Study Protocol

Full Title:	**Planning mode of birth in routine antenatal care – development of a decision aid (Plan-A)**
Study Acronym:	**Plan-A**
Sponsor:	**University of Aberdeen**
Sponsor Reference Number:	2-112-22
Funder:	National Institute of Health and Care Research
Chief Investigator:	Dr Mairead Black
REC Reference Number:	23/ES/0013
ISRCTN / Clinicaltrials.gov No:	researchregistry8238
Version Number and Date:	V10 16/12/2024
Study Coordinating Centre:	Centre for Healthcare Randomised Trials (CHART), University of Aberdeen
Study coordinator:	Mrs Gillian Ferry

Study Investigators

Chief Investigator
Dr Mairead Black, Reader in Obstetrics, University of Aberdeen.

Co-investigators
Professor Vikki Entwistle, Decision support, ethics and social justice expert, Health Services Research Unit; Philosophy, University of Aberdeen

Professor Louise Locock, Experience of health and illness, qualitative methods and coproduction expertise, Health Services Research Unit, University of Aberdeen

Dr Tara Fairley, Obstetrics and NHS management expertise. NHS Grampian

Professor Siladitya Bhattacharya, Women's health research expert and mentor. School of Medicine, Medical Sciences and Nutrition, University of Aberdeen

Professor Declan Devane, Midwifery, consensus building and evidence synthesis expertise. School of Nursing and Midwifery University of Galway'

Professor Miriam Brazzelli, Evidence synthesis expertise. Health Services Research Unit, University of Aberdeen

Mrs Gillian Taylor, Community midwifery expertise. Peterhead Maternity Unit NHS Grampian

Ms Mary Kilonzo, Health economics expertise. Health Economics Research Unit, University of Aberdeen

Dr Denitza Williams, Decision aid development expertise. Division of Population Medicine, School of Medicine Cardiff University

Ms Mo Ade, Public representative, ethnic minority lived experience in maternity care and coproduction

Ms Pauline McDonagh Hull, Public representative of maternity service users, coproduction expertise. Caesarean Birth

Ms Lucinda Ward, Public representative with lived experience of maternity services

AIMS (Association for Improvements in the Maternity Services), representative of maternity service users, main contact is Nadia Higson

Dr Shawn Walker, midwifery expertise - supportive birth mode plans and maternity research. University London College Hospital

Table of Contents

Protocol Approval

Planning mode of birth in routine Antenatal care – development of a decision-aid (Plan-A)

Signatures

By signing this document I am confirming that I have read, understood and approve the protocol for the above study.

Dr Mairead Black		16 December 2024
Chief Investigator	Signature	Date

Inclusivity Statement

This document refers to 'women' throughout. In all cases this term is used to describe both those who identify as women and those who were assigned female sex at birth but who do not identify as women. Please see a detailed statement on the use of language below:

A statement on language: although most people who are pregnant identify as women, this is not universally true. We want to explicitly acknowledge that some pregnant people will have a different gender identity than 'woman' and that our materials are intended to be useful to all pregnant people.

Plan-A project statement on use of sexed and unsexed language

While the Plan-A decision aid will be aimed at all pregnant people, the Plan-A project has a particular focus on supporting mode of birth planning for those who come from underprivileged backgrounds and minoritised groups. We aim to be as inclusive as possible and to ensure that this is reflected in the language we use in our communications with the public and with potential research participants. We are aware, however, that word choices that work well for some do not work well for others.

Not all people who become pregnant identify as women. The Plan-A decision aid should be relevant to these people and the project team are interested to hear from them in the course of the study. Wording such as 'pregnant people' or 'birthing people' is potentially more inclusive of those who don't identify as women, but it is, at the same time, difficult and off-putting for others whom the Plan-A project is also seeking to serve. Many people from underserved groups, including those with low health literacy, limited education, learning disability, from minority religious groups or who do not have English as a first language, have a need for plain English communication and/or language that they can relate to. In current circumstances, the word 'women' seems necessary here to ensure the accessibility of project information and to support participation in the Plan-A study. A further consideration relevant to the Plan-A study is that key statistics expected to be included in the Plan-A decision aid are likely to have been reported in relation to 'women' in the original studies but may also reflect birth outcomes of those who do not identify as women. These considerations mean we have had to make some decisions about how we will use language in the Plan-A study materials.

Our proposal is as follows.

- Where possible, in study adverts and other recruitment information, we will use second-person language such as 'Have you given birth in the past 10 years?', giving the text a personal feel and not requiring either sexed or gendered language.
- When nouns are required in our main participant-facing materials, we will use the gendered terms 'woman' or 'women' where required to refer to people to whom the study is relevant. Similarly, when we refer to statistics in the content of the decision aid, we will use the term 'women' to refer to all people to whom the original studies have observed. We will, however, include a brief note in these resources and on the study website acknowledging that the use of the term is not intended to exclude.
- As we plan to translate study materials into different languages to ensure accessibility, we also intend to develop equivalent additional study materials which do not use sexed terms such that these resources will be available for those who do not relate to the term 'woman'.
- In direct communication with individuals who are participating or considering participating in the Plan-A study, team members will be careful to reflect individual's preferred identities and pronouns.

Abridged statement for study materials.
Although most people who are pregnant identify as women, this is not universally true. We explicitly acknowledge that some pregnant people will have a different gender identity than 'woman' and that our materials are intended to be useful to all. Please see the Plan-A website for our statement on use of language in the Plan-A study.

List of Abbreviations

CI	Chief Investigator
CNORIS	Clinical Negligence and Other Risks Scheme
GCP/GRP	Good Clinical Practice/Good Research Practice
IPDAS	International Patient Decision Aids Standards collaboration
NHS	National Health Service
NHSE	National Health Service England
PI	Principal Investigator
PPI	Patient and Public Involvement
R&D	Research and Development
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TMF/SMF	Trial/Study Master File
WP	Work Package

Summary

Research question
What should a decision aid to support antenatal conversations on mode of birth plans between pregnant women and health professionals look like, how should it be embedded in practice and what may the resource implications of its use be?

Background
Since the Supreme Court Montgomery case in 2015, NHS maternity services have been legally obliged to support pregnant women to make informed choices between planning vaginal or caesarean birth, but many providers struggle to do so. This is despite national guidance advocating birth mode choice since 2011. (1-3) A key barrier is the lack of balanced and relevant information at antenatal consultations, where what matters to individual women can be explored. Decision aids can help address this issue by providing a robust and usable information resource and framework(s) to support conversations about healthcare options; in this case between pregnant women (+/- their partners) and health professionals to plan a preferred mode of birth.

Aims
To develop and pilot use of an evidence-based decision aid to support conversations between pregnant women (+/- their partners) and health professionals during routine antenatal care, on the options of planned vaginal or caesarean birth. The decision aid will be designed to reflect the diversity of pregnant women, including that some already strongly prefer either vaginal or caesarean birth. It will be accompanied by an evidence-based implementation strategy to support its use in routine antenatal care. We will also examine potential NHS resource implications of its use.

Methods
The project will use established decision aid development, implementation science and economic modelling methods across six linked work packages (WPs). (4) The research team includes four public representatives, researchers and health professionals from diverse backgrounds. Pregnant women, women who have recently given birth and health professionals will coproduce the decision aid and the implementation strategy for its use with the research team.

Systematic reviews of published evidence (WP1) will identify 1) pregnant women's decision support needs when planning birth mode; 2) influences on women's preferences for planned vaginal birth or caesarean birth; 3) experiences of communication during antenatal care among women from minority and under-served groups. Risks, benefits and consequences of planned vaginal birth and planned caesarean birth from the 2021 NICE Caesarean Birth guideline (with updated search) will be summarised along with published guidance on mode of birth planning in key clinical scenarios (e.g., previous caesarean birth). WP1 findings will inform WP2 (evolving interview study), WP3 (decision aid content prioritisation) and WP4 (decision aid and implementation strategy development). (2)

A qualitative interview study (WP2) will explore questions relating to the decision aid scope, purpose, audience, content, format and perceived barriers and facilitators of its use. Perspectives are expected to reflect interviewees' values and personal experiences (where they have previous planned mode of birth). Parents, prospective parents, GPs, obstetricians, and midwives in the UK will be interviewed virtually, or in-person where preferred. Multifaceted recruitment strategies will ensure a diverse sample

of the UK population, including participants with the protected characteristics and those from minority and underserved groups. The findings will inform WP3 and 4.

A Delphi consensus process (WP3) will ascertain stakeholders' priorities regarding which experiences and outcomes of planned vaginal birth or caesarean birth should be included in a decision aid and their relative importance. Parents, prospective parents, midwives, obstetricians, anaesthetists, GPs, health visitors and paediatricians will be included in a 2-round Delphi electronic survey (same people in round 1 and 2) and a virtual workshop. A long-list of potentially important outcomes from WP1 and 2, in addition to those already highlighted for discussion in national guidance will be included in the first round. No limit will be applied to survey sample size, but appropriate representation from those with protected characteristics will be a priority, and a goal set of at least 50% public participants. Priority ratings will be discussed at a consensus workshop, with attention paid to group differences and important but minority concerns.

The initial decision aid and draft implementation strategy will be developed by the research team and a patient and public involvement (PPI) panel (WP4), using WP1-3 findings and storyboarding techniques, and guided by National and International criteria for developing decision aids. (5-7) The decision aid - likely electronic and web-based with additional formats to promote accessibility – is expected to highlight the choice between planning vaginal birth or caesarean birth and provide evidence-based information along with guidance on how to incorporate individual values, preferences and responses to uncertainty in a 'Plan-A' decision. The decision aid is likely to be used primarily in consultations with health professionals, although may also be shared before and after consultations (guided by WP1-3 findings). Three rounds of workshops with pregnant women, women planning pregnancy or previously pregnant, obstetricians and midwives, will develop and refine the decision aid and implementation strategy. An initial storyboard outlining proposed decision aid content and subsequently a prototype decision aid with variant features will be presented to workshop participants and feedback sought on appearance, format, ease and timing of use. Some workshops will specifically focus on gaining input from minority and under-served groups. This user-testing will support generation of a beta-prototype decision aid for field-testing. The implementation strategy will be refined e.g., wording of how to promote behaviours or messages to health professionals and women/couples to support implementation of the decision aid in routine antenatal care.

A phase of field-testing the decision aid in practice (WP5) will assess usability and acceptability and inform refinement of the tool. Pregnant women and health professionals will provide verbal feedback on their experiences of using the decision aid in practice at five research sites, and a sample of the decision aid uses in consultations will be observed. A sub-sample of these women will be interviewed by telephone 6 weeks after birth to reflect on use of the decision aid in retrospect. Ease of use, sense of value and any concerns about its content, format or its use will be addressed to maximise fidelity. Barriers and facilitators to implementation will be explored using an implementation science framework, the Theoretical Domains Framework, (8) and used to inform strategies for decision aid implementation in subsequent evaluation studies. Findings will also inform WP6 economic models of potential resource implications of the decision aid use in future, e.g. by indicating potential impact on consultation number and time (WP6).

Existing economic models of planned mode of birth and data from WP 5 will inform economic model development (WP6). We will consider NHS resource implications of the decision aid use, including a range of theoretical changes in consultation duration/number and planned caesarean birth uptake rates, with and without potential reduction in litigation incorporated in the models.

1 Introduction

1.1 Background

1.1.1 What is the problem being addressed?

Childbirth is a safe and positive experience for the majority of women in the UK but half of all first-time mothers experience complications that lead to medical or surgical assistance during labour and birth. (9) Most women aim for vaginal birth and although the majority are likely to achieve this, when interventions and/or complications occur many women feel that they had insufficient information to inform choices and understand what was happening during the birth. (1,10) The clinical profile of pregnant women has changed over time, and advanced maternal age, obesity and pre-existing medical conditions are more common. (11) Although these factors are linked to an increased risk of complications, they are yet to be fully incorporated into routine information provision about mode of birth. As a result, many more women feel unprepared for problems when they arise, particularly when aiming for vaginal birth. (12) Equally, a rise in caesarean birth means that more women are at risk of life-threatening complications in future pregnancies and are not always aware of this. Critically, despite maternity care providers having a legal obligation to inform women of the risks of their planned birth and any alternative options, this obligation is infrequently met in antenatal settings. (1,13) This is in contrast to surgical settings where, since the 2015 Montgomery ruling, consent guidance and processes have been updated and training courses developed to support surgeons to meet their legal obligations through shared decision making. (14) Shared decision making, the term used by NICE (also referred to as 'informed decision making' by NHS England), requires acknowledgement that choice exists before exploring options in the context of women's (or patients') values and preferences. (15)

As vaginal birth has traditionally been seen as the default by antenatal care providers, planned caesarean birth is rarely discussed as an alternative unless women have specific risk factors or take the lead in initiating this discussion. (16) Modern maternity care recognises the importance of active choice in birth planning to meet social and legal expectations, but specific conversations about mode and risks of birth are not yet fully embedded within care pathways. (1) In countries where childbirth is generally safe, with minimal risk to the life of mother or baby, profound dissatisfaction can result from a lack of understanding of why surgical interventions or complications arose. (10) Physical and psychological effects of birth can affect women for years, including the risk of hysterectomy after planned caesarean birth and the risk of incontinence after vaginal birth. (2) An informed discussion about complications of birth and any strategies to minimise these (including warm compresses to reduce anal sphincter injury or planned caesarean birth to avoid dystocia) would help fulfil recommendations by national guidance and legal precedent that pregnant women become primary decision-makers. (1-3,17) A framework to support this discussion would benefit both women and the NHS. Since 2011, NICE has recommended that all pregnant women are engaged in an evidence-based conversation about planned vaginal birth and planned caesarean birth to inform birth mode preparations, stressing the importance of incorporating personal values and preferences in these discussions. (2) However, a 2020 survey of 1500 women who had recently given birth found that while 74% had the chance to discuss benefits of vaginal birth antenatally, only 42% had the chance to discuss its risks. Corresponding figures for caesarean birth were 42% and 51% respectively. The same Birthrights UK survey also found that 61% of women would have liked more information from the NHS to plan their birth. (1)

The 2015 UK Supreme Court Montgomery case has meant that vaginal birth can no longer be legally regarded as the default planned birth mode and health professionals should now be prepared to discuss caesarean birth as a valid alternative. The ruling made clear that women at risk of any birth complication

which may be of material significance to them should be informed of their options (including planned caesarean birth) in advance. It states that they should be offered the chance to discuss their options and make their own choices in a system that '*treats them so far as possible as adults who are capable of understanding that medical treatment is uncertain of success and may involve risks, accepting responsibility for the taking of risks…, and living with the consequences of their choices*'.[3] Thus, the law does not support clinicians to decide who should be offered a choice of planned vaginal birth or planned caesarean birth.

Several recent reports on UK maternity service failings (including the 2020 Ockenden report) have highlighted that some women are not afforded an opportunity to discuss caesarean birth when it might have been beneficial. (18,19) Targets aimed at reducing caesarean birth rates and some health professionals focus on achieving vaginal birth have led to offers of emergency caesarean birth being withheld and contributed to adverse birth outcomes. (18,19) More generally, some health professionals think that providing caesarean birth as an option conflicts with their professional values and/or could increase caesarean birth rates, so avoid conversations aimed at informing birth mode plans. Where these conversations do take place, health professional's individual biases (including those of obstetricians biased towards caesarean birth) influence the information provided. (20) There is a need to neutralise both mode of birth conversations and the information provided so that women understand their options (and are confident they will be supported through a plan for whichever mode of birth) and staff legal obligations are met.

1.1.2 Planned mode of birth outcomes and women's values

Absent or inconsistent antenatal birth mode planning is a large-scale problem. Around 630,000 women plan vaginal birth in the UK each year, while 86,000 plan a caesarean birth. (21-23) Both planned caesarean birth and vaginal birth offer benefits, but in a small number of cases both also have serious consequences. The magnitude of these benefits and risks vary, depending upon women's clinical characteristics. The updated 2021 NICE guideline on caesarean birth summarises the overall risks in a systematic review comparing planned caesarean birth with planned vaginal birth. (2) Planned caesarean birth has greater risk of peri-partum hysterectomy (an extra 80 cases/100,000 women), maternal death (an extra 21 deaths/100,000 women), and childhood asthma in offspring. In subsequent pregnancies, planned caesarean birth leads to placenta accreta (57 more cases/100,000 women) and more cases of uterine rupture (982/100,000 women) compared to a plan for vaginal birth. Planned vaginal birth is linked to an increased risk of urinary incontinence (absolute risk 20-49% vs 7-19%) and faecal incontinence (15.1% vs 7.8%) after 1 year. NICE recommends that all of these outcomes are routinely discussed with women to inform birth plans, but it is not known what value women attach to them. It is also unclear whether women value other health outcomes or consequences of each birth mode that are not yet addressed by NICE.

Planned vaginal birth allows the option of home birth and a lower chance of medical intervention than planned caesarean birth. (24) Vaginal birth is associated with the use of forceps or ventouse in up to 17%, and anal sphincter injury in 5%. (25) These interventions and complications, along with emergency caesarean birth in at least 15% of individuals (~100,000 women per year), contribute to dissatisfaction, post-traumatic stress disorder and litigation. (26,27) The increased sense of control offered by planned caesarean birth explains why planned repeat caesarean birth is very common. (28) Acknowledgement of the severity of many long-term effects of childbirth has prompted calls for better information provision and shared decision making from both women and experts assessing the impact of the 2015 legal changes on maternity care. (29,30) The large volume of unstructured information can make it challenging for health professionals to present the risks, benefits and consequences of each option in a

relevant and useful format, and is likely to be a major barrier to these conversations happening in routine care. Unlike planned caesarean birth, there is no definitive 'patient information' source for a balanced view on vaginal birth, nor guidance on how to conduct these conversations. (31) This has made it difficult to meet health professional's legal obligations to inform women of their birth mode options in advance. Instead, women seek information elsewhere, including from websites such as 'Mumsnet', 'Babycentre' or 'Facebook', from friends and family and from health professionals in an 'ad hoc' manner. (32)

1.1.3 Reducing litigation and supporting current policy through a framework for shared decision making

NHS compensation pay-outs for women and babies who experienced adverse health outcomes due to substandard care exceeded £2 billion in 2018/19 alone. (33) Improved consent processes, including mainstreaming information provision, supporting informed choice as the norm, and acknowledging caesarean birth as a reasonable alternative birth mode are key to reducing these costs. (34) NHS maternity policies (e.g. Best Start, Better Births) and the Maternity Choice and Personalisation initiative within the NHS England's (NHSE) Maternity Transformation Programme have promised to improve the provision of information, choice and personalised care. (35-37) Yet at present, there is inadequate support for mode of birth planning conversations in routine antenatal care. A framework that enables women and health professionals to engage in a shared decision-making process and helps the NHS fulfil its statutory requirements (including legal obligations) when planning the mode of birth is a critical unmet need.

1.2 Rationale for Study

A search of Medline, Embase, Web of Science and CINAHL for papers published between 1999 and March 2021 included the terms 'shared decision making', 'planned caesarean', 'planned vaginal birth', 'information needs', 'planning', 'choice' and 'birth'. We found 34 articles and four systematic reviews relevant to this work as outlined above and below.

As women differ in their tolerance of the risks and benefits of pursuing vaginal birth and having a planned caesarean birth, the choice is preference-sensitive and amenable to shared decision making. Shared decision making is central to the personal care and support plan which NHSE's Maternity Transformation Programme sets out to deliver to every pregnant woman in the antenatal period. This Programme has a specific focus on birth planning, yet clinicians, as noted above, find it difficult to engage in shared decision making in maternity care. (38,39) NHSE have specifically stated that '*doctors must provide information about all material risks – that is, risks that might matter to the woman, and any reasonable alternative or variant treatments'.* (40) NHSE have partly addressed the challenges of achieving this in the complex maternity setting through the development of 'iDecide', an intrapartum decision-making and consent tool, due to be piloted in 2022. (41) The iDecide team recognise that an antenatal tool to support planned mode of birth choice would be a valuable addition (personal correspondence with M Black). NHSE's approach recognises that shared decision making relies upon clinicians' knowledge and communication skills, and that augmenting these with a bespoke tool could support shared decision making in practice. (42) To that end our proposed study will use coproduction methods to develop a decision aid for antenatal mode of birth planning, together with an implementation strategy to support introduction of and use of the decision aid in practice.

Decision aids are designed to help people make informed choices that consider their values and preferences. In other clinical contexts (>100 randomised trials), use of a decision aid has been shown to improve patient's knowledge, reduce indecision and decision regret and decrease the use of major surgery. (42) A 2020 pilot study found that use of a shared decision making toolkit (decision aid,

counselling guide and provider scripts) led to a racially diverse population experiencing increased knowledge, greater sense of control, and feeling more listened to and supported when planning birth after previous caesarean birth. (43) Trials have previously shown decision aids to increase knowledge and reduce regret in women planning mode of birth after a prior caesarean birth, but there is no such decision aid for birth mode planning in routine care. (44) Decision aids can play a key role in reducing health inequalities, particularly benefitting disadvantaged groups such as those with low literacy levels. (45) This is especially relevant in maternity care, where adverse outcomes are more common in ethnic minority and socially diverse groups. (46) For diverse ethnic groups in particular, decision aids can enrich the communication between the patient and health professional and improve the quality of the decision made, facilitating personalised discussion. (47) Decision aids used by service users and health professionals together can make information easier to digest. In cultural contexts where women are not accustomed to making critical health-related decisions, decision aids can be shared with supporters or advocates too, to encourage wider discussion and help women to influence the choice. Recognising the importance of the contexts in which a decision aid will be used, the decision aid development process must include exploring what intended audiences want from it, and how, where and when it will be delivered. (48)

1.2.1 Evidence of insufficient mode of birth decision support

A recent systematic review of over 55 studies (49) found that support for women making a choice about mode of birth varied widely across professional groups and the public. (50) Many women preferred to make the choice with guidance from their midwives or obstetricians. In 2021, a study of 424 obstetricians (members of the UK Royal College of Obstetricians and Gynaecologists) found that only 15% would offer a planned caesarean birth to a woman with a known risk factor for vaginal birth complications and only 1 in 4 would discuss long-term pelvic floor damage as a vaginal birth risk. (51) A 2020 systematic review of 34 studies of women's and clinicians' views on planning caesarean birth found limited shared decision making taking place, with similar findings in a 2021 review of women's experiences of planned and unplanned caesarean birth in the UK. (13,52) Clinicians generally agreed with shared decision making, but recognised that it often does not occur, and women viewed decision aids and educational interventions positively. (52) Shared decision making is already partially embedded in maternity care conversations about antenatal screening, place of birth, birth mode after previous caesarean birth, and to a lesser extent in birth with a breech presentation and induction of labour. (53,54) Decision aids have also been developed or recommended where the need to improve the quality of these conversations has been recognised – for example the *Which? Place of birth* tool is available online. (54,55) However, the literature is devoid of evidence or guidance on how comprehensive birth planning conversations should be held.

1.2.2 Perceived benefits of the proposed work

This project will lead to the development of a decision aid for antenatal mode of birth planning, along with an implementation strategy to inform the use of the decision in antenatal care, and economic models to explore potential cost implications of its use. Meeting women's information needs, supporting their conversations with health professionals, and ensuring that their planned mode of birth aligns with their values should help them avoid or achieve personally important outcomes and foster more realistic birth expectations. This, in addition to greater engagement with the planning process, could improve women's birth experiences and reduce regret and complaints about care. (56) This support could be achieved through the development and use of a decision aid for birth mode planning which women (+/- their partners) and health professionals can use together. Such a tool would support information delivery on options on a level playing field (with no predetermined bias towards one birth mode). A decision aid implementation strategy will support women and health professionals to engage

in effective conversations, including meeting the needs of women from minority and under-served groups, thus supporting the NHS to meet its statutory requirements. This work could reduce inequalities by ensuring that women from minority and under-served groups are supported to make informed and personalised birth plans with a tool developed with their needs in mind. Economic modelling of the decision aid implementation would inform NHS maternity units of potential resource implications (e.g. increased consultation time) and cost savings (e.g. less litigation). By improving decision support for birth mode plans, the study output could improve short- and long-term maternal and infant health and cut NHS costs by reducing outcomes that women seek to avoid.

2 Study Objectives

2.1 Objectives

2.1.1 Primary Objective

To develop a decision aid to support shared decision-making conversations between pregnant women, their partners and health professionals when planning mode of birth (planned vaginal birth or caesarean birth) in routine NHS antenatal care.

2.1.2 Secondary Objectives

- To better understand how planned birth mode decisions are currently made in routine antenatal care and the decision support needs of women and health professionals (WP1 and 2)
- To identify and prioritise what matters to women, partners, and care teams in terms of risks, benefits, and consequences of planned mode of birth (WP3)
- To develop, user- and field-test a comprehensive decision aid to support mode of birth planning
- conversations between all pregnant women (with their partners) and their care team in routine antenatal care, with a focus on reducing health inequalities (WP4 and 5)
- To develop an implementation strategy to inform the process of embedding the decision aid within antenatal birth mode planning, addressing contextual factors as required such as skills, attitudes, and behaviours, to support pathways to impact. (WP2,4 and 5)
- To develop economic models to highlight potential NHS costs/savings of the decision aid use in routine antenatal care, including impact on consultation number/duration. (WP6)

2.2 Outcomes

2.2.1 Primary Outcome

Final decision aid

2.2.2 Secondary Outcomes

Final implementation strategy for decision aid use
Economic models of impact of decision aid use

3 Study Design

3.1 Study Description

This mixed methods project will follow National (NICE) and International (IPDAS) guidance on decision aid development. (6,7) We will develop a decision aid by synthesising relevant evidence in a systematic review, identifying the decision-making needs of pregnant women and other stakeholders, conducting a consensus process to prioritise key content, coproducing and real-time testing a prototype decision aid

in antenatal care settings and developing an implementation strategy for its use. Economic models of the potential impact of decision aid implementation will be developed.

3.1.1 Definitions

Planned vaginal birth: a plan to give birth vaginally regardless of whether this results in vaginal birth.

Planned caesarean birth: a plan to schedule a caesarean birth for any reason.

Decision aid: "A tool that presents evidence-based estimates of the benefits and risks of the available treatment options in sufficient detail that people are better able to judge their value…[these are] tailored to a person's health status and help them to make specific, personal choices about their [care]….[decision aids] are intended to supplement or support the interaction between the person and their clinician, rather than replace it". (57)

Co-production: used to describe how members of the public have worked, and will work as, or together with, researchers to conduct this research. The term implies "patients/service users/marginalised citizens making meaningful contributions to agenda-setting and the formation of research questions, not merely being 'involved' once these important decisions have been made by those who traditionally hold power in research'. (58)

Women: In all cases this term is used to describe both those who identify as women and those who were assigned female sex at birth but who do not identify as women.

Research team: Co-applicant team, research fellows and the named PPI lead.

PPI panel: Eight lay public representatives including the four co-applicant representatives.

Hub sites: NHS sites where recruitment will take place for in-person research activities, for targeted recruitment of health professionals and for recruitment of pregnant women.

3.2 Study Design

This explanatory mixed methods project will sequentially combine six linked work packages (WP) to co-produce a decision aid, an accompanying implementation strategy and economic models of its potential resource implications in practice. (4)

- WP 1 - Evidence synthesis of key influences on, and consequences of birth mode choice to inform decision aid content
- WP 2 - Qualitative interviews to explore decision support needs to inform decision aid development
- WP 3 - Delphi Panel to prioritise decision aid content
- WP 4 - Co-production and refinement of alpha prototype decision aid
- WP 5 - Practice-based field-testing of beta prototype decision aid
- WP 6 - Economic model development based on WP5 data and published models

A summary of the study design is shown in Figure 1. The broad methods for WPs 2-6 are outlined in this version of the protocol (sections 4-9). As each WP progresses there may be implications for the methods and documentation associated with subsequent WPs – it is anticipated that the protocol and associated documentation will evolve over time, and amendments submitted as described in section 18.1.

3.3 Setting

United Kingdom led by the University of Aberdeen. Five proposed 'hub sites' with an interest in maternity research will host key stages of the work. These sites serve diverse populations including rural (Highlands/Grampian) and urban dwellers (Midlands/London/North Wales), diverse ethnic backgrounds (London/Midlands), and high social deprivation (North Wales/Midlands). These sites also provide access to a broad range of health professionals working in maternity care, who are eligible to participate in the research.

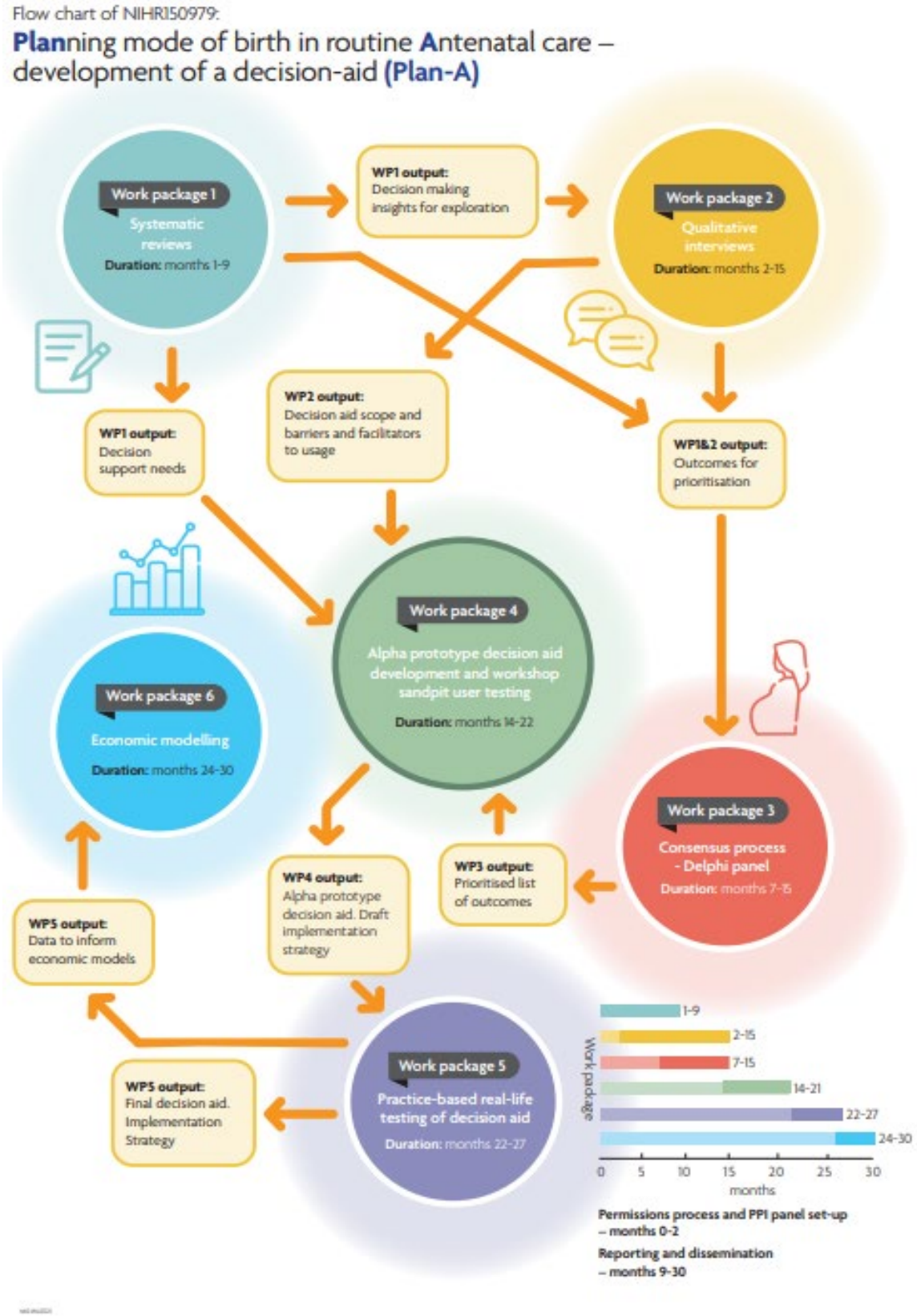
3.4 PPI panel

The PPI panel will consist of 8 women, 4 of whom are co-applicants and one of these co-applicants is from a minority ethnic background. The panel will also include representation of women: from areas with high social deprivation; single; in a same-sex relationship; born outwith the UK.

3.4.1 Study co-production process

Building on the extensive public involvement to date, the project PPI panel and the research team will work together in all WPs. An online discussion area in the Slack workspace will operate throughout the study, involving a closed group of any members of the PPI panel and research team who sign-up to the space. Face-to-face/video meetings between the research team and the PPI panel will take place at key points to interpret data and to support the decision aid development process (as described under each work package). The PPI lead will also host telephone drop-in sessions for the PPI panel to share thoughts outwith the Slack space.

Figure 1. Summary of study design



4 Work Package 1-Evidence synthesis

Key influences on, and consequences of, birth mode choice - including how patterns may emerge specific to sociocultural and socioeconomic groups - will be explored via evidence syntheses.

Specifically, new systematic reviews will synthesise qualitative data on: pregnant women's decision support needs when planning birth mode and the extent to which these are met (review 1), influences on women's preferences for planned vaginal birth or caesarean birth (review 2).

To improve sensitivity to the specific needs and challenges faced by women more likely to be adversely affected by discrimination or barriers to care, we will perform an overview of existing systematic reviews on experiences of communication with health professionals in NHS antenatal care among women from minority and underserved groups (review 3).

Particular attention will be paid, during all three evidence syntheses but especially review 1, to identifying inequalities in how, when and whether or not birth mode options are discussed with women during antenatal care.

The 2021 NICE caesarean birth guideline's systematic review on risks of planned caesarean birth versus planned vaginal birth will be updated and used to identify quantitative risk differences (review 4).

Reviews 1-3 will be registered on PROSPERO as a single study protocol.

4.1 Inclusion and exclusion criteria

The populations selected for inclusion in the reviews reflect that the decision aid being developed in this project is aimed at all women having routine mode of birth conversations during their antenatal care. The selected settings reflect that the implementation guide to be developed alongside the decision aid will be focused upon the UK NHS care setting.

The populations reflect the assumption that birth will be planned for term (37-42 weeks gestation). The decision aid is not designed for use after women develop a specific complication of pregnancy which influences mode of birth plans late in pregnancy. As such, the reviews which will shape the decision aid development must report data from relevant populations i.e. those who reflect on discussions they were part of during routine antenatal care, or who reflect on discussions which did not take place but may have been helpful if they had. This includes women with multiple pregnancies and women with previous caesarean scar as both are known about prior to, or early in, pregnancy so would form part of routine antenatal conversations about birth planning. Studies/reviews would not be excluded if some participants had developed pregnancy complications which affected mode of birth plans, but if the entire population was selected on the basis of them having the complications, then it would not be eligible for inclusion.

For reviews 1 and 2, systematic reviews will not be included (as these are expected to include data from before the relevant study period) but if identified in the search they will be utilised to check reference lists for any potentially eligible primary studies that were missed by the main search.

Studies will be included in/excluded from reviews as shown in Tables 1-3.

Table 1. Inclusion and exclusion criteria for review 1

	Inclusion criteria	Exclusion criteria
Population	• Pregnant women • Women previously pregnant • Women who gave birth after 37 weeks gestation or who expect to do so.	• Pregnant women with major placenta praevia or placenta accreta • Studies in which the population studied are women who all developed a specific complication (e.g. pre-eclampsia/preterm labour/vaginal bleeding) during pregnancy that could affect mode of birth plans.
Reported data on:	• Information which influenced women's planned/preferred mode of birth (caesarean or vaginal birth) or was important to them when planning mode of birth • Information not received which, if it had been received, may have influenced women's planned/ preferred mode of birth (caesarean or vaginal birth) or was important to them when planning mode of birth • Information on extent to which decision support needs are met before, during and after women are planning their mode of birth • Timing of decision support; what is optimal/suboptimal •	
Design	• Qualitative methods for data generation and analysis including mixed methods studies, ethnographic and phenomenological approaches	• Observational studies reporting quantitative data only • Systematic reviews • Commentaries
Setting	High-income countries based upon the World Bank classification. Studies that have recruited participants from both high and non-high-income countries will only be eligible for inclusion if it can be identified that at least 80% of the participants are from high income countries.	
Publication period	2011 onwards	

Table 2. Inclusion and exclusion criteria for review 2

	Inclusion criteria	Exclusion criteria
Population	• Pregnant women • Women previously pregnant • Women who gave birth after 37 weeks gestation or who expect to do so.	• Pregnant women with major placenta praevia/placenta accreta • Studies in which the population studied are women who **all** developed a specific complication (e.g. pre-eclampsia/preterm labour/vaginal bleeding) during pregnancy that could affect mode of birth plans
Reported data of relevance	• Whether or not women preferred and planned vaginal or caesarean birth in the antenatal period. • Why women, in the antenatal period, preferred and planned vaginal or caesarean birth and what shaped their plan. • Barriers and facilitators to women receiving and acting on information relevant to their mode of birth preference or plan. • Reports data on inequalities in how, when and whether birth mode options are discussed with women during antenatal care	• Studies exclusively reporting on antenatal information provision (or lack of it) as an influence on mode of birth plans (as will be covered by review 1).
Design	• Qualitative methods for data generation and analysis including mixed methods studies, ethnographic and phenomenological approaches	• Observational studies • Systematic reviews • Surveys • Commentaries
Setting	High-income countries based upon the World Bank classification. Studies that have recruited participants from both high- and non-high-income countries will only be eligible for inclusion if it can be identified that at least 80% of the participants are from high income countries.	
Publication period	2011 onwards	

Table 3. Inclusion and exclusion criteria for review 3

	Inclusion criteria	Exclusion criteria
Population	Pregnant women/women previously pregnant/women who gave birth after 37 weeks gestation or who expect to do so in minoritised/ under-served groups including on the basis of ethnicity, religion, disability, sexual orientation, trans or non-binary gender, socioeconomic deprivation, low maternal age, stigmatisation.	Population of unselected pregnant women with no specific attention to the differential experiences of minoritised groups reported.
Reported data of relevance	• Experiences of communication with healthcare staff during antenatal care • Experiences of values such as respect, trust and fairness shown by staff during antenatal care • Reports data on inequalities in how, when and whether birth mode options are discussed with women during antenatal care	
Design	Systematic reviews (qualitative or quantitative data syntheses) of primary studies	
Setting	Studies conducted in settings relevant to the UK (defined as reviews where the majority of studies are conducted in high-income countries based on World Bank classification and with at least one included study conducted in the UK).	
Publication period	2011 onwards	

For review 4, as per NICE 'Caesarean Birth' clinical guideline systematic review, inclusion and exclusion criteria will be applied to ensure that only studies which compared outcomes of planned, or where necessary actual, mode of birth are included. No language restrictions will be placed on these studies. (2)

For all reviews, a PRISMA flow diagram and a list of excluded studies will be compiled during the selection process

4.2 Search strategies

An Information Specialist based at the University of Aberdeen will design highly sensitive search strategies, using database-specific controlled vocabulary and text terms (see appendix for example terms for review 3). Existing reviews and clinical guidelines will be used to inform the search strategy. Databases to be searched include Medline, Embase, CINAHL, CENTRAL, MIDIRS, ASSIA, and the Social Sciences Citation Index. Given the challenge of ensuring accurate translation of qualitative research manuscripts, only those published in English will be included in reviews 1-3. The reference lists of all studies selected for full text appraisal will be perused for additional studies, and conference proceedings of national and international organisations will be checked. References will be exported to

a reference manager and deduplicated. Based on our team knowledge, we expect to identify up to 50 studies from high-income settings.

For review 4, the same search utilised by NICE for the 'Caesarean Birth' clinical guideline will be updated. There will be no language restrictions on included studies.

4.3 Study selection and data extraction strategy
For all reviews, one reviewer will screen the citations identified by the search strategies to identify potentially eligible citations and exclude duplicates. A second reviewer will independently screen a random sample of citations (20%).

One reviewer will assess the full-text versions of potentially relevant articles for eligibility and extract data using dedicated forms for each review. A second reviewer will check the accuracy of all data extracted by the first reviewer. Information on setting, demographic characteristics of participants (including maternal age, ethnicity, geographical location, religion, disability status, sexual orientation, gender identity, household income level), planned mode of birth of participants (if stated), and relevant outcomes/experiences will be extracted, and for review 3 (umbrella review methods (59)) study inclusion criteria for each review will also be extracted.

Any disagreement during study selection and data extraction will be resolved by discussion between reviewers and consultation with Dr Miriam Brazelli or Dr Mairead Black who have experience in conducting qualitative and complex evidence syntheses.

4.4 Quality assessment strategy
The CASP tool for qualitative research and the Development and Evaluation-Confidence in the Evidence from Reviews of Qualitative research (GRADE-CERQual) approach will be used to assess the risk of bias of studies included in Reviews 1 and 2 while the Joanna Briggs Institute (JBI) critical appraisal checklist for systematic reviews and research synthesis will be used for Review (60)

The NICE approach to quality assessment will be taken in review 4. This includes a checklist specific to cohort studies which are the design most likely to be relevant to this review. (61)

4.5 Data Synthesis
Across reviews 1-3, qualitative findings will be analysed using a thematic approach. Main recurring 'descriptive' themes will be identified on close reading of study/review reports. Constant comparison will help generate and refine higher-level 'analytical' themes and map relationships between these. We will attend to similarities and divergences between the experiences of women from different population subgroups, including any differences in how, when and whether they are engaged in a conversation about birth mode choices during antenatal care. The analysis will be conducted by the two employed Research Fellows with input from Dr Mairead Black, Dr Miriam Brazelli and Prof Vikki Entwistle. The evidence synthesis team will summarise findings from each review during regular progress meetings with the wider research team. Interpretation of overall findings and conclusions will be discussed and agreed upon in consultation with our research team and PPI panel.

In review 4 measures of effect will be utilised, or pooled measures calculated in meta-analyses as appropriate, to quantify the link between planned mode of birth and maternal and offspring outcomes reported since the latest NICE 'Caesarean Birth' guideline was published. Where meta-analysis is

utilised, random effects models will be employed if study heterogeneity is identified. Evidence will be summarized in tables using the GRADE approach to rate the certainty of evidence. (62)

4.6 Interpretation of review findings
The PPI panel and the WP1 research team will meet together on a 2-4 weekly basis in the latter half of WP1 to interpret the emerging findings from the reviews. Together they will agree upon the way in which the findings will influence the content of the decision aid and/or the implementation strategy. The WP team will include these recommendations in the WP report.

4.7 Outputs
The individual reviews will be published in peer reviewed journals and overall findings summarised in a WP report. WP report findings will inform: WP2 (identifying issues, including unmet decisional support needs and concerns about potential inequalities in antenatal care provision that may warrant probing in later interviews and careful attention in analysis); WP3 (informing initial list for decision aid content prioritisation in the Delphi consensus process); WP4 (informing decision aid content development and draft implementation strategy).

5 Work package 2 -Qualitative interviews to explore decision support needs.

This WP will explore current birth mode planning experiences to inform the scope and optimal format of the decision aid and key contextual requirements to ensure the decision aid is delivered and supported appropriately within the NHS. This WP will involve interviews with stakeholders (public and health care professionals).

5.1 Population (Inclusion/exclusion criteria)
The population selected reflect the stakeholders involved in birth planning conversations and the long-term management of birth-related complications and consequences.

- UK women, 16 years and over (currently/previously pregnant in the past 10 years, or planning pregnancy in the future)
- Partners of the above women, 16 years and over
- NHS clinicians (midwives, obstetricians, obstetric anaesthetists, GPs, health visitors and paediatricians).

Student midwives, medical students or women /partners who planned birth more than 10 years previously will not be included due to lack of sufficient experience relevant to current birth planning processes. In addition, women/birthing people/partners who lack capacity to consent will not be included in the study.

5.2 Sample size
A purposive maximum variation sample of approximately 40-50 women +/- partners and 40 health professionals is planned. (63) The sample size is determined by the desire to include women from five distinct areas of the UK, both rural and urban, across various socioeconomic backgrounds, educational status, ethnic and religious groups, age ranges, relationship status, sexuality and gender identities. The health professional sample size reflects the need for a range of relevant professionals across five settings (with up to eight per setting). Final recruitment numbers will be guided by the concept of 'information power' and will continue until no significant new themes are identified. (61)

In order to sample a range of views from maternity health professionals, at least two obstetricians, two midwives, one of each of GPs, anaesthetists, health visitors and paediatricians will be recruited per hub research site (5*8=40 health professionals minimum) by email cascade and by social media QR code sharing (to link to study website).

5.3 Setting

Five UK NHS hub research sites: Betsi Cadwaladr, Lanarkshire, Liverpool, Manchester and Royal Free London. Wider UK representation will be facilitated by non-NHS recruitment plans.

5.4 Recruitment of pregnant women and their partners:

5.4.1 General approach throughout Plan-A study

The INCLUDE ethnicity framework (developed by University of Aberdeen colleagues) and the Centre for Ethnic Health Research toolkit have informed the study plans. (64,65) The recruitment approach is designed to ensure maximal representation and input from minority groups, aiming to reflect that 28% of women giving birth in the UK were born outside the UK (most commonly India, Poland, Pakistan and Romania), 7% are of Asian ethnicity, at least 3% are Black and 2% are of mixed ethnic origin, at least 1.6% are in same-sex relationships, up to 60% are Christian, 4% Muslim, and ~ 5% don't speak English. (22) Specifically, NHS sites that particularly reflect diverse representations of women have been targeted. Recruitment will be facilitated in partnership with different groups and charities representing pregnant women including but not limited to Maternity Voices partnerships for the different research hubs considered. The Research Fellow will receive training in intercultural communication.

5.4.2 Recruitment approach to WP2

Pregnant women (at least 8 weeks gestation) and those who gave birth in the previous 6 weeks will be invited via a range of routes.

For some hub sites, maternity electronic patient record (EPR) portals on their electronic devices (mobile phones or tablets) will be utilised, and for all sites local social media will be utilised.

Four of the anticipated five hub sites use the Badgernet© (Clevermed) system to host the EPR. In these, the host site will be asked to use the EPR patient-facing portal to host information on the research project and, where in line with local information governance arrangements, to send push notifications to women's devices to alert them to the study advert in their portal. This whole population approach will ensure that all eligible women in those sites are reached, unless they do not utilise the portal (generally <3% of women in each area). For the sites that do not use Badgernet© (Clevermed) system (and all other sites, as an additional route to recruitment)), the study will be advertised on the local maternity website and social media pages for maternity service users. This will include a link to the study webpage which will include an email address, and a telephone number to reach the participant support line (with message service out-of-hours), and a text message option. There will also be posters placed in antenatal clinic/midwifery unit waiting areas in the hub sites which will contain information to allow potential participants to obtain further information on the study and details of how to take part (using QR code or study website and email details).

For women across the UK (including in the Hub site areas), additional online recruitment strategies will include widely used internet forums such as 'Mumsnet', newsletters from agencies including NCT, the

Royal College of Midwives (RCM) race and equality group the James Lind Alliance newsletter and web posts in health literacy groups e.g. www.healthliteracy.org.uk.

In addition, study adverts in the form of flyers will be placed in pre-natal yoga/Pilates/meditation class venues and gyms, bumps and babies events, the National Galleries, play cafes, local breastfeeding support groups and baby and toddler classes, run either by the council or by local charities including religious groups.

Recognising that cultural and social factors are likely to affect exposure to, and responses to, study adverts, additional strategies will be used to recruit women from minority and under-served groups. These include via community group leaders, existing community and support groups, media outlets and places of work (table 4). A range of characteristics will be sought across urban/rural, socioeconomic status, ethnicity, age, education level, parity, learning disability status, gender identity and birth preferences.

Health professionals will be invited to take part via email cascade by the PI in each hub research unit, professional networks including the Royal College of Obstetricians and Gynaecologists and the Royal College of Midwives newsletters, the Scottish Perinatal Network, UK Labour Ward Lead WhatsApp Group, British Intrapartum Care Society, and community/continuity midwifery networks, Heads of Midwifery networks, national Clinical Directors forums and the association of Radical Midwives.

Table 4. Recruitment strategies for minority and under-served groups.

Target group	Target associations for study adverts
Single parents	Internet forums such as 'Gingerbread'; Agency newsletters e.g. OnlyMums/Daddilife; Community awareness webpages with a focus on single parents.
Ethnic minority pregnant women/mothers/ parents	Raham project (ethnic minority pregnant women/new mothers' group); Community groups specific to minority ethnic groups; grassroot organisations for ethnic minority such as 'Five X More' with large social media reach. Recruitment videos in social media streams of parent and baby groups in ethnically diverse areas of hub research sites; Newspapers and local magazines in areas rich in key minority ethnic groups, religious or belief groups.
Transgender/lesbian	Facebook groups for pregnant individuals identifying as LQBTQ+
Low household income	Recruitment videos in social media streams of local parent and baby groups in socially deprived areas of Hub research sites, and via charities for socially disadvantaged women such as Birth Companions. Community awareness webpages focused on low family income e.g. budget menus, Homestart in Scotland
Ethnic minority women – not pregnant	Nail bar social media posts, gyms, and recruitment through targeted community gatekeepers such as religious leaders.
Religious groups	Twitter/ Instagram pages for key religious or belief groups
Parents with disability	Disability, Pregnancy and Parenthood (for parents with disability); Community awareness webpages with a focus on parenting with a disability

The PPI panel will support recruitment activities at all stages of the study e.g. making videos, advising on text to use in adverts, adapting approaches to women in specific communities to ensure cultural appropriateness, cultural sensitivity and cultural safety. Texts used in the sample flyer will be adapted as appropriate and used in adverts to suit the cultural needs of the target community as advised by the PPI panel. Study adverts will use audio/video as well as text-based formats in English and relevant non-

English languages. In addition, 'easy read' versions of the participant information sheets and consent forms will be developed with simplified language presented in accessible formats. The adjustment is designed to assist participants who may find lengthy texts challenging to understand due to limited literacy skills.
The PPI panel will also aid in identifying peer gatekeepers/influential members of ethnic minority populations that would facilitate recruitment. Research has shown that ethnic minority communities rely on individuals with community presence to translate research information. Other PPI panel responsibilities would include identifying key social media groups. (66)

Where WP1 reviews identify any groups which are under-represented in the existing evidence of what matters to women when planning mode of birth, we will oversample those groups in WP2 to ensure their voices are heard. We will offer the option of telephone or in-person interviews to reduce any concern about privacy on video and will be flexible about interview times. Translators will be offered for interviews to ensure women without understanding of English can be involved and shape the decision aid.

While the majority of potential participants are expected to show an interest in taking part by emailing the research team and answering questions about their eligibility to take part, support for the recruitment process will also be provided in the form of a telephone line. A member of study staff will monitor the phone during office hours. This will allow potential participants to have a conversation about the study without having to write an email or complete a form. This system will support the recording of details about the potential participant regarding their suitability to take part in the study ie. whether or not they meet inclusion criteria and any under-served groups that they may represent, instead of them having to do this by email.

When individuals indicate interest in the study by either email/or via telephone, an eligibility survey using Microsoft forms will be sent to the individual or administered by the researcher via telephone comprising of questions that will determine eligibility, sampling criteria and establish communication preferences. Sample of the questions are indicated below:

1. Kindly tell us your age range?
2. Are you currently pregnant/have you given birth/are you the partner of someone who is pregnant or has given birth or do you have a child up to 10 years old?
3. If you have previously given birth, did you have a vaginal, unplanned caesarean or a planned caesarean birth?
4. Sexual orientation
5. How would you describe your relationship status?6. Ethnicity
7. Religious affiliation
8. . Residency status –
    a. Homeless/supported living
    b. Refugee
    c. Asylum seeker
    e
9. Income status (total household income)
10. Communication preferences
11. Preferred contact details

The aim would be to sample all individuals and oversample from underrepresented groups. Individuals who do not meet the eligibility criteria would be informed via the means to which they had earlier communicated, or they wish to be communicated with.

Recruitment materials

As indicated above (5.4.2), recruitment information contained in the study flyer will be adapted to suit the different recruitment strategies. For instance, as Push notifications for the different patient facing portals in the hub sites. The flyers would also be developed into posters. Copies of the flyers would also be used as online adverts for internet forums and into audio/video adverts.

5.5 Consent

Prior to the commencement of any interviews, potential and eligible participants will be emailed a link to electronic web-based study information, or directed to the QR code on the study website to access the information in commonly spoken non-English languages, and information sent by post if preferred. Electronic information will include both text and non-text e.g. video versions. Additionally, easy-read versions will be developed to meet low literacy needs. For those who confirm (by email or telephone) their willingness to be interviewed after reading study information, consent will be documented in an online form (Microsoft Forms hosted by the University of Aberdeen, which will be accessed via an email link or QR code), or recorded verbally (in a separate audio file using a Dictaphone) if preferred by the participant, in the week prior to the interview starting. Depending on where/when and how consent is obtained, for instance, if consent is obtained prior to the interview, there may be a difference in the dates between the researcher and the participants signing the consent form. In addition, a copy of the signed and completed consent forms will be sent to participants for their retention.

5.6 Participant rewards for those taking part in an interview

All women and partners will receive a reward of a £25 shopping voucher to thank them for their time. Travel expenses will also be covered for individuals that attend face-to-face interviews.

5.7 Data collection process

Video, telephone or in-person interviews will be conducted as per participant preference by the research fellow, who is trained in qualitative interview process. Video interviews will be conducted using Microsoft Teams while in person interviews will be conducted at a venue as per participant preference. Interview topic guides will be developed using established frameworks for decision aid development (IPDAS and NICE criteria). (6,7) It will reflect existing evidence and, as with all study documents, will be subject to consultation with the PPI panel.

One interview will be conducted per participant which will last up to one hour. Interview sessions will be conducted either in person or online. In person interviews will be recorded using an audio recorder while online interviews will be conducted using Microsoft Teams and audio-recorded using an audio-recorder in the form of a Dictaphone with back-up recording on a university mobile phone for immediate upload to the university server to allow deletion from the device. Interviews will be transcribed verbatim by a trusted third-party transcription service approved by the University of Aberdeen. A secure file transfer system, such as the University of Aberdeen ZendTo service, will be used to send the audio recordings to a third-party transcription service and to receive the transcribed material back.

5.8 Topic guides

The interviews will explore interviewees' experiences of birth mode planning (where applicable) and their expectations of the decision aid and its use, with topics such as:

- perceptions of any birth mode planning decision support received previously
- target population for the decision aid (e.g. women/couples separately from health professionals then together, couples and health professionals together, or women and health professionals together)
- what information or advice the decision aid should provide
- key values to clarify in the decision aid and how the decision aid should identify these
- how the decision aid should acknowledge and support consideration of uncertainty
- format and mode(s) of decision aid use
- potential barriers and facilitators of its use within current care pathways
- ways of addressing variations in personal preferences

Three separate topic guides will be used for interviews with:

- women
- partners and parents
- health professionals

Within these, adaptations in language will be used to recognise that not all women will have already planned a birth (but may be about to do so), that not all health professionals will have supported birth planning conversations (but instead have managed consequences and complications of birth in women and offspring).

Each topic guide will contain broad open questions to start conversations on the relevant topics. Subsequent discussion will be directed by both what the participants say and probing questions used to ensure that the conversations stay relevant to the research questions.

Broad questions within topic guides will ensure:

- Participants are invited to share their experience of birth mode planning conversations or their experiences of when these did not take place but they felt they should have.

- An exploration of perceived barriers and facilitators of the decision aid use, either through aspects of decision aid design or via the supporting implementation strategy where behaviour changes may be encouraged. This exploration will be shaped by the Theoretical Domains Framework which will provide a useful theoretical lens through which to view proposed influences on decision aid use. The Theoretical Domains Framework reflects existing implementation science principles that has been used extensively to understand influences on both health professional and patient behaviour including in decision aid development in maternity care. (67)

- Possible formats of the eventual decision aid are explored e.g. electronic, web-based, traditional text-based resource with graphics, videos, animations, podcasts, infographics or a combination, and that use of the decision aid in video appointments (e.g. by screen-sharing) is considered.

- Specific needs of key groups (e.g. people with lower reading ability, limited English or learning difficulties) are explored.

- Consideration of who is best placed to start and develop birth mode option conversations e.g. midwives, antenatal educators, obstetricians, peer supporters or women/partners themselves.

5.9 Analysis
Findings will be analysed using the Framework approach, as existing studies of influences on birth choices highlight themes from which an analysis framework can be developed. (68)

The researchers will familiarise themselves with each data set and following initial familiarisation with transcripts will develop a thematic coding framework based on both known influences on birth choices and those identified as emerging from the data. Initial codes (text labels) from this framework will then be systematically applied to the transcript data. Data management and initial analytic coding will be facilitated by the use of NVivo. The primary focus during the analysis will be on the a priori study aims. Particular attention will be paid to the types of judgement, beliefs and attitudes (including concerns) that people expressed in relation to how birth plans are made, including views about the barriers and facilitators affecting informed birth mode planning. The data from parents and from professionals will be analysed separately; while we expect the framework for both datasets to include many common themes, we anticipate that points of difference will also emerge. This will ensure that the perspectives of each group are explored, before bringing together a comparative thematic analysis. Within the parent framework, we will pay attention to how responses differ by demographic characteristics and within the professional framework how they differ by professional group.

Emerging findings will be reviewed and discussed at monthly meetings of the research team. The research team will support the research fellow with compiling an overall report on the findings to be utilised in WP3, 4 and 5. This will include addressing ethical tensions, differing value judgements, areas of uncertainty regarding outcomes and how to ensure adequate reflections of diverse views in the final decision aid.

5.11 Output
A narrative and graphical report on the findings will inform the scope, purpose, format and target audience of the decision aid in addition to potential barriers and facilitators of its use (to be used in WP4 & 5). The findings will also be published in their own right.

5.12 PPI input:
PPI representation will be included at all monthly research team meetings and will be included in the WP report authorship.

6 Work package 3 - Delphi survey and consensus meeting to prioritise the content of decision aid

Given the numerous possible outcomes (risks, benefits and consequences) of each mode of birth, a formal prioritisation step will be utilised to inform which outcomes are deemed by stakeholders to be most important. This will influence the focus given to each outcome in the decision aid e.g. order of

presentation and which 'layer' it is featured in. While all outcomes that NICE recommend will be included in the decision aid, their ordering and presentation will be influenced by the Delphi. Additional outcomes offered by stakeholders in WP1 or 2, or in the first round of the Delphi will also be considered. Specific attention will be paid to outcomes prioritised by minority groups and whether these could be important in sections of the decision aid relevant to women with a common concern (e.g., cultural pressure to opt for either vaginal birth or caesarean birth). A two-round electronic Delphi survey will be followed by a final consensus meeting to allow analysis of individual and stakeholder group views, and reflective discussion.

6.1 Population and Sample Size

Population included will be the same as described for WP2. No upper limit will be applied to the number of participants in the survey rounds, but efforts will be made to include minority and under-served groups (over-sampling as required) and achieve an absolute minimum of 60 women, 10 partners and 10 from each of the 7 health professional stakeholder groups for each survey round. (69)

A sub-set of survey participants will be selected for the consensus meeting, with the target group ranging from 14-17 individuals. We will strive to include at least one representative from each professional stakeholder group and two women/partner representatives from each region of the UK.

6.2 Setting

UK wide (round 1 and 2) with virtual consensus meeting (round 3) online.

6.3 Recruitment

Recruitment approaches will be as for WP2 (section 5.4.2), except that the Centre for Ethnic Health Research will support recruitment from minority ethnic groups by providing links with community organisations, identify how best to engage and recruit ethnic minority groups and in supporting the research to identify potential participants. Participants in WP2 are eligible to participate in this work package, in addition to new participants. Opportunities to respond to the study advert will include a direct link (web link and a QR code) to the participant information sheet. (WP3). The participant information sheet will contain a direct link to the survey. Invitations will make clear that partners can also participate in the survey (independently from women) by utilising the same link to the survey information.

The consensus meeting will use optional camera and chat function in the video conferencing software (Microsoft Teams) to manage some participants' anxieties about speaking to a large group.

6.4a Inclusion Criteria

UK Women, 16 years and over (currently or pregnant in the past 10 years, or planning pregnancy); partners of these women, NHS health professionals (midwives, obstetricians, anaesthetists, GPs, health visitors and paediatricians) based in the five hub research areas as per WP2.

6.4b Exclusion criteria

Participants who do not have the capacity to consent will be excluded. Participants who are unable to understand written and spoken English will be excluded since the survey is conducted in English. Additionally, student midwives, medical students or women/birthing people/partners who planned birth

more than 10 years previously will not be included due to lack of sufficient experience relevant to current birth planning processes.

6.5 Consent

Electronic study adverts to take part in the Delphi survey will link to information about the study and request participation in at least two rounds of the Delphi process. The study Information will contain a link to the first round of the survey. Consent will be explicit with an initial survey question confirming consent to take part and have their survey responses used in the study. This will be a mandatory question to ensure consent is confirmed before the survey commences, and to ensure permission to use their email address to provide the link to the second round of the survey. The survey will include a section for participants to indicate permission to be contacted again and willingness to be invited to the final consensus discussion group. Consent to participate in the first round will suffice for both rounds of the survey. A separate online consent form using Microsoft forms will be utilised, accessed via email link or QR code, or on paper if preferred, for the final consensus discussion group and will be provided to the participants ahead of the consensus meeting by the research team. If a potential participant prefers/requests for a paper consent form, then that will be posted by the research team.
Only individuals who have provided consent will receive meeting details for the consensus meeting. All data collection will be GDPR compliant.

6.6 Process

Established principles of consensus-building will be followed to develop an electronic Delphi questionnaire using specialist Delphi software. The participant's email address and stakeholder role will be collected to ensure subsequent contact and ensure accurate sample characteristics respectively. Introductory information within the questionnaire will recap the study aim and the importance of completing the first two rounds.

Round 1 will list risks, benefits and consequences of planned vaginal birth and planned caesarean birth identified from the updated NICE caesarean birth guidance systematic review (from WP1) as a minimum along with any additional outcomes identified as important from WP1 and WP2. Respondents will be asked to score each outcome using a Likert scale to indicate perceived importance when making a decision about mode of birth. These outcomes will be listed individually but displayed under relevant group headings to aid analysis. The research team and PPI panel will review the draft survey to ensure comprehension and that the format will support the analysis process. Respondents will prioritise items on the list of potential birth risks, benefits and consequences and will suggest additional outcomes not yet included.

The questionnaire will be piloted on a diverse sample of 5 women from the sampling population, using a 'think aloud' technique to assess content and face validity and to test study processes. (70) The study will proceed once any revisions to the survey wording have been made in response to pilot data.

Round 1 will collect demographic information to inform interval review of respondent characteristics to direct further recruitment efforts if necessary to achieve an adequately representative sample, and two reminder emails will be sent to non-responders at each round. A sample of the demographic questions are indicated below:

1. Please tell us which age group you belong to?
2. What would you say your sexual orientation is? (optional)
3. What is your current relationship status?

4. How would you describe your ethnicity?
5. What religion do you identify with, if any?
6. What is the highest level of school or education you have completed?
7. What is your country of residence
8. How would you describe where you live? Urban or rural
9. Residency status : Homeless
Supported living
Asylum seeker
None of these apply to me

10. How would you describe your total household income?
11. What is your current status?- Pregnant
Planning a pregnancy
Have a child up to 10 years old
Partner of a pregnant woman
Healthcare professional
12. Email details

Participants will not be able to identify other participants or others' individual responses. Frequency distributions and median/interquartile ranges will be used to analyse the results of rounds one and two. Subgroup analysis of minority and under-served groups' responses will highlight areas of unique or greater concern to those groups.

Round 2 will provide the same list of outcomes as round 1 with their median scores from round 1 and asked to rate these again. It will also incorporate suggested outcomes from round 1 that the study team deem to be independent of those outcomes already listed. A link to the survey will be emailed to the participants in around 4-8 weeks after the end of the first round of survey.

Round 3 is an audio-recorded one-day virtual workshop with a representative subgroup of participants. It will commence by providing participants with lists of outcomes for which consensus has been achieved (70% scored 7-9 and <15% scored 1-3 and vice versa across women/partners and health professionals groups or by the public vote alone) and has not been achieved in round 2. Median score for each outcome in round 1 and 2, the scores by stakeholder group and a reminder of participants own original scores will be included. (71) Any outcomes without consensus will be discussed, before finalising the priority lists for outcome inclusion in the decision aid. The independent facilitator (a member of the research team) will document any gaps or concerns raised by a minority about the final list to support reflection and recognition of limitations, and to inform tailoring of decision aid elements aimed at minority groups. A verbatim transcription of the discussions will also evidence some of the thinking behind why certain outcomes are important.

6.7 Data collection process

Data collection will be facilitated by the research team using two rounds of online questionnaires/survey using the REDCAP software followed by a virtual consensus meeting. Electronic invites containing links to study information will be sent to potential participants using the recruitment approaches in WP2. Participants will be asked to consent to taking part in at least two-rounds of the survey. The final consensus group will be an online meeting(discussion) facilitated by the research team via video/audio

conferencing using Microsoft Teams software for video and a Dictaphone for audio recording. Consensus meeting discussions will be transcribed verbatim by a trusted third-party transcription service (NJC Secretarial) approved by the University of Aberdeen.
Additionally, each survey might take up to 30 minutes to complete. The consensus meeting will be split into two days, with a max of 4 hours each day.
A sub-sample of women who completed the questionnaires will be invited, with the aim of including around 7 women from a range of differing socioeconomic backgrounds, educational status, ethnic and religious groups, age ranges, relationship status, sexuality, and gender identities PLUS a mix of at least one obstetrician, one community midwife, one paediatrician and one anaesthetist. There will be an optional camera and chat function in the video conferencing software to manage some participants' anxieties about speaking to a large group.

6.8 Participant compensation
Women and partners who participate in the survey will have a chance to win one of two £50 vouchers. Women and partners who attend the consensus meeting will receive a £200 shopping voucher after attending both 4hr sessions, to thank them for their time.

6.9 Output
Frequency distributions and median/interquartile ranges will be used to analyse the results of rounds one and two using Statistical Package for Social Sciences (SPSS) V28. A WP report will detail the risk, benefits and consequences of each planned birth mode to include in the decision aid (for use in WP4) in graphic and tabular synthesis, including any areas of concern for minority or under-served groups to include in relevant tailored sections of the decision aid.

7 WP 4 – Alpha prototype decision aid development with sandpit stakeholder feedback and user-testing in workshops.

7.1 Population
Women, 16 years and over, who are currently pregnant, experienced pregnancy or planning pregnancy (and partners where desired); obstetricians and midwives who support birth plans.

Exclusion: Non-English-speaking participants in the workshops. This is a practical and logical step. As the prototype decision-aid will be developed in English (for text-based or video content) we accept that involving non-English speaking participants will not be realistic with current resources and time-frames at the workshop stage. We will ensure broad inclusion of such participants in interviews to ensure that their views shape future decision aid use in other languages. In addition, women/birthing people/partners who lack capacity to consent will not be included in the study.

7.2 Setting
Online plus the five hub research sites.

7.3 Recruitment
Approach to recruiting women (and partners) from across the UK will be as for WP2 and 3 (section 5.4.2). Charities and community groups supporting women from minority ethnic backgrounds will be approached to facilitate recruitment of women from ethnic minority groups to 2-3 workshops as described in WP2. (65) The eventual sample will ensure a diverse representation of women from low-income households, diverse age groups, single parent household and diverse ethnic groups.

Potential participants are expected to show an interest in taking part by emailing the research team and answering questions about their eligibility to take part. Support for the recruitment process has also been provided in the form of a telephone line. A member of study staff will monitor the phone during office hours. This will allow potential participants to have a conversation about the study without having to write an email or complete a form. This system will support the recording of details about the potential participant regarding their suitability to take part in the study ie. whether or not they meet inclusion criteria and any under-served groups that they may represent (see 5.4.1), instead of them having to do this by email. Additionally, charities and community groups who support women from minority ethnic backgrounds will be given the option of passing on contact information from interested women who may feel more comfortable notifying the charity of their interest in the study rather than the Plan-A team directly. In this instance the Plan-A team will request confirmation from the charity (via email or text) that they have permission to contact the potential participant. A research fellow or the PI will contact the potential participant via phone or send an eligibility link via email.

When individuals indicate interest in the study by either email or via telephone, an eligibility survey using Microsoft forms will be sent to the individual or administered by the researcher via telephone. It will comprise of questions that will determine eligibility, sampling criteria and establish communication preferences. Sample of the questions are indicated below:

1. What is your age range? Under 25, 26-34, 35-39, 40 years+
2. Are you planning pregnancy/currently pregnant/have you given birth/are you the partner of someone who is pregnant or has given birth? do you have a child up to 10 years old?
3. If you have previously given birth, did you have a vaginal, unplanned caesarean or a planned caesarean birth?
4. What is your sexual orientation
5. How would you describe your relationship status?
6. Ethnicity
7. Religious affiliation
8. Residency status –
    a. Homeless/supported living
    b. Refugee
    c. Asylum seeker

9. Income status (total household income)
10. Communication preferences
11. Preferred contact details

The aim is to sample a wide range of individuals and oversample from underrepresented groups. Potential participants will complete an online MS Form. This data will be downloaded to an Excel spreadsheet stored on a secure UoA network drive accessible only to core members of the research team. Individuals who do not meet the eligibility criteria would be informed via the means by which they had earlier communicated, or they wish to be communicated with. All MS Forms will be deleted once recruitment is complete. To facilitate accurate reporting of sampling and recruitment, the spreadsheet data will be retained until the project is complete.
Health Professionals will be invited to take part via email cascade by the Principal Investigator (PI) in each hub site and, for health professionals outwith the hub sites, via the networks listed in WP3. Dates for separate virtual and in-person workshops will be made available to participants as confirmed.

7.4 Consent
Potential participants will be given an electronic participant information sheet more than 7 days prior to a scheduled workshop, with both email and QR code options, or by post if preferred. Consent documentation will be completed online prior to the workshop for virtual workshops using Microsoft forms hosted by the University of Aberdeen or on paper for in-person workshops. Where a paper version of the participant information is required prior to the workshops, the participant information letter will be posted alongside a consent form in a paid and addressed envelope, for ease of return. Upon taking of consent, one signed copy of the consent will be returned to participant for their records.

7.5 Process
This WP will utilise WP1-3 findings to inform the initial decision aid content and presentation, including what layers it will contain and what subsections will be aimed at women from under-served groups or with key clinical characteristics.

The research team and PPI panel will use the findings of WPs 1-3 to develop an alpha prototype decision aid with software developers and an accompanying implementation strategy. The decision aid will be developed as an electronic and web-based version, possibly delivered via tablet computer, and will likely also exist in a downloadable version that can function without internet access. Based on WP1-3 findings, a visual aid (potentially infographics) which provides an overview of the decision aid content, to be used as a prompt for structure of conversations in consultations, will also be developed to support implementation. If time and resource allows, we may also develop an easy-read version of the decision aid for those who prefer to read a resource written in very simple language, or who find lengthy text difficult to read. The easy-read version would be accessible to all potential users via the same web-based routes. The decision aid is expected to be shared with women before and after consultations, e.g. via a letter with a QR code and web link, an email or web portal provided by their healthcare provider. Language will be tailored to ensure it is sensitive and inclusive to all users including women, their partners and advocates. Based on WP 1-3 findings, we plan that the decision aid will be multi-layered to account for differing levels of detail desired by users, and that it will contain sections for women with specific characteristics or concerns. Example sections may address how mode of birth conversations and decisions can be affected by cultural considerations, previous caesarean birth, living with long-term health conditions and previous vaginal birth. Such sections may include links to existing approved information resources where detailed duplication would not be warranted e.g. birth after caesarean birth information.

The research team and PPI panel will use storyboarding to map out the content of the decision aid and develop the prototype in line with a woman's antenatal journey. (5) The decision aid is not planned to be designed to lead the user/consultant to a decision but rather it will be designed to provide information to prompt conversations between pregnant women and maternity care providers, which will allow individuals to make an informed choice. The decision aid will explicitly describe the choice between pursuing vaginal birth or planning caesarean birth, detail what these involve, describe the positive and negative features of each (with an indication of how likely these are to occur) and will include a range of service-user stories to illustrate what it is like to experience the consequences of each type of birth. We anticipate including one or more values clarification components in the form of prompts for users to make notes on what is important to them, and what they want to discuss further with their care provider. Software developers will support translation of the decision aid components into user-friendly 'pages'. The decision aid will be 'sandpit tested' by users in stakeholder workshops.

Three rounds of workshops are planned (table 5).

Table 5. Stakeholder workshop schedule.

Round 1		Round 2	Round 3	
Virtual	**In-person**	**Virtual**	**Virtual**	**In-person**
1 workshop for women only	1 workshop for women only	2*workshop for women only including one for women from ethnic minority group	2*virtual workshops for women (+/- partners), midwives and obstetricians (from across the UK)	6*workshops for women (+/- partners), midwives and obstetricians (one workshop with women from minority ethnic groups)
		2*workshops for midwives and obstetricians		

**= number of times*

In the first round of workshops the decision aid will be presented in the storyboard form to highlight how the woman's birth planning journey is reflected in the decision aid development process. This will involve two workshops: one in-person workshop in the NHS Grampian area and one virtual workshop.

A draft implementation strategy will be developed based upon WP1-2 findings and the Theoretical Domain Framework approach. (72)It is expected to outline how the decision aid is intended to be used and the system features, attitudes, skills, and behaviours expected to support decision aid use. It is likely to include sections specific to women from minority and under-served groups, how to address how to overcome barriers to shared decision making including a trauma-informed approach to conversations, how to show respect and communicate with cultural appropriateness, and how to ensure the decision aid is accessible. It may detail what messages (and when) to share with health professionals and women to promote shared decision making and communicate the potential benefits of using the decision aid. It may advise on healthcare professional skill development (e.g. via training by local champions) and any behaviour change interventions to support the decision aid use.

The second round of stakeholder workshops will be held online (virtual). The third round will include one in-person workshop per hub area and two online workshops to maximise inclusion. A total of two workshops in the first round (one online and one in-person), four virtual workshops in the second round (two for women and two for health professionals) and eight in the third round (two online and six in-person, for all stakeholders) are planned, with 10-12 participants in each (table 5). The conduct of one or two workshops for women from minority ethnic groups will ensure that some of those at highest risk of adverse outcomes in UK maternity care have input to the decision aid development. These workshops will attend particularly to issues of cultural sensitivity.

During the 2–4-hour workshops (likely longer in round 1 and 2 and shorter in round 3) the prototype decision aid and a summary of the draft implementation strategy will be presented to attendees. Feedback, in the form of conversations, will be sought on its appearance, format, ease and timing of use and the wording used, using a semi-structured topic guide by a research fellow, who is trained in qualitative interviewing. This will be discussed to inform refinement of the decision aid and implementation strategy between the three workshop rounds. The topic guide will be based on the User Experience Model by Peter Morville(Morville approach) and will evaluate how valuable, useful, desirable, accessible, credible, findable, and useable the decision aid is. (73) Specific feedback on cultural sensitivity will be sought from key minoritized groups. Health professionals and women (+/- partners) will be asked to comment on relevant aspects of the draft implementation strategy, considering whether it adequately addresses what human resource, equipment, signposting, service infrastructure, attitudes and skills are needed to support smooth implementation and ongoing use. Audio-recordings of workshops (transcribed verbatim) and notes taken at the time will evidence discussions. Online workshops will be conducted using Microsoft Teams and both in person and online workshops will be audio recorded using a Dictaphone. This will be immediately uploaded to the university server to allow for deletion from the device. Audio-recordings of workshop conversations will be transcribed verbatim by a trusted third-party transcription service approved by the University of Aberdeen. A secure file transfer system, such as the University of Aberdeen ZendTo service, will be used to send the audio recordings to a third-party transcription service and to receive the transcribed material back.

It is anticipated that most participants will attend only one round of the workshops. However, participants from under-represented populations, such as ethnic minority, younger maternal age, low income and residency status, who have taken part in round 1 may be re-invited by the research team to attend round 2 or 3. This is to ensure maximal input from minority and underrepresented groups. Additionally, if an HP requests to see a new iteration of the DA, they will be invited to attend another workshop.

7.6 Participant rewards for those taking part in the workshops

All women and partners will receive a reward of shopping vouchers calculated at £25 per hour to thank them for their time. In person workshops will be facilitated within the local areas and travel expenses will be covered for individuals that attend.

7.7 Output:

The beta-prototype decision aid will be ready for real-time usability and acceptability testing and refinement in WP5 and draft implementation strategy.

8 Work package 5 – Practice-based evaluation (‘field-testing’) of beta prototype decision aid and implementation strategy in a real-life setting

8.1 Population and Sample Size

Population will include Women (16 years or older) between 8 and 37 weeks of pregnancy receiving routine care in a hub site from midwives and obstetricians. Participants will also include healthcare professionals (midwives and obstetricians) who provide their care. Women who are unable to consent for themselves will not be included in the study. Some of the women will be approached 6 weeks postpartum for follow up interviews.

The beta prototype decision aid will be piloted in real life-settings with prior agreement from women and healthcare providers to evaluate their experiences of using the decision aid, barriers, and facilitators. The draft implementation strategy will also be piloted with healthcare providers to obtain their views on the strategy's wording and content. A research fellow will observe and record ~10 of ~40 interactions between health professionals and women in all the sites using a Dictaphone. Audio recorded consultation interactions will be transcribed verbatim and scored using observer OPTION-5 measure and thematically analysed. Observer OPTION-5 is a 5-item measure used to assess for elements of shared decision making in practice and if the characteristics of shared decision making were being exhibited within the consultation. Additionally, follow-up call/interviews will be facilitated within 24 hours (if possible) after the consultations to provide verbal feedback from women and health professionals following the observed interactions.

Following the unobserved ~30 interactions, online interviews with women will be arranged (within 24 hours of the interaction where possible), and for the health professionals within one week of their final interaction with women. Notes will be taken during observed consultations, while interviews with the health professionals and women after each consultation will be audio-recorded using a Dictaphone and transcribed verbatim. Up to 10 of the 40 women will also be interviewed by telephone 6 weeks after giving birth to obtain their retrospective views on the prototype decision aid. This will include at least one woman from each hub site, three from minority ethnic groups and at least one in a first pregnancy and one in a second pregnancy.

Feedback will be obtained on the prototype decision aids ease of use, sense of value and any concerns about its content or its use. Concerns about content or format will be addressed to maximise fidelity. Potential barriers and facilitators of implementation in practice will be sought from observations and feedback and utilised to finalise the implementation strategy. These could relate to how and when the decision aid is introduced, key timepoints for use, technical barriers to its use, navigation support available and women's and health professional's attitudes towards the decision aid use. Facilitators could include example scripts or videos for health professionals to demonstrate ways in which to introduce the tool and discuss its contents, or to help manage scenarios where women want minimal information. The Theoretical Framework of Acceptability will be used alongside the Theoretical Domains Framework to structure interview feedback. All observation and interview findings will be used to make any final changes to the prototype decision aid itself and the implementation strategy with input from the PPI panel and wider research team.

8.2 Setting

Betsi Cadwaladr, Lanarkshire, Liverpool, Manchester and Royal Free London hub sites. The likely setting of pregnant women's first appointment to discuss birth mode plans includes midwifery antenatal clinics, although in some cases this could be an obstetric clinic.

8.3 Recruitment

Invitation emails will be sent to health professionals in each Hub site via the local principal investigator. Health professionals will receive e-mail/QR code electronic participant information leaflets and the option of email or QR code to an online consent form to confirm their interest in taking part. As the prototype decision aid will be tested by healthcare professionals during routine antenatal appointments, health professionals who are willing to test the decision aid will identify pregnant women who may be willing to be involved and who will be between 8 and 37 weeks pregnant at the time of their next antenatal consultation. A study invitation letter/email will be sent out to the women by their care team

within the appropriate timescale ahead of their antenatal appointment (at least 7 days). The study invitation letter/email will contain a link to the study information. Women will indicate their willingness to take part either by contacting the research team or by informing their care team. The women will then be approached by the research team prior to their appointment to complete either a paper or verbal (recorded) consent form. Potential participants will be offered the option of telephone or video interviews and there will be flexibility about interview times. Support for the recruitment process will also be provided in the form of a telephone line. A member of study staff will monitor the phone during office hours. This will allow potential participants to have a conversation about the study before taking a decision if they want to take part. The findings of WP2 and 3 suggest that women want access to the decision aid before they discuss birth mode plans, so the study team will send a link to the prototype decision aid itself once consent is confirmed to allow them to access it prior to their appointment. Women and health professionals' views about access, ease of use and navigation will be obtained in interviews after their use of the prototype decision aid in antenatal appointment(s). More specifically, data will be collected on:

- Their views about the effort invested in understanding the prototype decision aid including the wordings used
- Effectiveness of the information contained in the prototype decision aid in addressing their concerns and their values
- How their access to the prototype decision aid influenced their conversation with their healthcare providers for women participants
- How they would feel about using the decision aid in the future
- How acceptable they found the prototype decision aid
- Their views on the implementation strategy wording and content
- Potential barriers and facilitators of its use within antenatal consultations
- Health professionals' views on the draft implementation strategy

Two separate topic guides will be used for interviews with women and health professionals. Initial questions in the interview guide for women will cover sociodemographic details such as:

- Their age category
- Current relationship status
- Ethnicity
- Country of residence
- Level of education
- Household income
- Current status; whether pregnant or postpartum
- Stage of pregnancy if pregnant

And for health professionals, sociodemographic questions will cover questions such as:

- Questions about number of years of experience working in maternity services
- Role within the NHS
- Ethnicity

8.5 Inclusion/Exclusion Criteria

Women between 8 and 37 weeks pregnant receiving routine care in a hub site from midwives and obstetricians who are willing to participate. Midwives and obstetricians willing to use the prototype

decision aid and provide feedback on their experiences in practice in the hub research sites, including those who are not initially keen to use the decision aid in practice but who are prepared to use it for the purposes of this research.

8.6 Consent

Both health professionals and women will have the option of paper, online or verbal consent. If verbal consent is used, a paper record of this consent will be provided subsequently for reference.

Women's Consent

Findings of WP2 and 4 suggest that women would prefer access to the decision aid before they discuss birth mode plans. A study invitation letter/email (containing a link to the PIS) will be sent to women by their care team ahead of their antenatal appointment (at least 7 days). If the invitee responds positively (by email or phone to the Plan-A team), then the Plan-A research team will take consent (paper, online or verbal) and subsequently access to the prototype decision aid will be provided by email or text message. Alternatively, women will be asked by their care provider, at an earlier antenatal appointment, if they are interested in participating, providing them with a PIS and letter of invitation. Women will be asked to confirm their interest to their clinicians who will then pass their details on to the Plan-A study team. The Plan-A team will then contact the participant to arrange to take consent (online or verbal) and then provide the link to the prototype decision aid by email or text message. Where a paper version of the consent is required prior to the consultation, a consent form will be posted alongside a pre-paid addressed envelope, for ease of return if desired. Women can also be approached by the research team immediately prior to their appointment to complete paper consent for observed consultations or online/verbal consent for unobserved consultations but would not have prior access to the prototype decision aid.

Health Professional's Consent

The Plan-A Research Fellows will take consent from health professionals in advance of any decision aid testing, consent can be taken via paper, online or verbal format. When a health professional expresses interest in testing the DA, they will have the option to either use a QR code that links to an online consent form or contact the Plan-A team by phone or email. The team will then obtain consent before the consultation proceeds.

8.7 Participant compensation for those taking part in interviews

All women will receive a £25 shopping voucher to thank them for their time.

8.8 Output

The research team and the PPI panel will further make improvements/modifications on the content and format of the prototype decision aid based on the outcome of this WP. Once modifications are made, the outcome will be a decision aid and implementation strategy. The decision aid will be ready for formal evaluation of impact on knowledge, decisional conflict, decisional regret, clinical outcomes and complaints about care in a future definitive study; the final decision aid implementation strategy will strengthen pathways to impact by highlighting key factors that facilitate a shared decision-making

process in routine birth mode planning in a diverse population of pregnant women. Changes in consultation duration/number will inform economic models in WP6.

9 Work Package 6: Economic modelling will be conducted to assess the potential cost implications of the implementation of the decision aid to the NHS

An economic model will be developed to assess the potential implications of implementing the DA on cost to the health service provider in the UK (NHS) and health consequences for mothers and infants.

9.1 Model structure

The model structure will be developed in in conjunction with the clinical expert co-applicants. It is anticipated that this will build on existing modelling that was undertaken to inform NICE guidance on mode of birth for women without an obstetric indication for CS. This was a decision tree model in which the costs of birth and managing associated intrapartum complications and adverse maternal and neonatal outcomes were accounted for based on a review of the risks of planned vaginal birth versus planned CS (NICE 2011). This approach model will be adapted to compare the use of a decision aid to guide the choice between CB and VB, versus current practice. Impacts on costs and outcomes will be modelling through changing the proportional distribution of CB to VB. The structure will be developed and finalised in consultation with the project advisory group. The finalised model will be used to estimate the potential health care costs and consequences associated with use of the decision aid. The analysis will be undertaken from the perspective of the NHS and personal social services which is in accordance with NICE guidance methodology (NICE 2013).

9.2 Model inputs

9.2.1 Clinical inputs

Risks of intrapartum complications and adverse maternal and neonatal outcomes, by model of delivery, will primarily be informed by the systematic review that was undertaken to inform the NICE model. We will update parameters where relevant based on focussed reviews of the literature on clinical inputs and risks with data from WP1.

9.2.2 Costs

The resource used in the implementation of the decision aid tool such as number and duration of consultations, and staff involved will be informed by data collected during the testing of the decision aid in WP5. These resource inputs will be valued using the current nationally available unit costs (REF PSSRU and NHS Ref costs), and the cost of implementing the decision aid incorporated in the economic model. The cost of the different modes of delivery will be sourced from the published sources, namely the NHS reference costs, as will costs of managing complications and adverse outcomes.

Although litigation costs, as transfer payments, are not usually included in the NICE reference case for economic evaluation, the modelling undertaken to inform NICE guidance on mode of birth acknowledged that maternity claims account for a substantial proportion of negligence claims made against the NHS. West et al. 2019 attempted to quantify the value of claims attributable to the planned mode of birth using reports and accounts published by NHS Response, the organisation responsible for managing litigation and compensation for harm in England. This suggested that the indemnity costs attributable to mode of birth were substantially greater for planned vaginal birth. The potential impact

of the decision aid on litigation costs to the NHS will be quantified in a sensitivity analysis using data from this study.

9.2.3 QALYs

To explore the potential impacts of complications and adverse outcomes on the health of mothers and infants, we will follow the approach used in the published NICE model to determine expected lifetime quality adjusted life year (QALY) losses associated with different complications and adverse outcomes – compared to the reference of an uncomplicated birth with no adverse outcomes. This approach will allow us to assess the cost per QALY gained with the decision aid versus current practice.

9.3 Cost consequence and cost effectiveness analysis

Using the developed model, analyses will be undertaken to investigate how DA implementation could impact upon NHS costs and health consequences for mothers and infants by changing the percentage uptake of CB. The results will be presented in terms of cost consequence balance sheet, comparing the different categories of costs and the incidence of different outcomes and complications between the approaches. Additional exploratory analyses will be performed to consider the impact of litigation on overall costs.

In addition to the cost-consequence approach, the difference in expected costs and QALYs will be combined in an incremental cost-effectiveness ratio (ICERs). Sensitivity analyses will be conducted to test how results change when varying the impact of the DA on the uptake of CB. Sensitivity analysis will also be used to explore the robustness of findings to plausible variation in other key input parameters. Probabilistic sensitivity analysis will also be conducted, whereby risks and utility inputs are randomly drawn from assigned probability distributions, the model will be run many times and the output recorded. The results of the probabilistic analyses will be presented in the form of cost-effectiveness scatter plots and cost-effectiveness acceptability curves.

10 Participant support

10.1 Participant support to minimise drop-out and support participation

A telephone line will provide access to support for all participants. Clerical support staff and the project coordinator will take calls and pass queries to the research team as required.

10.2 Rewards and recognition for study participants

In exchange for the time taken by participants in WP2, and 5 (interviews), each will be offered a £25 shopping voucher and will be invited to dissemination events. Participants who take part in the consensus group discussion will be offered £50 shopping voucher to thank them for their time. Participants who take part in the survey will stand a chance to win one of two £50 shopping vouchers. Participants who take part in the workshops in WP4 will be offered £25 shopping vouchers per hour to thank them for their time. Potential participants who have limited internet access will be offered a mobile data voucher to support participation in virtual interviews, consensus meetings and workshops. For in person interviews, travel costs may also be covered for participants.

10.3 Monitoring equality, diversity and inclusion

We will collect data on the protected characteristics of all recruited participants and will review these at both day-to-day and monthly team meetings to identify gaps in representation of the target population. The recruitment strategy will be altered as needed to ensure a sample which is representative of the UK population at reproductive age.

11 Dissemination, outputs and anticipated impact

Output from WP1 will comprise three published systematic reviews of direct relevance to maternity care guideline development groups and maternity researchers globally. In addition to their influence on WP1-3 and 6, these will influence future National guideline development and patient information resources.

In addition to informing WP3 and 6, output from WP2 will be useful for the researchers with an interest in how a potential decision aid is viewed in the context of routine maternity care, what stakeholders see as the benefits and opportunities of using decision aids in this context and what barriers to, and facilitators may be in place for their use. Once reported in a published summary, these findings could inform units in their efforts to develop staff attitudes which support shared decision making in maternity care.

In addition to informing WP4, output from WP3 be published and disseminated as it will highlight the priority information that should be offered to women when planning their mode of birth, even before the decision aid is developed and evaluated. This will be extremely valuable to those preparing local information resources for pregnant women and when training clinicians to engage in informed decision-making around mode of birth plans.

In addition to generating the beta-prototype decision aid and the final implementation strategy for its use in practice, WP5 will also inform WP6 with data on decision aid use. The decision aid will be ready for evaluation in a subsequent step-wedged randomised trial or quality improvement programme, where its impact on knowledge, decision regret and perceived quality of care will be assessed. The implementation strategy will 1) inform study design on how to embed the tool in practice, and 2) inform units of the steps needed to embed the decision aid in practice and of more broad elements of care that support the embedding of shared decision making to meet statutory requirements of antenatal care. Given the enormous appetite for improved shared decision making in UK maternity care at present, and NHS England's embracing of decision aids in maternity care, it is expected that the tool will be warmly welcomed and adopted in practice following positive evaluation. Discussions between the Chief Investigator (CI) and the NHS England 'iDecide' team have identified opportunities to share findings of this work to inform the personalisation stream of the NHSE Maternity Transformation Programme (letters of support provided). In Dr Tara Fairley's role as maternity lead of the Scottish perinatal network, key findings will be shared via this route to enhance the delivery of choice as part of the Scottish Government's Best Start maternity plan. Future evaluation of the decision aid will provide data required to underpin a medical device certification application with the Medicines and Healthcare products Regulatory Agency. Funding for ongoing updates of the decision aid will be sought, primarily from UK government streams as the decision aid has potential to be adopted by NHSE and NICE. Discussions regarding this requirement for future funding have already begun with the programme manager of the Personalisation stream of the NHSE Maternity Transformation Programme.

Output from WP6 will offer a framework for future detailed health economic assessment of decision aid implementation within definitive evaluation studies. In the interim, these will inform NHS Trusts and

Boards of potential economic implications of decision aid use in practice, either on clinic consultations number/duration, caesarean birth uptake and/or impact on litigation following childbirth.

12 Participant data

12.1 Ineligible and Non-Recruited Participants

If any of the WPs 2-5 are oversubscribed or participants are found to be ineligible, the research team will contact the potential participant and explain this.

No information will be retained for ineligible or non-recruited participants.

12.2 Participant safety and well-being

This is not an interventional study so there will be no safety reporting within the study.

We are aware that some of the topics may be distressing for women and their partners to discuss. The research team has developed a distress protocol which will guide the response to such situations. This includes pausing the data collection process, checking with the participant if they feel able to continue and offering an opportunity to stop participation. If/when they are able to resume data collection (interview or workshop participation), resume data collection when appropriate, restart recording and let the person know. If the participant does not feel able to continue with the process, the interviewer will acknowledge the difficulty of the situation, express concern and suggest simple measures to remove focus from the distressing topic. Additionally, if appropriate, the researcher will suggest that the participant contacts a relevant support network. The participant will be encouraged to contact the research team if they need to discuss the interview or questions that have arisen from it at a later point. The research team will also request permission to follow up in a few days to check how they are doing. If the individual agrees, the researcher will follow up with a courtesy call or email to thank them for their contribution and check how they are doing.
In considering an appropriate response to participants distress, the research team will inform all participants that, should they become or noted to be distressed, the researcher will seek permission to speak to them individually and offer support. If necessary, or because a participant expresses escalating distress, the researcher will help the participant to follow the usual mechanisms in the event that they become upset or distressed. This would include the participant contacting their GP if medical support is thought to be helpful. The researcher will follow up with the participant to ensure contact has been made.

12.3 Data collection and management

Data management plan

Data collection

WP2- Qualitative data will be collected using semi structured interviews either in person or via Teams video call. Consent data will be mostly collected in an electronic format except for physical copies of consent forms. Online copies of consent forms will be filled using Microsoft forms while verbal consent will be recorded using a Dictaphone. Additional data for WP2 will include online copies of the eligibility

survey using Microsoft Forms, audio/ video recordings of interview data using Microsoft Teams and a Dictaphone. Physical interviews will also be audio recorded.

WP3- Survey data will be facilitated by the research team using online questionnaires/survey. Consent taking is indicated as part of the first and second rounds of the survey. The consent part of the survey will be stored on the survey software along with the survey form. Data collection will be facilitated by the research team using two rounds of online questionnaires/survey using the REDCAP survey software (hosted by the University of Aberdeen) followed by a virtual consensus meeting. The final consensus meeting will be an online meeting(discussion) facilitated by the research team via video/audio conferencing using Microsoft Teams software for audio/video and a Dictaphone for audio recording. Audio recorded consensus meeting discussions will be transcribed verbatim by a trusted third-party transcription service (NJC Secretarial) approved by the University of Aberdeen. Additional data for WP3 will include electronic copies of consent forms for the consensus meeting, physical copies of consent forms for consensus meetings, audio recordings and transcripts of the consensus meeting.

WP4- Physical and online workshops in WP4 will be audio recorded using a Dictaphone and facilitated by the research team. Additional data for WP4 will include paper or online (using Microsoft forms) consent forms, audio recordings of workshops and transcripts of the audio recordings.

WP4- Data collection in WP4 will be facilitated by the two research fellows. Data will consist of audio recordings of conversations, transcripts, and notes from workshop conversations. Additional data for WP4 will consist of physical copies of consent forms for in-person workshops and electronic copies of consent forms for virtual workshops. The workshops will take place in both in-person and virtual formats. Virtual workshops will be facilitated by the research team via video/audio conferencing using Microsoft Teams software for audio/video and a Dictaphone for audio recording. Audio recorded conversations will be transcribed verbatim by a trusted third-party transcription service (NJC Secretarial) approved by the University of Aberdeen. In-person workshops will take place in community and hospital facilities, chosen to ensure maximal accessibility for participants.

WP5- Data collection in WP5 will be facilitated by the two research fellows. Data will consist of audio recordings of observations and interviews transcripts and feedback notes from unrecorded observations. Additional data for WP5 will consist of electronic (Microsoft forms) and physical copies of consent forms for interviews. ***Data storage***

Hard copy consent forms will be securely stored in locked cabinets in the University of Aberdeen. All electronic consent forms will be generated and stored on secure password-protected university servers with access limited to the research team. Identifiable data will be stored separately from research data. Interview sessions will be conducted either in person or online and facilitated by the research fellows. In person interviews will be recorded using an audio recorder while online interviews will be conducted using Microsoft Teams and audio-recorded using an audio-recorder in the form of a Dictaphone with back-up recording on a university mobile phone for immediate upload to the university server to allow deletion from the device. Interviews will be transcribed verbatim by a trusted third-party transcription service approved by the University of Aberdeen. A secure file transfer system, such as the University of Aberdeen ZendTo service, will be used to send the audio recordings to a third-party transcription service and to receive the transcribed material back.

All data obtained from interviews will be anonymised at the point of transcription and only anonymous quotes will be used in presentations and publications. All participants identity will be pseudonymised using personal identification numbers. The research team will ensure that individuals and NHS units are unidentifiable from any quotations used in published results, presentations and publications. Records of interviews, focus group discussions and consensus meetings will be destroyed immediately after transcription while electronic data obtained as transcripts will be stored securely on password protected drives on password protected computers on the University of Aberdeen SQL server. Access to collated participants data will be restricted to the CI and appropriate research team members.

Two Research Fellows will conduct the interviews and lead data analysis. The research fellows will be responsible for sending the survey link. They will also be responsible for organising transcription, ensuring secure transfer of digital audio files to the transcriber and subsequent anonymisation/pseudonymisation of transcripts. File transfer will be conducted according to the current guidelines laid out in the University of Aberdeen's operating procedures. A contract will be put in place with the third-party transcription company. The research fellows will also be responsible for organising appropriate storage of the digital files and transcripts, which will be stored on password protected University computers that are backed up on a secure SQL server. Survey responses will be stored on the REDCAP software and hosted on the University of Aberdeen server. All survey data will be stored on University of Aberdeen servers.

As research sites are only involved in identifying potential participants, no data will be stored locally in other research sites. All generated data will be stored either remotely on University of Aberdeen servers or locally in locked cabinets for physical copies of forms.

Remote access to the network will be subject to robust authentication, and VPN (Virtual Private Network) connections to the network are only permitted for authorised users, ensuring that use is authenticated, and data is encrypted during transit across the network. No personal data will be downloaded or stored on laptop local hard drives.

Data selection and preservation

Data will be kept in accordance with the University of Aberdeen's RECORDS RETENTION SCHEDULE. Archiving of study documents will be carried out for five years after completion of the study using the archiving facilities in the Health Services Building at the University of Aberdeen. The sponsor Standard Operating Procedure (SOP) will be adhered to.

13. Labs and Samples Analysis

Not applicable – there are no samples or laboratory involvement in the project.

14. Statistics and Data Analysis

14.1. Sample Size Calculation

The sample sizes and composition are described in the sections on each of the WPs 2 to 5 (sections 4-8).

14.2 Missing Data
This is primarily a qualitative study so missing data is not relevant.

Missing responses at round 2 of a Delphi survey can be an issue. We will aim to minimise this by ensuring that those who complete round 1 are aware that they should also complete round 2.

14.3 Transfer of Data
Audio recordings will be transferred to the third-party transcription service via a secure file transfer process (for example the University of Aberdeen ZendTo service). Transcripts will be returned from the transcription service in the same way.

Anonymised study data will be shared between research team members to aid analysis and interpretation. The data will be held on University of Aberdeen servers and shared using Sharepoint verification code access to named research team members.

15 Trial/Study Management and Oversight Arrangements

15.1. Study Management Group
The study will be co-ordinated by a Study Management Group, consisting of the grant holder (CI), WP leads and external PIs (relevant to stage of study), study coordinator, study research fellow(s), PPI lead and study secretary.

15.2. Study Management
A study coordinator and research fellow will oversee the study and will be accountable to the CI. The research fellow will be responsible for collating and managing the study data. The study coordinator will oversee study milestones and outputs and will maintain study files. However, this remains the overall responsibility of the CI.

Each work package will be led by a core group within the research team alongside PPI panel members. A Gantt chart will be utilised to monitor study progress against planned milestones.

A study-specific delegation log will be prepared, detailing the responsibilities of each member of staff working on the study.

15.3. Study Advisory Group
A Study Advisory Group will be established to oversee the conduct and progress of the study. The terms of reference for the group will be included in a charter than independent members will be asked to agree to.

Members include an academic midwife (Prof Sara Kenyon), an obstetrician representing the Royal College of Obstetricians and Gynaecologists (Dr Philip Owen), a midwife representing the Royal College of Midwives (Prof Helen Cheyne - Chair), a decision aid development expert (Andy Hutcheon - NICE) and public/charity representatives Shamaila Bashir (MVP PPI), Lesley-Sheena Robbins (MVP and doula PPI), Clair Halliday (NCT PPI) and Mandy Shepherd (MVP PPI).

15.4. Data Monitoring Committee

N/A. The data generated by this study will be largely observational qualitative data in nature, along with consensus data. The data will be monitored and reviewed by the study management group and study advisory group.

16. Inspection of Records

The CI, PIs and all institutions involved in the study shall permit study related monitoring, audits, and REC review. The CI agrees to allow the Sponsor or, representatives of the Sponsor, direct access to all study records and source documentation.

17. Good Clinical Practice

17.1. Ethical Conduct of the Study

The study will be conducted in accordance with the principles of good clinical practice (GCP)/good research practice (GRP).

In addition to Sponsorship approval, a favorable ethical opinion will be obtained from the appropriate REC and appropriate NHS R&D approval(s) will be obtained prior to commencement of the study.

17.2 Confidentiality

All forms, reports, and other records will be identified in a manner designed to maintain participant confidentiality. All records will be kept in a secure storage area with limited access to study staff only. Clinical information will not be released without the written permission of the participant, except as necessary for monitoring and auditing by the Sponsor or its designee. The CI and study staff involved with this study will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the Sponsor or its designee will be obtained for the disclosure of any said confidential information to other parties.

17.3. Insurance and Indemnity

The University of Aberdeen is Sponsoring the study.

Insurance –

- The University of Aberdeen will obtain and hold a policy of Public Liability Insurance for legal liabilities arising from the study.

- Grampian Health Board will maintain its membership of the Clinical Negligence and Other Risks Insurance Scheme (“CNORIS”) which covers the legal liability of Grampian in relation to the study].

- Where the study involves University of Aberdeen staff undertaking clinical research on NHS patients, such staff will hold honorary contracts with Grampian Health Board which means they will have cover under Grampian’s membership of the CNORIS scheme.

Indemnity: The Sponsor does not provide study participants with indemnity in relation to participation in the Study but has insurance for legal liability as described above.

17.4 Data Protection

The CI and study staff involved with this project will comply with the requirements of the UK General Data Protection Regulations (GDPR) and the Data Protection Act 2018. The HRA recommended wording to fulfil transparency requirements under the GDPR for health and care research has been included in the patient information leaflets.

The CI and study staff will also adhere, if appropriate, to the current version of the NHS Scotland Code of Practice on Protecting Patient Confidentiality. Access to collated participant data will be restricted to the CI and appropriate research team members.

Computers used to collate the data will have limited access measures via usernames and passwords.

Published results will not contain any personal data that could allow identification of individual participants.

18 Study Conduct Responsibilities

18.1 Protocol Amendments, Deviations and Breaches

The CI will seek approval for any amendments to the Protocol or other study documents from the Sponsor (in the first instance), REC and NHS R&D Office(s). Amendments to the protocol or other study documents will not be implemented without these approvals.

In the event that a CI needs to deviate from the protocol, the nature of and reasons for the deviation will be recorded in the CRF, documented and submitted to the Sponsor. If this necessitates a subsequent protocol amendment, this will be submitted to the Sponsor for approval and then to the appropriate REC and lead NHS R&D Office for review and approval.

In the event that a serious breach of GCP is suspected, this will be reported to the Sponsor immediately using the form “Breach Report Form”.

18.2 Study Record Retention

Archiving of study documents will be carried out for five years after completion of the study using the archiving facilities in the Health Services Building at the University of Aberdeen. The sponsor Standard Operating Procedure (SOP) will be adhered to.

18.3 End of Study

The end of study is defined as the completion of the beta-prototype decision aid and implementation plan. The Sponsor, CI and/or the TSC have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the Sponsor and REC within 90 days, or 15 days if the study is terminated prematurely.

A summary report of the study will be provided to the Sponsor and REC within 1 year of the end of the study.

19. Reporting, Publication and Notification of Results

19.1 Authorship Policy
Ownership of the data arising from this study resides with the study team and their respective employers. On completion of the study, a final study report will be prepared for eventual publication in the NIHR journals library.

19.2 Publication
The clinical study report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study.

Summaries of results will also be made available to Investigators for dissemination within their clinical areas (where appropriate and according to their discretion).

19.3 Peer Review
This study plan has been peer reviewed by the NIHR HSDR committee who approved the funding including external reviewers for NIHR. All reports of work arising from the Plan A project, including conference abstracts, outputs describing the methodological aspects of the study, and any outputs describing results should be peer reviewed by the Study Management Group. This Group will be responsible for decisions about submission following internal peer review. Submission may be delayed or vetoed if there are serious concerns about the scientific quality of the report. If individual members of the group are dissatisfied by decisions, the matter may be referred to the Study Advisory Group.

APPENDIX 1: References

(1) Birthrights UK M. A quarter of mothers say their decisions were not respected when giving birth. 2020; Available at: https://www.birthrights.org.uk/2020/09/03/a-quarter-of-mothers-say-their-decisions-were-not-respected-when-giving-birth/. Accessed 09/07, 2020.

(2) National Institute for Health and Care Excellence. Caesarean Birth NG192. 2021;NG192.

(3) The supreme court. Judgement: Montgomery (appellant) vs Lanarkshire Health Board (respondent) (Scotland). 2015; Available at: https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf. Accessed 02/04, 2016.

(4) Coulter A, Stilwell D, Kryworuchko J, Mullen PD, Ng CJ, van der Weijden T. A systematic development process for patient decision aids. BMC Med Inform Decis Mak 2013;13 Suppl 2:S2-6947.

(5) Lupton D, Leahy D. **Reimagining digital health education: Reflections on the possibilities of the storyboarding method**. Health Education Journal 2019.

(6) National Institute for Health and Care Excellence. Standards framework for shared-decision-making support tools, including patient decision aids. 2021; Available at: https://www.nice.org.uk/corporate/ecd8. Accessed 11/21, 2021.

(7) Stacey D, Legare F, Boland L, Lewis KB, Loiselle MC, Hoefel L, et al. 20th Anniversary Ottawa Decision Support Framework: Part 3 Overview of Systematic Reviews and Updated Framework. Med Decis Making 2020 April 01;40(3):379-398.

(8) Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implement Sci 2012 April 24;7:37-5908.

(9) Jardine J, Blotkamp A, Gurol-Urganci I, Knight H, Harris T, Hawdon J, et al. Risk of complicated birth at term in nulliparous and multiparous women using routinely collected maternity data in England: cohort study. BMJ 2020 October 01;371:m3377.

(10) Coates D, Thirukumar P, Henry A. Women's experiences and satisfaction with having a cesarean birth: An integrative review. Birth 2020 June 01;47(2):169-182.

(11) Kenny LC, Lavender T, McNamee R, O'Neill SM, Mills T, Khashan AS. Advanced maternal age and adverse pregnancy outcome: evidence from a large contemporary cohort. PLoS One 2013;8(2):e56583.

(12) Ellekjaer KL, Bergholt T, Lokkegaard E. Maternal obesity and its effect on labour duration in nulliparous women: a retrospective observational cohort study. BMC Pregnancy Childbirth 2017 July 12;17(1):222-017.

(13) Djatmika C, Lusher j, Meyrick J, Byron-Daniel J. Caesarean section as an informed choice in the UK: a systematic review. British Journal of Midwifery 2021;29(10).

(14) Royal College of Surgeons of Edinburgh. Course Details | Informed Consent: Sharing the Decision (ICONS) | RCSEd. 2021; Available at: https://www.rcsed.ac.uk/events-courses/course-details-informed-consent-sharing-the-decision-icons. Accessed 11/26, 2021.

(15) NHS England. Shared Decision Making. 2018; Available at: https://www.england.nhs.uk/shared-decision-making/. Accessed 02/15, 2019.

(16) Wagner M. Choosing caesarean section. Lancet 2000 November 11;356(9242):1677-1680.

(17) Aasheim V, Nilsen ABV, Reinar LM, Lukasse M. Perineal techniques during the second stage of labour for reducing perineal trauma. Cochrane Database Syst Rev 2017 June 13;6:CD006672.

(18) Ockenden D. Ockenden report. Emerging findings and recommendations from the independent review of maternity services at the Shrewsbury and Telford Hospital NHS Trust. 2020.

(19) Kirkup CBE D. **The Report of the Morecambe Bay Investigation**. 2015.

(20) Coates D, Donnolley N, Henry A. The Attitudes and Beliefs of Australian Midwives and Obstetricians About Birth Options and Labor Interventions. J Midwifery Womens Health 2020 December 27.

(21) Information Services Division Scotland. Births in Scottish Hospitals, Year Ending 31st March 2018. 2018.

(22) Office for National Statistics. Births in England and Wales: 2018. 2019; Available at: https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/livebirths/bulletins/birthsummarytablesenglandandwales/2018. Accessed 04/30, 2020.

(23) Bragg F, Cromwell DA, Edozien LC, Gurol-Urganci I, Mahmood TA, Templeton A, et al. Variation in rates of caesarean section among English NHS trusts after accounting for maternal and clinical risk: cross sectional study. BMJ 2010 October 06;341:c5065.

(24) Birthplace in England Collaborative Group, Brocklehurst P, Hardy P, Hollowell J, Linsell L, Macfarlane A, et al. Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: the Birthplace in England national prospective cohort study. BMJ 2011 November 23;343:d7400.

(25) Gurol-Urganci I, Cromwell DA, Edozien LC, Mahmood TA, Adams EJ, Richmond DH, et al. Third- and fourth-degree perineal tears among primiparous women in England between 2000 and 2012: time trends and risk factors. BJOG 2013 November 01;120(12):1516-1525.

(26) Burcher P, Cheyney MJ, Li KN, Hushmendy S, Kiley KC. Cesarean Birth Regret and Dissatisfaction: A Qualitative Approach. Birth 2016 December 01;43(4):346-352.

(27) Yildiz PD, Ayers S, Phillips L. The prevalence of posttraumatic stress disorder in pregnancy and after birth: A systematic review and meta-analysis. J Affect Disord 2017 January 15;208:634-645.

(28) Black M, Entwistle VA, Bhattacharya S, Gillies K. Vaginal birth after caesarean section: why is uptake so low? Insights from a meta-ethnographic synthesis of women's accounts of their birth choices. BMJ Open 2016 January 08;6(1):e008881-2015.

(29) Hull PCB. 'Women's Voices' are exposing truth about pelvic floor trauma. 2019; Available at: https://caesareanbirth.org/2017/10/17/womens-voices-are-exposing-truth-about-pelvic-organ-prolapse/#comments. Accessed 08/22, 2019.

(30) Chan SW, Tulloch E, Cooper ES, Smith A, Wojcik W, Norman JE. Montgomery and informed consent: where are we now? BMJ 2017 May 12;357:j2224.

(31) Royal College of Obstetricians and Gynaecologists (RCOG). Choosing to have a caesarean section. 2015; Available at: https://www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/pregnancy/pi-choosing-to-have-a-c-section.pdf. Accessed 08/23, 2019.

(32) Sanders RA, Crozier K. How do informal information sources influence women's decision-making for birth? A meta-synthesis of qualitative studies. BMC Pregnancy Childbirth 2018 January 10;18(1):21-017.

(33) NHS Resolution. Annual Reports and Accounts 2018/19. 2019.

(34) Scottish Public Services Ombudsman. Informed consent; Learning from complaints. 2017.

(35) The Scottish Government. The Best Start: Maternity and Neonatal Care Plan Executive Summary. 2017;1.

(36) National Maternity review. Better Births: Improving outcomes of maternity care in England. A five year forward view for maternity care. 2016;1.

(37) NHS. Maternity choice and personalisation. 2020; Available at: https://www.england.nhs.uk/mat-transformation/mat-pioneers/. Accessed 09/07, 2020.

(38) NHS England. Personalised care and support planning guidance: Guidance for local maternity systems. 2021;1.

(39) Nicholls J, David AL, Iskaros J, Lanceley A. Consent in pregnancy: A qualitative study of the views and experiences of women and their healthcare professionals. Eur J Obstet Gynecol Reprod Biol 2019 July 01;238:132-137.

(40) NHS England. Universal Personalised Care: Implementing the comprehensive model. 2019;1.

(41) Birthrights UK. iDecide: a new consent tool is on its way... 2020; Available at: https://www.birthrights.org.uk/2020/01/30/idecide-a-new-consent-tool-is-on-its-way/. Accessed 04/07, 2021.

(42) Stacey D, Legare F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev 2017 April 12;4:CD001431.

(43) Chinkam S, Steer-Massaro C, Damus K, Shorten B, Shorten A. A Shared Decision-Making Toolkit for Mode of Birth After Cesarean. J Perinat Educ 2020 January 01;29(1):35-49.

(44) Montgomery AA, Emmett CL, Fahey T, Jones C, Ricketts I, Patel RR, et al. Two decision aids for mode of delivery among women with previous caesarean section: Randomised controlled trial. Br Med J 2007;334(7607):1305-1309.

(45) Durand MA, Carpenter L, Dolan H, Bravo P, Mann M, Bunn F, et al. Do interventions designed to support shared decision-making reduce health inequalities? A systematic review and meta-analysis. PLoS One 2014 April 15;9(4):e94670.

(46) Knight M BK. Saving Lives, Improving Mothers' Care - Lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2015-17. 2019.

(47) Nathan AG, Marshall IM, Cooper JM, Huang ES. Use of Decision Aids with Minority Patients: a Systematic Review. J Gen Intern Med 2016 June 01;31(6):663-676.

(48) Munro S, Wilcox ES, Lambert LK, Norena M, Kaufman S, Encinger J, et al. A survey of health care practitioners' attitudes toward shared decision-making for choice of next birth after cesarean. Birth 2021 February 04.

(49) Coates D, Thirukumar P, Spear V, Brown G, Henry A. What are women's mode of birth preferences and why? A systematic scoping review. Women Birth 2020 July 01;33(4):323-333.

(50) Loke AY, Davies L, Mak YW. Is it the decision of women to choose a cesarean section as the mode of birth? A review of literature on the views of stakeholders. BMC Pregnancy Childbirth 2019 August 09;19(1):286-019.

(51) Rachaneni S, Gurol-Urganci I, Basu M, Thakar R, Sultan A, Freeman R. Short statured primigravidae: Options for the obstetric management from a survey of UK obstetricians. Eur J Obstet Gynecol Reprod Biol 2021 January 01;256:379-384.

(52) Coates D, Thirukumar P, Henry A. Making shared decisions in relation to planned caesarean sections: What are we up to? Patient Educ Couns 2020 June 01;103(6):1176-1190.

(53) Wang XR, Cotter H, Fahey M. Women's Selection of Mode of Birth for their Breech Presentation. J Obstet Gynaecol Can 2020 November 05.

(54) Coates D, Donnolley N, Foureur M, Henry A. Women's experiences of decision-making and attitudes in relation to induction of labour: A survey study. Women Birth 2021 March 01;34(2):e170-e177.

(55) Which?. Where to give birth. 2021; Available at: https://www.which.co.uk/reviews/birthing-options/article/where-to-give-birth-a23Lt6u4NC9P. Accessed 04/07, 2021.

(56) Durand MA, Moulton B, Cockle E, Mann M, Elwyn G. Can shared decision-making reduce medical malpractice litigation? A systematic review. BMC Health Serv Res 2015 April 18;15:167-015.

(57) National Institute for Health and Care Excellence. Glossary: Patient decision Aid. 2021; Available at: https://www.nice.org.uk/Glossary?letter=P. Accessed 04/10, 2021.

(58) Williams O, Sarre S, Papoulias SC, Knowles S, Robert G, Beresford P, et al. Lost in the shadows: reflections on the dark side of co-production. Health Res Policy Syst 2020 May 07;18(1):43-020.

(59) Okoth K, Chandan JS, Marshall T, Thangaratinam S, Thomas GN, Nirantharakumar K, et al. Association between the reproductive health of young women and cardiovascular disease in later life: umbrella review. BMJ 2020 October 07;371:m3502.

(60) The GRADE-CERQual working group. GRADE-CERQual. 2018; Available at: https://www.cerqual.org. Accessed 04/10, 2021.

(61) Appendix D Methodology checklist: cohort studies The social care guidance manual. 2016; Available at: https://www.nice.org.uk/process/pmg10/chapter/appendix-d-methodology-checklist-cohort-studies.

(62) The Grade Working Group. GRADE. 2021; Available at: https://www.gradeworkinggroup.org/. Accessed 04/10, 2021.

(63) Coyne IT. Sampling in qualitative research. Purposeful and theoretical sampling; merging or clear boundaries? J Adv Nurs 1997 September 01;26(3):623-630.

(64) Treweek S, Banister K, Bower P, Cotton S, Devane D, Gardner HR, et al. Developing the INCLUDE Ethnicity Framework-a tool to help trialists design trials that better reflect the communities they serve. Trials 2021 May 10;22(1):337-021.

(65) Centre for Ethnic Health Research. Centre for Ethnic Health Research – Toolkits. Available at: https://centreforbmehealth.org.uk/wp-content/uploads/2020/07/Checklist_COVID_BME_v2.pdf. Accessed 04/10, 2021.

(66) McAreavey R, Das C. A delicate balancing act: Negotiating with gatekeepers for ethical research when researching minority communities. 2013; Available at: https://journals.sagepub.com/doi/10.1177/160940691301200102.

(67) Agbadje TT, Menear M, Gagnon MP, Legare F. Theory-based approach to developing an implementation plan to support the adoption of a patient decision aid for Down syndrome prenatal screening. Implement Sci 2021 May 25;16(1):56-021.

(68) Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med Res Methodol 2013 September 18;13:117-2288.

(69) Harman NL, Bruce IA, Callery P, Tierney S, Sharif MO, O'Brien K, et al. MOMENT--Management of Otitis Media with Effusion in Cleft Palate: protocol for a systematic review of the literature and identification of a core outcome set using a Delphi survey. Trials 2013 March 12;14:70-6215.

(70) Darker CD, French DP. What sense do people make of a theory of planned behaviour questionnaire?: a think-aloud study. J Health Psychol 2009 October 01;14(7):861-871.

(71) Williamson PR, Altman DG, Bagley H, Barnes KL, Blazeby JM, Brookes ST, et al. The COMET Handbook: version 1.0. Trials 2017 June 20;18(Suppl 3):280-017.

(72) Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. . 2017.

(73) Wesolko D. Peter Morville's User Experience Honeycomb. 2016; Available at: Nijagal MA, Wissig S, Stowell C, et al. Standardized outcome measures for pregnancy and childbirth, an ICHOM proposal. BMC health services research 2018;18(1):953. doi: 10.1186/s12913-018-3732-3 [published Online First: 2018/12/13]. Accessed 04/07, 2021.

APPENDIX 2: Example search strategy

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions <1946 to October 18, 2022>

1 Pregnancy/ or Prenatal Education/ or Prenatal Care/ or Maternal Health Services/
2 (ante natal or antenatal or pre natal* or prenatal*).tw.
3 ((birth* or c?esarean or VBAC) adj4 (choice? or choos* or chose or deci* or plan* or option? or intent* or desir* or request* or prefer*)).tw.
4 1 or 2 or 3
5 Minority Groups/ or Minority Health/ or Culturally Competent Care/ or Cultural Competency/ or Race Factors/ or exp Racial Groups/ or exp Ethnicity/ or "Ethnic and Racial Minorities"/ or Vulnerable Populations/ or "Sexual and Gender Minorities"/ or "Emigrants and Immigrants"/ or Pregnancy in Adolescence/ or Socioeconomic factors/ or Healthcare Disparities/ or Stereotyping/
6 (minorit* or ethnic* or Black or BAME or BME or Asian or African or Caribbean or racial or race or relig* or colo?r or non-white or "people of colo?r" or immigrant? or migrant? or divers* or LGB* or marginali?ed or orientation or underserved or disadvantaged or vulnerable or socioeconomic or discriminat* or depriv*).tw.
7 (low* adj3 (status or income? or literacy or group?)).tw.
8 single parent/ or single parent family/
9 ((single or lone) adj3 parent?).tw.
10 exp Disabled Persons/
11 ((disabled or disabilit* or impair*) adj5 women).tw.
12 rural health services/ or rural population/
13 (rural* or non-urban or (remote adj5 (communit* or population? or setting?))).tw.
14 or/5-13
15 exp United Kingdom/
16 (GB or Britain or (British not "British Columbia") or UK or United Kingdom* or (England not "New England") or English or Northern Ireland* or Northern Irish* or Scotland* or Scottish or (Wales not "New South Wales") or Welsh*).tw,in,jn.
17 15 or 16
18 4 and 14 and 17
19 limit 18 to (meta analysis or "review" or "systematic review")
20 ((systematic adj3 review) or review or synthesis).ti.
21 18 and 20
22 19 or 21
23 (((low or middle) adj3 countries) or LMIC).tw.
24 Developing Countries/
25 23 or 24
26 22 not 25
27 limit 26 to yr="2011 -Current"