

**Research priorities for Intrapartum  
Clinical Study Executive Group**

**January 2015**



Our research priorities are currently taken from those identified from the NICE Guidelines on Induction of Labour, Intrapartum Care and Caesarean Section. While the Key Research recommendations from each Guideline are presented first, they are not in order of importance. This is not an exhaustive list and we would welcome good quality studies answering clinically relevant questions outside these.

## **Key priorities for research from 2008 NICE Induction of Labour Guideline<sup>1</sup>**

### **1. Prolonged pregnancy**

Research is needed to identify babies at particularly high risk of morbidity and mortality who will benefit from induction and therefore avoid induction for babies who do not need it.

#### *Research question*

Pregnancies that continue after term run a higher risk of fetal compromise and stillbirth; can ways be found to identify pregnancies within that population that are at particular risk of these complications?

#### *Why is this important?*

Although the risks of fetal compromise and stillbirth rise steeply after 42 weeks, this rise is from a low baseline. Consequently, only a comparatively small proportion of that population is at particular risk. Because there is no way to precisely identify those pregnancies, delivery currently has to be recommended to all such women. If there were better methods of predicting complications in an individual pregnancy, induction of labour could be more precisely directed towards those at particular risk.

### **2. Preterm prelabour rupture of membranes**

A large study is needed to compare immediate induction of labour with expectant management beyond 34 weeks, taking into account duration of preterm prelabour rupture of membranes, gestational age, and maternal steroid and antibiotic treatment.

#### *Research question*

What are the relative risks and benefits of delivery versus expectant management in women whose membranes have ruptured spontaneously between 34 and 37 weeks?

#### *Why is this important?*

Intrauterine sepsis is more likely to develop in pregnancies that continue after the membranes have ruptured, putting both the woman and the baby at risk. In some such pregnancies, labour begins spontaneously at a variable interval after the membranes have ruptured, avoiding the need for induction. The value of antibiotic therapy and the administration of corticosteroids to the woman is unclear in this situation. A randomised study of active versus expectant management, taking account of time since membrane rupture, gestational age and maternal therapy, would be valuable.

### **3. Setting for induction of labour**

Studies are needed to assess the safety, efficacy and clinical and cost-effectiveness of outpatient and inpatient induction in the UK setting, taking into account women's views.

*Research question*

Is it safe, effective and cost-effective to carry out induction of labour in an outpatient setting? What are the advantages and disadvantages of such an approach, taking into account women's views?

*Why is this important?*

In line with the way healthcare has developed in many areas of acute care, there is an increasing desire to reduce the time women spend in hospital. Several units are already exploring outpatient induction of labour policies and there is a need to study this approach in order to determine relative risks and benefits, as well as acceptability to women.

**4. Membrane sweeping**

Research is needed to assess effectiveness, maternal satisfaction and acceptability of:

- multiple versus once-only membrane sweeping, at varying gestational ages, stratifying for parity
- cervical massage when membrane sweeping is not possible, in women with unfavourable cervix.

*Research question*

What are the effectiveness and acceptability of, and maternal satisfaction with, the following:

- multiple versus once-only membrane sweeping, at varying gestational ages, depending on parity
- membrane sweeping versus cervical massage?

*Why is this important?*

Membrane sweeping is considered to be a relatively simple intervention that may positively influence the transition from maintenance of pregnancy to the onset of labour, reducing the need for formal induction of labour. However, there are disadvantages, such as possible vaginal bleeding and discomfort. Research into when and how frequently membrane sweeping should be carried out to maximise its effectiveness and acceptability would be of value.

**5. Vaginal PGE<sub>2</sub>**

Research is needed to assess the effectiveness, safety, maternal satisfaction and acceptability of different regimens of vaginal PGE<sub>2</sub>, stratified by clinical indications, cervical and membrane status, parity and previous caesarean section.

*Research question*

What are the effectiveness, safety and maternal acceptability of:

- different regimens of vaginal PGE<sub>2</sub>, stratified by: clinical indications; cervical and membrane status; parity; and previous caesarean section
- different management policies for failed induction of labour with vaginal PGE<sub>2</sub> (additional PGE<sub>2</sub>, oxytocin, elective caesarean or delay of induction, if appropriate)?

*Why is this important?*

Despite extensive studies carried out over the past 30 years to determine the most effective ways of inducing labour with vaginal PGE<sub>2</sub>, uncertainties remain about how best to apply these agents in terms of their dosage and timing. It would be particularly useful to understand more clearly why vaginal PGE<sub>2</sub> fails to induce labour in some women.

## **Key priorities for research from 2014 NICE Intrapartum Care Guideline<sup>2</sup>**

### **1. Effect of information giving on place of birth**

How does the provision of accurate, evidence-based information affect women's decision-making processes and choice of place of birth?

#### *Why this is important?*

A report by Coxon et al. (2013) identifies in detail why women make choices about where to give birth and how these choices can be influenced. Influences may include written and verbal information (both online and from midwives and doctors), previous experience, and word-of-mouth advice from friends and family. The Birthplace study concluded that giving birth outside an obstetric unit is the optimal choice for low-risk women. This finding should be used to restructure the way in which information is provided, so that it is presented in a more accurate, less risk-based way in order to support women's choices. This change should be evaluated in a quantitative observational study and/or qualitative study that records any changes in women's choice-making about place of birth. Outcomes include understanding why and how women make choices about where to give birth and how this can influence the provision of appropriate and accessible information, a measure of informed decision-making, and fearfulness and absence of fearfulness when choosing place of birth.

### **2. Long-term consequences of planning birth in different settings**

What are the long-term consequences for women and babies of planning birth in different settings?

#### *Why this is important?*

The long-term consequences of birth experiences and birth outcomes are poorly understood, particularly in relation to place of birth. A large population-based observational study would compare women's experiences and outcomes in different birth settings (with subgroup analysis by mode of birth) in relation to the wellbeing of the women and their children over different periods of time (for example, 2, 5, 10, 15, 20 and 30 years). A secondary analysis could compare different providers where birth philosophies are different. Outcomes would be compared by accessing medical records and through qualitative interviews. Primary outcomes are long-term physical morbidity, pain after birth, readmission to hospital, infection, psychological morbidity (for example, postnatal depression, bonding, relationship breakdown with partner, fear of giving birth in future) and breastfeeding rates. Secondary outcomes are impact on attachment between mother and child, obesity in children, autoimmune disease, chronic illness, educational achievement and family functioning.

### **3. Education about the latent first stage of labour**

Does enhanced education specifically about the latent first stage of labour increase the number of nulliparous women who wait until they are in established labour before attending the obstetric or midwifery unit (or calling the midwife to a home birth), compared with women who do not receive this education?

#### *Why this is important?*

Studies show that antenatal education about labour and birth in general makes a difference to some birth outcomes, but there is limited evidence focusing on education about the latent first stage of labour specifically. The aim of this study (randomised controlled trial or prospective observational study) would be to compare 2 groups of women experiencing their first labour and birth: a group who receive an education session in late pregnancy covering what to expect in the latent first stage of labour and how to recognise the onset of established labour, and a group who have not received this focused education. Primary outcomes would be mode of

birth, satisfaction with the birth experience and the woman's physical and emotional wellbeing after birth. Secondary outcomes would be use of pharmacological pain relief, use of oxytocin to augment labour, and time from first contact in confirmed established labour to birth.

#### **4. Intermittent auscultation compared with cardiotocography**

What are the natural frequencies of the avoidable harms that cardiotocography is intended to prevent for women who are assessed as being at low risk of complications at the start of labour? Does using cardiotocography in labours where complications develop confer a net benefit compared with intermittent auscultation?

##### *Why this is important?*

Cardiotocography is used in current practice to monitor the fetal heart rate when there is a concern that fetal hypoxia may develop. It is regarded as unethical, in most circumstances, to conduct clinical research where women whose labour is categorised as 'high risk' are not offered cardiotocography. There is therefore no high-quality evidence about the size of the benefit or harm derived from the use of cardiotocography compared with intermittent auscultation, either in individual cases or across a whole population. Further analysis is needed to evaluate the actual (or probable) benefits and harms associated with this screening test. This would be based on analysis and modelling using data and assumptions derived from existing evidence from a range of countries, comprising data from any studies and/or historic data sets that record the natural frequencies of avoidable damage caused by intrapartum events. These data could then be used to ascertain both the natural frequencies of adverse events and whether widespread use of cardiotocography reduces these. Primary outcomes would be intrapartum fetal death, neonatal encephalopathy, cerebral palsy or other significant neurodevelopmental injury, and maternal morbidity. Other outcomes might include long-term physical and psychological outcomes (health across whole of life), health and social care costs, implications for informed decision-making, and analysis of ethical considerations.

#### **5. Postpartum haemorrhage**

What is the most effective treatment for primary postpartum haemorrhage?

##### *Why this is important?*

There is uncertainty about the most effective drug treatments and dosage regimes, and about which other treatments should be used, for women who develop a postpartum haemorrhage. The most effective sequencing of interventions is also uncertain. The psychological impact of postpartum haemorrhage for women can be significant, and identifying the approach that minimises this impact is important. Randomised controlled trials comparing different dosage regimes for oxytocin and misoprostol, as well as comparisons with ergometrine and carboprost, are needed. Trials of mechanical measures such as intrauterine balloons or interventional radiology as early second-line treatment (rather than an alternative drug treatment) are also needed. Alternatively, a trial comparing the effectiveness of a complex intervention (for example, an educational component, sequence of interventions, immediate feedback and quality improvements) compared with standard care could be undertaken. Important outcomes include blood and blood product transfusion, need for further intervention, need for hysterectomy and psychological outcomes for the woman.

### **Key priorities for research from 2011 NICE Caesarean Section Guideline<sup>3</sup>**

#### **1. Risks and benefits of CS**

What are the medium- to long-term risks and benefits to women and their babies of planned CS compared with planned vaginal birth?

The main focus would be the outcomes in women which could be measured at 1 year (medium term) and 5–10 years (long term). These outcomes could include:

- urinary dysfunction
- gastrointestinal dysfunction
- dyspareunia
- breastfeeding
- psychological health

Infant outcomes could include medical problems, especially ongoing respiratory and neurological problems.

*Why this is important?*

Morbidities arising intraoperatively or in the days after a caesarean section have been reasonably well described in the literature. Much less is known, however, about physical and emotional outcome measures in the longer term.

The Confidential Enquiries into Maternal Death in the UK, most recently published as ‘Saving mothers lives 2006–2008’<sup>4</sup> devote a significant proportion of their work to investigating ‘late’ causes of maternal death. These include events arising in the medium term, namely, up to 1 year after a woman has given birth, many of which originate from the preceding pregnancy. The infectious, psychiatric and other conditions arising in or related to pregnancy do not always cause death but are responsible for arguably a greater burden of morbidity in the medium and long term, long after the pregnancy is over.

To provide more meaningful information to women when they are choosing their mode of birth, there is a pressing need to document medium- to long-term outcomes in women and their babies after a planned CS or a planned vaginal birth. First, it should be possible to gather data using standardised questions (traditional paper-based questionnaires and face-to-face interviews) about maternal septic morbidities and emotional wellbeing up to 1 year after a planned CS in a population of women who have consented for follow-up. Internet-based questionnaires could also be devised, to achieve the high response rates required for a full interpretation of the data. Similarly, it would be important to collect high-quality data on infant morbidities after a planned CS compared with a planned vaginal birth. A long term morbidity evaluation (between 5 and 10 years after the CS) would use similar methodology but assess symptoms related to urinary and gastrointestinal function.

## **2. Maternal request for CS**

What support or psychological interventions would be appropriate for women who have a fear of vaginal childbirth and request a CS?

Interventions for evaluation could include:

- support from a named member of the maternity team
- continuity of carer
- formal counselling
- cognitive behavioural therapy

Outcomes could include:

- mode of birth planned at term
- psychological outcomes (postnatal depression, posttraumatic stress disorder, self-esteem, mother-infant bonding)
- breastfeeding

*Why this is important?*

Fear of vaginal childbirth may stem from:

- fear of damage to the maternal pelvic floor
- damage to the baby during childbirth
- self-doubt on the ability to physically achieve vaginal birth
- previous childbirth experience
- unresolved issues related to the genital area

Currently there is a wide variation in practice and limited resources lead to limited availability of effective interventions. Interventions that may be appropriate include:

- antenatal clinics dedicated to providing care for women
- with no obstetric indications who request a CS
- referral to a psychologist or a mental health professional
- referral to an obstetric anaesthetist
- intensive midwifery support

Continuity of healthcare professional support from the antenatal to the intrapartum periods and 'one to one' midwifery care during labour are also often lacking and may make a difference to women who are anxious or afraid.

All of these interventions have different resource implications and there is no clear evidence to suggest that any are of benefit. The proposed research would compare in a randomised controlled trial two or more of these interventions in women requesting a CS. In the absence of any evidence, there is a case for comparing these interventions with routine antenatal care (that is, no special intervention).

This research is relevant because it would help to guide the optimal use of these limited resources and future guideline recommendations.

**3. Decision-to-delivery interval for unplanned CS**

**a. What factors influence the decision-to-delivery interval when there is a category 1 level of urgency for CS?**

Factors to be investigated could include:

- staff grade/level of experience
- skill mix within the multidisciplinary team
- task allocation
- methods of communication
- time of day
- availability of ongoing staff training about emergency
- procedures and levels of attendance

The research could be conducted using simulation methods and video observation to determine what factors influence the decision-to-delivery interval for category 1 CS. The videos could also be used to train staff.

*Why this is important?*

'Crash' CS is a psychologically traumatic event for women and their partners and is also stressful for clinical staff. Staff and resources may have to be obtained from other areas of clinical care. This should be undertaken as efficiently and effectively as possible, minimising anxiety and ensuring the safety of the mother and her baby.

For category 1 CS there is a recognised urgency to deliver as quickly as is reasonably possible. The majority of research in this area is quantitative and looks at the impact of the decision-to-delivery interval on various aspects of fetal and maternal outcomes rather than the interplay of factors that can affect this time period itself. Much of this evidence is retrospective. Although some work has been conducted in the UK to examine where the systematic delays lie and how to avoid them<sup>5</sup>, more work is needed to determine how to optimise the decision-to-delivery interval. This work should use qualitative as well as quantitative research methods to assess which factors influence the decision-to-delivery interval for a category 1 CS. Evaluation of these factors could be used to inform future NICE guidance, for example specific guidance for management of category 1 CS. Such information could also be used by hospitals for maternity services planning and at a team level would assist with audit and ongoing evaluation and training of the multidisciplinary team.

A large amount of NHS and other state funding is used to provide continuing care for infants who are disabled as a result of birth asphyxia and in providing lifelong support for the child and their family. In addition, large sums of public money are spent on litigation and compensation in some of these cases through the Clinical Negligence Scheme for Trusts (CNST). If research helped to minimise the impact of birth asphyxia this would reduce the costs of continuing care to the state and the burden to the child, their family and the wider community.

More realistic and more relevant expectations for the decision-to-delivery interval based on evidence would inform debate in the legal system and may help to reduce the cost to the state of related litigation.

**b. A prospective study to determine whether the decision-to-delivery interval has an impact on maternal and neonatal outcomes when there is a category 2 level of urgency for CS.**

Important primary outcomes would be

- fetal wellbeing (such as cord blood gases, Apgar score at 5 minutes, hypoxic encephalopathy, neonatal respiratory problems, unanticipated admission to neonatal intensive care unit (NICU), duration of stay in the NICU)
- maternal wellbeing (such as haemoglobin levels on day 2, need for blood transfusion, duration of hospital stay controlled for prolonged neonatal stay and general health/wellbeing)

Valuable secondary outcomes could include:

- fetal trauma at delivery
- iatrogenic maternal bladder or bowel injury
- postoperative maternal infectious morbidity
- establishment of breast-feeding
- psychological outcomes for women, such as the development of postnatal depression/post-traumatic stress disorder

*Why this is important?*

This research is important to inform the ongoing debate about the management of category 2 CS. The 'continuum of risk' in this setting has been recognised. However, the majority of work in this area, looking at maternal and fetal outcomes, generally considers unplanned caesarean sections as a whole group without making any distinction between degrees of urgency. Furthermore much of this work is retrospective. The majority of women who undergo intrapartum CS fall into the category 2 level of urgency<sup>6</sup> and therefore specific information for this group could affect and benefit many women and contribute to the delivery of equity of care.

Delay in delivery with a compromised fetus may result in major and long-term harm including cerebral palsy and other major long-term disability. The immediate and long-term effect on a family of the birth of a baby requiring life-long specialised care and support is enormous. If such harm could be avoided by appropriate haste this would be an important improvement in outcome. However, if such haste is of no benefit then any related risk of adverse maternal outcome needs to be minimised.

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More realistic and more relevant expectations for the decision-to-delivery interval based on evidence would inform debate within the legal system and may help to reduce the cost to the state of related litigation.

### **c. Repeat of the National Caesarean Section Sentinel Audit<sup>6</sup>**

The original CS guideline included a set of 'auditable standards'. It would be a straightforward task to produce an updated set of auditable standards based on the important topics covered in the updated guideline. These could include:

- consent
- indications (including maternal request)
- procedural aspects
- maternal and fetal outcomes

Many of the outcomes documented in a new CS audit would relate directly to recommendations in this CS guideline update. Researchers may also want to consider categorising different reasons underlying maternal request for CS such as previous poor childbirth experience, longstanding fear of childbirth, belief that CS is safer for the baby etc.

An additional useful feature of the audit would be to record key related data, such as the proportion of CS for a breech presentation that had an attempted external cephalic version.

#### *Why this is important?*

During the 10 years since the National Caesarean Section Sentinel Audit was undertaken (2000–2001), many of the findings may have changed significantly. The audit examined who was having a CS and why, as well as the views of women having babies and the obstetricians looking after them. The audit found that a 20% CS rate was considered too high by 51% of obstetricians. UK CS rates now average about 25%.

A repeat of the CS Sentinel Audit would reveal any changes in indications and the views of women and obstetricians. The current literature does not adequately address the issue of maternal request for CS and this is one aspect the audit may address. Women's views on maternal request for CS for when there are no obstetric indications are particularly relevant. Such requests may be on the rise and the reasons are not always clearly expressed or documented.

The methodology of the audit is established, making a repeat feasible. This should be given high priority because the benefit to the NHS would be significant.

## **Remaining research recommendations from 2008 Induction of labour Guideline**

### **1. Information and decision making**

Studies are needed to compare women's views and experiences on the different methods of induction of labour with those during spontaneous labour.

Studies are needed to assess the needs of pregnant women throughout the induction of labour experience to identify the support they require and prefer.

### **2. Induction of labour in specific circumstances**

#### *a. Prolonged pregnancy*

Studies should be undertaken to compare effectiveness, safety, maternal satisfaction and compliance of different expectant management protocols.

Research is needed into racial differences in the UK to identify the possible differences in the distribution of perinatal risk specific to gestational weeks and possible benefits of intervention before 41 weeks.

#### *b. Preterm prelabour rupture of membranes*

Research is needed to compare effectiveness, cost-effectiveness, safety and maternal satisfaction of different management policies for induction of labour.

#### *c. Previous caesarean section*

Studies should compare the effectiveness, cost-effectiveness, safety and maternal satisfaction of induction of labour by different methods, repeat elective lower segment caesarean section and expectant management in women with previous caesarean section.

#### *d. Maternal request for induction of labour*

Audit research is needed to assess the prevalence of maternal request for induction of labour and the reasons for such request.

#### *e. History of precipitate labour*

Studies are needed to quantify the risks for women with history of precipitate labour, and to compare effectiveness, safety and maternal satisfaction of different management policies.

### **3. Methods of induction of labour**

#### *a. Non-pharmacological methods – herbal supplements*

Further research is required to evaluate the effectiveness, safety and maternal satisfaction of the use of herbal supplements as a method of induction of labour.

#### *b. Non-pharmacological methods – acupuncture*

Further research is required to evaluate the effectiveness, safety and maternal satisfaction of acupuncture as a method of induction of labour.

#### *c. Non-pharmacological methods – homeopathy*

Further research is required to evaluate the effectiveness, safety and maternal satisfaction of homeopathy as a method of induction of labour

#### *d. Non-pharmacological methods – castor oil, hot bath and enemas*

Further research is required evaluate the effectiveness, safety and maternal satisfaction of the use of castor oil, hot baths and enemas as methods of induction of labour.

e. *Non-pharmacological methods – sexual intercourse*

Further research is required to evaluate the effectiveness, safety and maternal satisfaction of sexual intercourse as a method of induction of labour

f. *Non-pharmacological methods – breast stimulation*

Further research is required to evaluate the effectiveness, timing, methods, frequency, safety and maternal satisfaction of breast stimulation as a method of induction of labour.

g. *Mechanical methods*

Future trials on the use of mechanical methods should include women in whom prostaglandins during labour would pose increased risks, such as women with previous caesarean birth. These trials should clearly stratify groups by parity, cervical status and previous vaginal birth.

**4. Monitoring of induction of labour**

Studies are needed to identify the most effective way of monitoring women during the induction of labour process.

**5. Pain relief for induction of labour**

Research is needed to evaluate the effects of regional analgesia on progress and outcome of induced labour, stratified for differing cervical status. Studies are needed to assess the role support plays in alleviation of pain during induction of labour.

**6. Prevention and management of complications of induction of labour**

*Failed induction*

- a. Research is needed to establish frequency and interval of vaginal PGE2 to achieve successful induction of labour.
- b. Research is needed to examine different management policies for failed vaginal PGE2 induction (additional PGE2, amniotomy, oxytocin, elective caesarean section or delay of induction if appropriate).

**Remaining research recommendations from 2014 update of Intrapartum Care**

**Place of birth**

- 1. What are the resourcing and staff training needs associated with advising women at low risk of developing intrapartum complications to give birth outside an obstetric unit and providing a service that facilitates choice of birth setting that includes birth at home, in a freestanding midwifery unit, and alongside midwifery unit and birth in an obstetric unit. What is the impact on satisfaction for women and midwives?**

*Population:* Maternity services providing intrapartum care. Women at low risk of developing intrapartum complications, midwives and other health care professionals involved in providing intrapartum care.

*Intervention:* Advising women to give birth outside an obstetric unit and providing a choice of birth at home, in a freestanding midwifery unit, an alongside midwifery unit or an obstetric unit  
*Comparison:* previous model of service provision and uptake including the previous distribution of births between home, freestanding midwifery unit, alongside midwifery unit and obstetric unit.

*Outcomes:* Resource use, identified training needs and satisfaction for women and midwives

*Study design:* economic and service evaluation with a qualitative component

*Why this is important?*

Until recently, most births have taken place in an obstetric unit. The evidence relating to safety of birth outside an obstetric unit either at home or in a midwifery-led unit has resulted in a recommendation that low risk women should give birth outside an obstetric unit. This change should lead to a change in service provision by commissioners in order to meet the altered demand. There is also likely to be a change in working practices for midwives, who are more likely to support out of hospital births, and as a result, births that take place within an obstetric unit, although reduced in number, are likely to be women at higher risk of complications. The costs of these changes should be studied, along with satisfaction of both women and midwives. Midwives' training needs should be identified relating to offering choice of place of birth, as well as skills required to work outside a high-risk obstetric unit.

**2. Development and validation of a commissioning tool to enable the calculation of the effect of changes in the configuration of the provision of options for place of birth in an individual health economy, network or District.**

*Population:* a Health Economy, District or network providing maternity services for a specified population.

*Intervention:* a change in the provision of alternate places of birth – e.g. the opening of a freestanding and / or alongside midwifery unit or the development of a home birth team

*Comparator:* current service configuration/provision

*Outcome:* The costs of provision of maternity services (antenatal care through to postnatal care) for all women giving birth within that maternity service, taking into account alterations in service provision; number of women choosing each birth setting and actual place of birth including transfer rates; rates of normal births, and intervention rates such as emergency caesarean section; rates of maternal and neonatal morbidity and associated hospital admissions.

*Study design:* service evaluation based on observational data.

*Why this is important?*

The current model of assessing costs associated with place of birth is based on the alterations in intervention rates (predominantly caesarean section) by increasing the number of births outside an obstetric unit. However, releasing those potential savings may be difficult because of the number of fixed costs associated with the obstetric unit. Developing new midwifery units is seen to add costs if corresponding savings are not made in the obstetric unit. Initial capital costs of opening a freestanding midwifery unit, as well as different staffing requirements; more senior midwives may be needed compared to alongside midwifery units or obstetric units; will have an impact on the cost-effectiveness of introducing a new service.

It is also important to take into account all uses of an alternative birth setting in terms of antenatal and postnatal care and consider costs to the maternity service as a whole. Commissioners need an economic model that allows them to understand the effect of changes in service provision and how that can alter or not alter the fixed and revenue costs associated with the provision of maternity care for women at high risk of developing complications when developing the provision of services to support birth outside an obstetric unit.

**3. What are the key components in midwifery-led settings that result in lower intervention rates?**

*Population:* Women at low risk of developing intrapartum complications.

*Intervention:* Intrapartum care planned for a midwifery-led birth setting (home, freestanding midwifery unit or freestanding midwifery unit)

*Comparison:* Intrapartum care planned for an obstetric unit

*Primary outcomes:* Pain relief; coping strategies offered and used; use of water; 1 to 1 care; type of recordkeeping used; involvement of partner in birth and postnatal period. Philosophy and culture of organisation and in birth setting.

*Secondary outcomes:* midwives experiences of job satisfaction within midwifery-led environments.

*Partners experiences of care given. Women and partners' views of environment.*

*Study design:* Observational study with qualitative component

*Why this is important?*

The lower intervention rates observed in midwifery-led settings has been demonstrated consistently across a number of studies. Thus far, however, it has not been conclusively demonstrated what it is about care delivered in these settings that makes this difference. A number of components of care might play a part including one-to-one midwifery care, continuity of carer, intermittent rather than continuous fetal monitoring or a culture that sees labour and birth as a natural process to be worked with rather than 'treated' or 'managed'. A better understanding of what contributes to this observed difference could help improve outcomes and women's experience of care still further, hopefully across all settings.

### **Latent phase of labour**

- 4. What is the effectiveness of a care package which includes telephone triage by a midwife plus antenatal education about what to expect during the latent phase and first stage of labour and pain-relieving techniques that can be used during the latent phase before midwifery care begins. Compared to a care package of standard care, how satisfied are women with each package of care, and what is the cost effectiveness of each package of care?**

*Population:* nulliparous and multiparous women at low risk of intrapartum complications

*Intervention:* care package including telephone triage by a midwife, plus antenatal education about what to expect during the latent phase and first stage of labour and pain-relieving techniques for use in the latent phase.

*Comparator:* standard care

*Primary outcome:* child health/development outcome at 2 and 5 years

*Secondary outcomes:* mode of birth, transfer to obstetric care, maternal and neonatal morbidity and women's satisfaction with labour and birth experience

*Study design:* randomised controlled trial or prospective observational study

*Why this is important?*

Women in the latent first stage of labour frequently attend hospital for assessment and are advised to return home because they are in the latent stage. Provision of a care package which reduces the number of women attending hospital in the early stages of labour is reported to improve satisfaction as well as outcomes for these women. An analysis is necessary in order to establish the most effective and cost-effective care package with the optimal satisfaction for women receiving the care package. A sub-group analysis to further investigate any difference in outcomes when the care is delivered by a familiar or unfamiliar midwife would also be of value.

- 5. What is the effectiveness of an initial face-to-face assessment by a midwife of women who report being in labour being carried out in the woman's home, compared to the assessment being carried out in the planned place of birth (where this is not at home), and how satisfied are women with the assessment?**

*Population:* nulliparous and multiparous women at low risk of intrapartum complications planning birth in a midwifery unit or an obstetric unit.

*Intervention:* first assessment of women who report being in labour, carried out at the woman's home  
*Comparison:* first assessment of women who report being in labour, carried out at a birth setting other than the woman's home (the woman's planned place of birth)  
*Outcomes:* planned and actual birth location, mode of birth, transfer to obstetric care, maternal and neonatal morbidity, women's satisfaction with the experience of assessment (one month after the birth, and one year after the birth.)  
*Study design:* Randomised controlled trial or prospective observational study

*Why this is important?*

Women in the latent stage of labour frequently attend hospital for assessment and are advised to return home because they are in the latent stage. Provision of a care package which reduces the number of women attending hospital in the early stages of labour is reported to improve satisfaction as well as outcomes for these women. An initial home assessment by a midwife is an important component of care provision that may contribute significantly to these improved outcomes, and thus warrants evaluation as a stand-alone intervention.

**Monitoring during labour**

**6. A randomised controlled trial of intermittent auscultation vs. continuous cardiotocography in otherwise low risk pregnancies complicated by meconium stained liquor**

Population: women assessed at the onset of labour as being at low risk of developing intrapartum complications who go on to have meconium stained liquor

Intervention: continuous cardiotocography

Comparator: intermittent auscultation

Primary outcome: neonatal mortality or developmental delay at 2 years

Secondary outcomes: caesarean section, woman's experience of labour; neonatal unit admission, requirement for respiratory ventilation, neonatal encephalopathy

Study design: Randomised controlled trial

*Why this is important?*

Women at low risk of intrapartum complications have lower rates of intervention (e.g. caesarean section) and no difference in neonatal outcomes when the fetus is monitored using intermittent auscultation rather than continuous cardiotocography. The studies that demonstrated this involved conversion from intermittent auscultation to cardiotocography if a fetal heart rate abnormality was detected on intermittent auscultation or if risk factors developed such as meconium stained liquor. However, it may be that in the presence of meconium-stained liquor with no other concerns intermittent auscultation would have been as effective from the fetal point of view but with the benefit of a reduced risk of intervention. A randomised controlled trial with sufficient power to consider long term neonatal outcomes is required to determine whether intermittent auscultation could be used to reduce intervention in labour whilst maintaining the safety for the fetus where there is meconium-stained liquor.

**7. In women that require continuous electronic fetal monitoring during labour, what is the effectiveness of cardiotocography using telemetry compared with conventional cardiotocography?**

Population: all women requiring continuous electronic fetal monitoring during labour

Intervention: continuous cardiotocography using telemetry

Comparator: conventional cardiotocography

Primary Outcome: neonatal outcomes (including long term outcomes at 2 years)

Secondary outcomes: length of labour, use of pain relief, women's experiences.  
Study design: observational study

*Why this is important?*

The use of telemetry to monitor the fetal heart rate and uterine contractions in labour has the potential to enable women to be more mobile and active than with conventional monitoring. There is very little recent research evidence exploring whether the use of telemetry in labour to continuously monitor the fetal heart rate and uterine contractions has any effect on neonatal outcomes, length of labour or use of pain relief. Women's experiences of telemetry also remain an area for investigation. Both quantitative and qualitative aspects of telemetry use in labour should be explored and the cost effectiveness of telemetry cardiotocography evaluated.

**Third stage of labour**

**8. What are the risks and benefits for women and babies of physiological management of the third stage of labour compared to 'modified' active management for women giving birth outside an obstetric unit?**

Population: Women in labour at low risk of developing intrapartum complications giving birth outside an obstetric unit

Intervention: Physiological management of the third stage of labour

Comparator: Active management of the third stage of labour

Primary outcomes: Woman's haemoglobin levels, health and wellbeing of baby at 2 years

Secondary outcomes: Need for blood transfusion, length of time from birth of baby to birth of placenta, retained placenta, postpartum haemorrhage, neonatal jaundice, breastfeeding rates, women's experiences, midwives experiences.

Study design: randomised controlled trial or prospective observational study

Secondary analyses might include: birth of placenta in water, squatting, use of birthing stool, kneeling, semi-recumbent, lying.

In a 2x2x2 factorial design in physiological management have 2 sub-groups one for leaving cord intact until birth of placenta and one for cutting cord after pulsation of the cord stops. Divide these sub groups into diagnosing retained placenta at 30 minutes and 60 minutes, giving IM syntocinon.

*Why this is important?*

Whilst the risks associated with physiological management of the third stage of labour have been reported there has been little focus of the potential benefits and so to date the balance of risks and benefits has not been fully established. Management of the third stage involves a number of different factors and the timing of these may influence the ultimate outcomes for the woman and her baby. These could be studied at the same time using a nested factorial study design as described above.

**9. What is the optimum dosing regimen of oxytocin when used as an intravenous infusion to manage primary post-partum haemorrhage (PPH) in women after vaginal birth?**

Population: women with a singleton pregnancy at term with a low risk of developing intrapartum complications experiencing a primary postpartum haemorrhage

Intervention: reduced dosing regimens of oxytocin e.g. using a 20 iu infusion over a four hour compared to 40 iu over the same period

Comparator: commonly used standard regimens (e.g. 40 i.u. infused over 4 hours)

Outcomes: need for blood transfusion, need for further uterotonics, need for other further treatment.

Study design: randomised controlled trial

### *Why this is important?*

Post-partum haemorrhage is the commonest cause of maternal morbidity in the UK and remains a significant cause of maternal mortality. Uterotonic agents, in particular oxytocin, are an intrinsic part of the management of most causes of postpartum haemorrhage. A wide variety (total dose and infusion rate) of intravenous regimens are used with a very limited evidence base. Oxytocin has important cardiovascular effects when given as an intravenous bolus and also has a mild anti-diuretic effect which can lead to hyponatremia when given in larger doses. Recently some evidence has emerged that lower doses of oxytocin may be as effective as standard doses. Randomised controlled trials are required to assess whether reduced dosing regimens compared with commonly used standard regimens are effective in the management of postpartum haemorrhage.

### **10. What is the most effective additional uterotonic agent used in conjunction with oxytocin to manage postpartum haemorrhage in women after vaginal delivery where oxytocin alone has failed to stop the bleeding?**

Population: women with a singleton pregnancy at term experiencing a primary postpartum haemorrhage.

Intervention: Additional uterotonic agent used after oxytocin where further medical treatment is needed e.g. carboprost, misoprostol

Comparison: alternative additional uterotonic

Outcomes: need for blood transfusion, need for further uterotonics, need for other further treatment.

Study design: Cross-over randomised controlled trial

### *Why this is important?*

Post-partum haemorrhage is the commonest cause of maternal morbidity in the UK and remains an important cause of maternal mortality. Uterine atony is the most significant cause of PPH and uterotonic agents are the first line of treatment. Oxytocin is usually the initial drug with the addition of a variety of other agents when escalation treatment is required. However the most effective combination of drugs has not been elucidated. Randomised cross-over trials are required to assess the most effective combination of drugs (oxytocin plus carboprost versus oxytocin plus misoprostol) to manage postpartum haemorrhage following vaginal delivery, in terms of requirement for additional uterotonics, need for further treatment and blood transfusion.

## **Remaining research recommendations from 2007 Intrapartum Care Guideline<sup>7</sup>**

### **1. Care throughout labour**

- a. Studies should evaluate the impact of a standardised training programme for maternity care support workers in the intrapartum period. Outcomes should include: maternal and neonatal mortality, adverse outcomes, long-term outcomes, women's satisfaction and costs as outcomes.
- b. Studies are needed that investigate the components affecting a woman's satisfaction with her birth experience, including her emotional and psychological wellbeing. A robust method of assessing a woman's satisfaction is also needed.
- c. There should be studies carried out to investigate the effects of caseload midwifery (defined as one midwife providing care and taking responsibility for a group of women from the antenatal, through intrapartum to the postnatal period) on women, babies and healthcare professionals, including cost-effectiveness and long-term outcomes.

- d. Use of either H2-receptor antagonists or antacids in labour should be evaluated for women who have or develop risk factors, who have opioids or who may need a general anaesthetic.

**2. Coping with pain in labour: non-epidural**

- a. A combination of randomised trials and qualitative research should investigate the effect of a package of care, involving the use of non-invasive techniques throughout labour and birth, on women's birth experiences. This should include studies that explore which aspects of the package of care affect both women's experience and maternal and neonatal outcomes.
- b. An RCT to compare the effect of pethidine [IM] and diamorphine [IM], and to explore optimum doses. Outcomes should encompass analgesic effect, and short- and long-term neonatal outcomes (including breastfeeding).

**3. Pain relief in labour: regional analgesia**

- a. There is a need for studies:
  - i. to optimise the management of labour in women with epidurals to reduce the excess instrumental birth rate, including the routine use of oxytocin in the second stage, in nulliparous women with a low-dose epidural
  - ii. to explore the optimum duration of the passive and active second stage of labour, for women with an epidural
  - iii. to assess the impact of low-dose epidurals with opioids (fentanyl) on neonatal outcomes, including resuscitation and breastfeeding.

**4. Normal labour: First stage of labour**

- a. A prospective cohort study on impact of length of labour on outcomes is needed.
- b. Studies looking at the efficacy of the use of the partogram, and the comparison of a partogram with an action line and one without, should be carried out.
- c. Further studies are required to investigate methods of assessing pain relief, attitudes to pain, effects of labour pain, and long-term outcomes.
- d. The start dose of oxytocin for augmentation, and the increments, should be the subject of further research.
- e. Studies are needed that investigate the effectiveness of any strategies to increase spontaneous vaginal birth where diagnosis is made of delay in the first stage of labour.

**5. Normal labour: Second stage of labour**

- a. Studies are needed to investigate strategies to reduce the chance of having perineal trauma.

**6. Normal labour: third stage**

Studies should be carried out to investigate the timing of cord clamping and balance of risk/benefit to both mother and baby.

**7. Normal labour: care of the baby and woman immediately after birth**

Research is needed into the optimum analgesia required during perineal repair.

#### **8. Prelabour rupture of membrane at term**

- a. A randomised controlled trial to evaluate the effect of routine administration of prophylactic antibiotics on neonatal infection, in women with term prelabour rupture of membranes, over 24 hours.
- b. The investigation and management of babies born with risk factors for infection requires further evaluation.

#### **9. Meconium-stained liquor**

There is a need for development of a standardised scoring system for degree of meconium staining and association with neonatal outcomes.

#### **10. Complicated labour: monitoring babies in labour**

- a. A further randomised controlled trial of ST segment analysis should be undertaken.
- b. Further study investigating computerised expert systems should be undertaken.

#### **11. Complicated labour: first stage**

The start dose of oxytocin for augmentation, and the increments, should be the subject of further research.

#### **12. Complicated labour: third stage**

- a. Further randomised controlled trials investigating the effectiveness of the use of nitroglycerine in the treatment of retained placenta should be conducted.
- b. Further research should identify the best drug combinations, route and dose for the treatment of postpartum haemorrhage.

### **Remaining research recommendations from Caesarean Section Guideline**

#### **1. Breech presentation**

Further research is needed to determine the effect of caesarean section compared with vaginal birth for women with:

- preterm breech
- a breech presentation that is diagnosed in the second
- stage of labour

#### **2. Multiple pregnancy**

RCTs are needed to evaluate the benefits and risks to mothers and babies of CS for delivery of twin and triplet pregnancies.

#### **3. Preterm birth and CS**

RCTs are needed to evaluate the impact of CS on the benefits and risks to mothers and babies born preterm.

#### **4. Small for gestational age**

RCT evidence is needed to determine the effect of planned CS on neonatal mortality and morbidity for 'small for gestational age' babies.

#### **5. Morbidly adherent placenta**

- a. How accurate is 3D ultrasound compared with 2D ultrasound or MRI scanning for diagnosing morbidly adherent placenta?

- b. What is the effectiveness of procoagulant agents (such as recombinant factor VIIa, beriplex, tranexamic acid, fibrinogen concentrate) in reducing blood loss in women with morbidly adherent placenta?
- c. What is the effectiveness of point of care testing for haematological indices in women with an established postpartum haemorrhage and in cases of morbidly adherent placenta in reducing maternal morbidity?
- d. What is the effectiveness of the components of the package of care for morbidly adherent placenta such as imaging techniques (e.g. interventional radiology including balloon catheters), stenting of ureters, removal of the placenta, and cell salvage in reducing morbidity associated with maternal blood loss?
- e. What is the appropriate gestational age of elective birth for babies of women with a morbidly adherent placenta?
- f. What is the effectiveness of performing an elective hysterectomy to reduce morbidity associated with blood loss in women with morbidly adherent placenta?

#### **6. Mother-to-child transmission of maternal infections**

- a. RCTs are needed to evaluate the effect of planned CS in addition to immunoglobulin and vaccination on MTCT of hepatitis B.
- b. RCTs are needed to determine whether planned CS should be offered to prevent MTCT of HSV to women with recurrence of HSV at birth and in women in whom the primary HSV infection occurs in the first trimester of pregnancy.

#### **7. Place of birth**

- a. RCTs comparing planned birth in a stand-alone birthing centre to birth in conventional maternity facilities or midwifery led units.
- b. Qualitative research is needed to explore women's opinions on place of birth and the impact of place of birth on their birth experiences.
- c. Further RCTs are needed to determine the effect of 'delayed admission in labour' on the likelihood of CS.

#### **8. Factors reducing the likelihood of CS**

RCT evidence is needed to determine the impact of partograms based on different curves of labour on CS rates and morbidity outcomes.

#### **9. No influence on likelihood of CS**

RCT evidence is required to evaluate the effect of parenteral analgesia (intramuscular and intravenous morphine based analgesia) used during childbirth on the likelihood of CS.

RCTs are needed to establish the safety and efficacy of complementary therapies used during labour.

#### **10. 'Failure to progress' in labour and CS**

- a. More RCTs are required to determine the effect of oxytocin augmentation as single interventions or as part of a package of interventions (such as 'active management of labour') on the likelihood of CS and other outcomes including women's satisfaction with care.

- b. Further research on the short and longer term health impacts of CS during the second stage compared to operative vaginal delivery are needed.

### **11. Eating during labour**

RCTs that evaluate the effects of eating during labour compared with restricting intake on labour outcomes are needed. Cohort or case control studies on the risk factors for aspiration and other morbidities for women having CS are needed.

### **12. Surgical techniques for CS**

- a. RCTs are required to determine the effectiveness of adhesive drapes at CS in reducing blood spillage and cross infection and improving safety for staff in the operating room.
- b. RCTs are needed to evaluate the effectiveness of incisions made with diathermy compared with surgical knife in terms of operating time, wound infection, wound tensile strength, cosmetic appearance and women's satisfaction with the experience.
- c. RCTs are needed to determine the effect of delayed cord clamping on neonatal outcomes including transient tachypnoea of the newborn and risk of maternal fetal transfusion in rhesus negative women for term and preterm births.
- d. RCTs are required to determine the effectiveness of mass closure compared to layered closure of the abdominal wall incision at CS particularly for transverse abdominal incisions.
- e. Research is required to assess the effect of the various surgical techniques for CS on future surgery such as repeat CS and the incidence of complications during future surgery such as hysterectomy and urogynaecological procedures.
- f. More RCTs are needed to determine the effect of wound drainage of postoperative morbidity especially in women more at risk of this outcome such as obese women.
- g. More RCTs are needed to determine the effect of staples compared to subcuticular sutures for skin closure at CS on postoperative pain, cosmetic appearance and removal of sutures and staples.
- h. What is the most effective antibiotic to prevent maternal infectious morbidity post-CS when given prior to incision?
- i. What is the physical, psychological and social impact of maternal infectious morbidity post- CS?
- j. More evaluation of interventions such as seeing baby born via a lowered screen; music playing in theatre; silence in theatre so mother's voice is the first baby hears and lowering the lights in theatre during CS are needed.

### **13. Neonatal encephalopathy and cerebral palsy**

Further evaluation of the long and short term risks and benefits of CS compared with vaginal birth for babies is required.

#### **14. Thermal care for babies born by CS**

Research is required to establish the thermal care requirements for babies born by CS.

#### **15. Pain management after CS**

Further research is needed to determine the effect of wound infiltration with local anaesthetic at CS on the need for post-CS analgesia.

#### **16. Respiratory physiotherapy after CS**

Research is needed to establish the effect of non-respiratory physiotherapy for women following CS on post-CS recovery.

#### **17. Debriefing for women after CS**

More RCT evidence is required to determine the effect of midwifery-led debriefing following CS.

#### **18. Pregnancy and childbirth after CS**

- a. A comparison of the long term psychological and physical outcomes between women who have chosen and/or been advised towards a VBAC or a planned repeat CS.
- b. An evaluation of the effectiveness of continuity of carer on the proportion of women planning and achieving a VBAC, and the short and long term psychological and physical outcomes of women following a planned VBAC.

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