase the number of cases collected from larger centres. We will also attempt to include cases in labour both weekdays and weekends, day and night). Data on maternal and neonatal characteristics (including birth weight, neonatal glucose level, admission to the neonatal intensive care unit and indication) will be collected. Information on deviations from their local clinical guidelines will be collected on study forms.

Work package 2. **Lead: Walker (supported by Jones)**

Delphi consensus building survey. Three rounds of surveys requiring completion will be sought from each participant with each survey expected to take around 15 minutes. We will utilise the information that has been collected in work package 1 to support the consensus building process. The principle of the Delphi technique is consensus building amongst a group of experts utilising a succession of surveys interspersed by feedback of results from each survey. The online Delphi survey will be conducted using the COMET Delphi Manager software. Each round of the survey is planned to take around three weeks, allowing time for responses to be submitted and automated reminder emails to be sent to non-responders after two weeks.

An initial email invitation will be sent to potential participants and contain a brief explanation of the study, estimated time for completion of each round (10-15 minutes) and emphasising the importance of completing all the rounds of the survey. Upon registration, participants will be asked for their name, geographical location and primary professional role. Participants' names and contact details will be recorded so that personalised reminders to complete the survey can be sent. However, to maintain full anonymity following online registration, the software will assign a unique study identifier to each participant, which will be linked to their survey responses that cannot be traced to individual names.

During the survey, the first round will involve questions focusing on four main aspects:

1. Which populations (T1DM / T2DM / GDM (diet) / GDM (on treatment)) requires assessment of glucose control in labour? Which group should be the priority?
2. Intensive control is usual in current practice (glucose target 4-7mmol/L). How important is it to obtain evidence of outcomes of more permissive glucose levels and what target would they be willing to recruit into/participate in any future study of more permissive levels e.g. 8, 10, 12 mmol/L? How often should we test glucose levels in those not on insulin?
3. What technologies should be studied in a trial both for monitoring, e.g. standard finger prick, continuous glucose monitoring sensors, and treatment e.g. continuous variable rate intravenous (sliding scale) insulin infusion, insulin pumps, closed loop?
4. What maternal and neonatal outcomes are important to collect in a trial e.g. neonatal hypoglycaemia, but at what level? What should be the primary outcome(s)?

Endocrinologists, midwives and obstetricians will be asked to comment upon all four aspects of the survey. Neonatologists and women will consider outcomes only.

Participants will be asked to rank responses using the Grading of Recommendations Assessment Development and Evaluation (GRADE) Likert scale. This utilises a 9-point Likert scale (1 to 9) to rank importance. For the first round, a list of outcomes derived from previous studies of intrapartum glycaemic control will be included with participants able to suggest other important outcomes to be added to the list. Valid new outcomes will be developed and the survey adapted for subsequent rounds of ranking. In subsequent rounds, each participant will be presented with the average distribution of scores from the previous round alongside their own score for each outcome or intervention. Participants will be asked to consider the responses from the other participants and review their score, either confirming or changing it. Space will be provided for participants to explain their reasons for changing an individual score. Invitation to participate in round two onwards is contingent upon completing the preceding round as participants will be presented with their own scores from the previous round.

Work package 3. **Lead: Mitchell (supported by Bradshaw, Ojha, Petrou, Thornton, Walker)**

Trial design with a consensus workshop; a one-day meeting either face to face or online.

The aim of the consensus workshop will be to:

- collate views on the results of the work packages to this point
- establish consensus on trial outcomes through review and vote on the Delphi survey results
- discuss possible aspects of a trial design
- consider feasibility of trial and aspects to consider in qualitative interviews
- consider the PICO elements for a future trial

Potential stakeholders include obstetricians, endocrinologists, neonatologists, midwives, trialists/methodologists, PPI groups and women who have experienced labour with diabetes. A total of 30 participants is planned and will aim to include around 3 participants from each of the stakeholder groups.

Following the workshop, co-applicants with expertise in the design and conduct of clinical trials will design a trial with involvement from the established PPI advisory group. Key elements of the design will be developed utilising the results of the earlier work packages including views on which population should be studied, what intensive and permissive values may be included,

what technologies should be studied, what the training requirements for the trial conduct would be, and what would be the important outcomes that should be included.

The design of the trial will take into account data from previous work packages and the consensus workshop and focus on:
1. **Population**: Given that there are important variances in the different forms of diabetes (T1DM, T2DM, GDM) we will use the information that we have gathered during this study to decide if it is feasible to conduct a future trial of intensive vs permissive control for all women, or stratified by type. If this were not feasible, what forms of diabetes should be prioritised for a trial.
2. **Intervention**: 'permissive' is defined as allowing a greater or freedom of behaviour and for the purposes of the trial permissive control will be defined. We envisage that this could either take the form of a higher upper range of glucose being acceptable, testing frequency or inclusion of newer technologies such as sensor devices.
3. **Control**: intensive control will be defined by analysis of current clinical guidelines in practice within the UK to ensure that the trial is pragmatic and allows for the greatest number of units to participate as a recruiting centre.
4. **Outcomes**: both maternal and fetal/neonatal outcomes that are important to both clinicians and pregnant women will be identified and the primary maternal and neonatal outcomes defined. Consensus is also required on whether both the primary end-points need to be significant to declare study success (co-primary) or not (multiple primary end-points) (20).
5. **Type**: A variety of trial designs will be considered: superiority or non-inferiority.
6. **Randomisation and consent method**: site level (cluster trial design) or individual level consent and randomisation will be considered.
7. **Training requirements for the conduct of the study**: information from the survey of midwives will be key to establishing this aspect.

Our PPI advisory group will have the opportunity to advise and co-develop study documentation including a lay summary, draft patient information and proposed outcome measures together with guidance and prompts. They will be asked to consider:

- Their understanding of what the study team is proposing
- The clarity and explanation of possible outcomes
- The clarity of the patient information sheet
- Are there any important areas that have been missed?
- Are we asking the right questions for women in this future trial?
- Do they have any other concerns?

Documentation will be sent electronically for review and virtual meeting(s) held to allow for understanding and discussion. This documentation will also be made available to participants prior to the qualitative interviews (work package 4) to help them understand the trial design.

The cost-effectiveness elements of the trial design will also be considered during the trial design stage and will:

(i) assess the availability of routine data sources that can be used to complement and validate resource utilisation data collected through bespoke trial case report forms
(ii) identify appropriate sources of unit costs for potential resource consequences and assess how much primary costing research will be required for a definitive trial-based economic evaluation
(iii) identify the best possible way of expressing the cost-effectiveness of intensive versus permissive intrapartum glycaemic control approaches, including using preference-based outcome measures amenable to cost-effectiveness based decision-making.

Work package 4. **Lead: Ayers (supported by Jones, Pallotti)**
Qualitative semi-structured interviews with women and health care professionals. As an explanation of the proposed trial, developed by the PPI advisory group in WP3 will either be sent to those that consent to participate in qualitative interviews and/or shown at the time of the interviews. It is anticipated that the following (high level) topics will be explored during interviews. All topics will be outlined in the semi-structured interview guide:

- Experience of intrapartum glycaemic control
- Acceptability of the proposed trial (e.g. methods and frequency of testing, glycaemic targets)
- Maternal/clinical barriers and facilitators to implementing intensive/permissive glycaemic control and conducting the research
- Site-specific contextual barriers and facilitators to implementing and conducting the research
- What would be the benefits and challenges of delivering this research (e.g. how might we improve engagement)?
- What would be the training requirements for midwives and clinicians?
- What would be women/clinicians' priorities in the conduct of the research?
- Willingness to randomise/be randomised into a future trial?

Interviews will be conducted by telephone or online video conferencing software by an experienced qualitative research fellow using the semi-structured interview schedule. Interviews will be audio-recorded. Participants' experiences and views on acceptability, barriers and facilitators to any future trial will be explored using a semi-structured interview schedule developed from a theoretical framework of acceptability (21). Interviewing will continue until data saturation is achieved, where major themes are reoccurring from previous participants and no new major themes are being discovered. Based upon our previous experience of similar studies (22) it is anticipated that around 20-30 participants will be required within each group (patient/healthcare professionals). Interviews should take approximately 45 minutes. Participants will be asked to provide basic socio-demographic information such as age, ethnicity and diabetes type/job role (as applicable).

If, after their interview, a participant no longer wants their interview transcript to be used, it will be withdrawn. Withdrawal requests should be received within 14 days of interview as, once the analysis has been completed, the interview transcript cannot be removed. However, quotes from the interview will not be used in any future report.

To protect participants' personal information, audio recordings will be identified by participant number. They will be recorded using an encrypted digital recorder. At the end of the interview files will be uploaded to a secure password-protected server and deleted from the digital recorder.

Transcription will be done by a transcription service under a data-sharing agreement which is General Data Protection Regulation (GDPR) compliant. Audio recordings, interview transcripts and data analysis files will be encrypted and stored on a password-protected, encrypted computer at City, University of London. Audio recordings will be deleted at the end of the study.

Compliance

Not applicable.

Criteria for terminating the study

Not applicable

ANALYSES

Methods

Work package 1a: Data extraction determined by the JBDS and BAPM recommendations, will be performed by one member of the study team and, to assess and ensure accuracy, double extraction is planned in 10% of guidelines, higher if we observe a high error rate. We will compare characteristics between the units that respond and those that do not (e.g. size of units/annual delivery numbers) to allow us to comment on whether the results are likely to be generalizable.

Work package 1b, 1c and 1d: Data will be summarised using descriptive statistics for quantitative data and content analysis for qualitative free text data. For work package 1d analyses will be presented overall and according to diabetes type. We will summarise maternal characteristics, adherence to guidelines, maternal and neonatal outcomes. Data analyses will be conducted by the work package lead with support from our study statistician (Bradshaw).

Work package 2: Responses will be summarised using descriptive statistics for quantitative data and line listings for qualitative free text data. For each round of the Delphi survey, the distribution of outcome ratings will be assessed as a single panel using histograms and also pending sufficient numbers by stakeholder group. Response rates, attrition bias, score changes between rounds, eligibility criteria, outcome scores and suggestion for primary outcome will be presented. Consensus statistics for each outcome will be presented and any factor that there is a 'Consensus in' or 'No consensus', will then be taken forward to a future consensus workshop.

We will use the definitions of consensus described in Table 1. Inclusion of an item in the subset to be discussed at the consensus meeting will require agreement by the majority of survey participants regarding the critical importance of the metric, with only a minority considering it unimportant. To investigate potential attrition bias, we will compare item mean scores and percentage of respondents scoring each metric as 'critical' in the previous round(s) for participants who did not complete a round with those of participants who went on to complete further rounds.

Table 1: Definition of consensus (23).

Consensus Classification	Description	Definition
Consensus in	Consensus that the technique should be included	≥70% participants scoring 7 to 9 AND <15% participants scoring 1 to 3
Consensus out	Consensus that the technique should not be included	≥70% participants scoring 1 to 3 AND <15% of participants scoring 7 to 9
No consensus	Uncertainty about importance of the technique	Anything else

Work package 4: Digital audio recordings will be transcribed verbatim, anonymised, and checked for accuracy. Identifiable information will be removed. Data will be analysed using

framework analysis which is suitable for work with multidisciplinary teams and studies where data is compared within and between different subgroups. A combined inductive-deductive approach will be used which enables specific research questions to be addressed as well as identifying unexpected or new themes related to acceptability of the proposed clinical trial. One researcher will do the coding and a selection checked for reliability. Data will be analysed using NVivo software. Regular meetings of the research team where problematic issues are documented, discussed, and resolved will ensure credibility.

Sample size and justification

No formal sample size calculations are required for this scoping study.
WP1a: 132 Consultant-led delivery suites will be approached, we will aim for a response rate of >60%.

WP1b: The survey will be available to all 3000 RCM members and we aim to have responses from around 300 members (10%). This response rate is deemed acceptable as many RCM members are specialist or community midwives who may not provide intrapartum care and not all midwives are active on digital platforms.

WP1c: As potential participants do not belong to groups with finite membership, it is not possible to provide a percentage response rate. Based on previous research, a response from 200 women will be considered reasonable.

WP1d: We anticipate 36 maternity units to participate in this work package.

WP2: As there is no standard method for sample size calculation for Delphi processes, we will use a pragmatic approach based on practicality and time available. The aim will be to recruit the largest panel possible, encouraging individuals from each stakeholder group to participate via email invitations to the online survey. A minimum of 30 participants will be accepted but there will not be an upper limit to the number of respondents to the Delphi survey.

WP3: A maximum of 30 participants will be invited to the workshop from all stakeholder groups.

WP4: Sample size will be guided by data saturation but is expected to be approximately 20-30 participants in each group.

ADVERSE EVENTS

There are no interventions included in this study. The occurrence of an adverse event as a result of participation within this study is not expected and therefore no adverse event data will be collected.
Should any emotional discomfort arise as a result of taking part in the qualitative interviews (WP4), participants will be signposted to the available services, such as support helplines or third sector organisations, and followed up by sending further information if requested by the participant. They will be directed to their GP or midwife to facilitate further support and debriefing if required.

ETHICAL AND REGULATORY ASPECTS

This study requires Sponsor approval and REC favourable opinion as it involves contact with patient and staff for research purposes. Work packages WP1b, WP1c, WP2 and WP4 requires Research Ethics Committee favourable opinion. Qualitative interviews (WP4) will be conducted

by an experienced researcher. It is unlikely that interviews will cause distress to participants or sensitivity around the topic, but if this arises it will be handled sensitively by the researcher and further support offered as discussed above.

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC). Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The project does not require NHS R&D or Health Research Authority permission as it does not involve recruitment of participants via the NHS for research purposes. All work packages have been submitted and received Research Ethics Approval favourable opinion from the University of Nottingham Faculty of Medicine and Health Science.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice and the UK Department of Health Policy Framework for Health and Social Care, 2017.

INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator or their nominee and the participant shall both sign and date the written Consent Form before the person can participate in the study.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Study records.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No study-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Consent Form by the REC and use of the amended form (including for ongoing participants).

For Surveys: Completion and subsequent return of surveys will be taken as implied consent and separate written informed consent will not be sought. We also plan to send survey participants a lay summary of the results of the study if they provide a contact email address

and consent for this will be included within the information regarding the survey that the participants will agree to prior to completing the study.

RECORDS

Case Report Forms

Each participant interviewed will be assigned a study identity code number, allocated at entry to the study, for use on a brief demographic information collection form, audio recordings, transcriptions and the electronic database. The documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available).

For the qualitative study the investigator will make a separate confidential record of the interview participant's name, date of birth, and Participant Study Number (the Study Recruitment Log), to permit identification of all participants enrolled in the trial, in accordance with regulatory requirements and for follow-up as required.

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialed and dated.
The Chief Investigator shall sign a declaration ensuring accuracy of data recorded in the CRF.

For the online surveys the results will be downloaded as Excel files and the audit and service evaluation will collect data on a specifically designed data collection form in on the Redcap database platform. Data here will be anonymized and entered using a unique study ID for each patient. Identifiable patient information will not be collected.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, study records, field notes, interview transcriptions and audio records. A CRF may also completely serve as its own source data. Only study staff shall have access to study documentation other than the regulatory requirements listed below.

Audio from the interviews will be recorded with an encrypted digital audio recording device. The audio recorded files will be transferred from the audio recording device to a password protected One Drive on the servers at City University of London which are regularly backed up.

Audio files will be labelled with the study identity code number. Audio files will be sent to an external data transcribing organization 'Essential Secretary' bound by data protection regulation.

Transcripts of the audio files will be labelled with a study identity code number and stored on a password protected One Drive on the City, University of London, servers. Transcript codes will be held on a password protected database which will be shared within the research team only. Audio files and transcripts will be stored for seven years and then archived at secure archive facilities at the University of Nottingham.

Direct access to source data / documents

The CRF and all source documents shall made be available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities.

DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018. The researchers will only collect the minimum required information for the purposes of the study. Study documents will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the study staff and investigators and any relevant regulatory authorities (see above). Computer held data including the study database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one-way encryption method).

Information about the study in the participant's medical records / hospital notes will be treated confidentially in the same way as all other confidential medical information.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

Surveys in WP1 will be conducted using Online Surveys (onlinesurveys.ac.uk) software. Survey responses will be anonymous except for those who express an interest to join the Delphi survey in WP2, as they will be asked to provide an email address to allow ongoing contact. This principle also applies to those who complete the Delphi survey and express an interest in attending the consensus workshop (WP3) and the qualitative study in WP4. Full details of the data security for Bristol Online Survey are given here: https://www.onlinesurveys.ac.uk/help-support/online-surveys-security/. The Delphi survey will be distributed using COMET Delphi Manager software. The only identifiable information collected from the survey respondents, if provided, is their email address to allow the study team to invite them to participate in further work packages and also to send a summary of the results of the study. This information will be restricted to personnel approved by the Chief Investigator and the data shall be deleted after completion of the study.

For the UKARDOG service evaluation (WP1d) a list of patient's hospital numbers will be held on a password protected NHS Trust computer and linked to an study number which will be created at the time data patients data is entered into the secure data collection tool hosted by the University of Nottingham. For example, Royal infirmary Hospital, No: AA123456 will be linked to service evaluation No RIE01. This will facilitate linkage of patient records should further information be requested by the study team or steering committee from the UKARCOG data. No patient identifiable data will leave the Trust and any data linkage will be made bythe clinical care team at the individual NHS Trust and the anonymised information only sent to the study team linked to the study ID. This ethical approval will also allow data from an NHS Trust to be held securely by another institution, University of Nottingham.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

Insurance and indemnity for clinical study participants and study staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of

HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff with both public liability insurance and clinical trials insurance in respect of claims made by research subjects.

STUDY CONDUCT

Study conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, timeliness of visits); accountability of study materials and equipment calibration logs.

STUDY DATA

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation.

Study data and evidence of monitoring and systems audits will be made available for inspection by the REC as required.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all anonymised audio recordings, study databases and associated meta-data encryption codes.

DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising identification code numbers to correspond to research data in the computer files.

The researcher will ensure the participants confidentiality is maintained when using telephone or online video call methods by using university encrypted devices. This will include a City University of London laptop attached to the University network, which is password protected and encrypted to maintain its security. For telephone interviews, calls will be made using the researcher's university issued mobile device, all contact information (Name, Telephone Number) will be removed from this device once the interview is complete. No one other than the researcher will see this User ID or contact information. There will be no retention of personal data on the devices or platforms used.

As the interviews will be carried out remotely, the researcher will use a private/home office space where only the researcher is present. This will allow them to maintain confidentiality of any information shared.
All interviews will be audio recorded using a City University of London issued audio recording device with encryption software, ensuring this device is GDPR compliant. After the data has been collected it will be transferred from the device onto the researcher's City, University of London laptop and stored on the encrypted University Network Drives. The data will be collected via audio recording only.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Anonymised data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

The research findings will be disseminated via a published HTA monograph, research papers published in high-impact peer reviewed journals and presentations at medical and midwifery conferences locally, nationally and internationally. Our patient/public partners (e.g. Diabetes UK, Gestational Diabetes) and other charities that are involved in the study will disseminate the results of this study and the need for a clinical trial to parents, through their own established networks. The study team, supported by the PPI advisory group will additionally use social media channels (Twitter, Facebook, MumsNet) to disseminate the findings through short vignettes and infographics.

USER AND PUBLIC INVOLVEMENT

We will utilise the Bump2Baby Parents' group for some of our PPI activities. Bump2Baby is an online PPI group, set-up and facilitated by researchers at the Nottingham Clinical Trials Unit, in order to involve parents and parents-to-be in the design and conduct of maternal and newborn health studies. The group runs on Facebook and Instagram, and parents are asked, using a variety of different posts, to share their views and opinions. Bump2Baby will form part of our overall PPI strategy for this study.

Additionally the study will also include a PPI advisory group, which will be an integral part of the team that delivers this research study. Our PPI co-applicant will chair a PPI advisory group for the duration of the study whose role is to advise the study team on study conduct, documentation, interpretation and dissemination of results. The PPI advisory group will report directly to the Chief Investigator through its chair.

To ensure that current and future families support the results of this study and any future study that we recommend it is imperative that the views of the diverse population affected by diabetes is considered and at least half the members of the PPI advisory group will be from BAME

backgrounds. They can advise the research team on the approaches and wording of surveys and other information, which are most likely to elicit a positive response from their communities. We will encourage and support the PPI advisory group members to discuss appropriate elements of the project with their peers, and collect more parents' views on key issues, in order to ensure as many perspectives as possible are reflected in our findings. We have also planned and included costs for members of the PPI advisory group to attend their local existing groups (e.g. mother and baby groups) to approach women from BAME and seldom-heard groups to participate in both the planned survey and qualitative study, and our PPI co-applicant will run training for them on listening skills and presenting information to groups. The PPI advisory group members will be asked to participate in the Delphi survey and workshop. They will have the opportunity to advise and co-develop study documentation including a lay summary, draft parent information and proposed outcome measures together with guidance and prompts.
During data analysis the PPI advisory group will be given the opportunity to review the results and contribute to its interpretation and when results are published they will be asked to contribute to the production of the lay summary, infographics and dissemination to maximise opportunities for families to hear about this research. We will encourage group members to join the research team at appropriate conferences and events and to contribute the patient view to presentations.

The commitments of the PPI co-applicant and the PPI advisory group have been deliberated; costs to recompense for their time commitments have been fully discussed and agreed by our PPI co-applicant and are in line with INVOLVE rates. As gestational diabetes disproportionally affects women of Asian ethnicity, it is important to ensure we include a diverse group of PPI members. As such, we will work with groups such as the South Asian Health Foundation and the Centre for Black and Minority Health in Leicester in order to provide our advisory group members with a variety of sources of sensitive support and mentoring, as well as appropriate cultural training for the research team.

STUDY FINANCES

Funding source

This study is funded by the NIHR Health Technology Assessment (HTA) Programme (NIHR130175).

Participant stipends and payments

Participants will not be paid to participate in the study. Individuals participating in the online surveys in WP1b, WP1c and WP2 will be invited to enter into a prize draw of £100. In WP4 a gift voucher on £10 will be given to each lay participant as a token of appreciation.

SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name)_____

Signature:_____

Date: _____

AMENDMENT HISTORY

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

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