

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

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, the rest of the research recommendations are in the order they are in the relevant Guideline and not in order of importance.

This is not intended to be an exhaustive list and we would welcome good quality studies answering clinically relevant questions outside these.

### **Key priorities for research from 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 PGE2**

Research is needed to assess the effectiveness, safety, maternal satisfaction and acceptability of different regimens of vaginal PGE2, 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 PGE2, stratified by: clinical indications; cervical and membrane status; parity; and previous caesarean section
- different management policies for failed induction of labour with vaginal PGE2 (additional PGE2, 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 PGE2, 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 PGE2 fails to induce labour in some women.



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

### **1. Planning place of birth**

The best possible studies comparing different places of birth should be undertaken in the UK. Prospective research to assess clinical outcomes, including safety, for all places of birth should be undertaken, as well as qualitative data collection to assess women's experiences of birth.

### **2. Wellbeing of women**

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.

### **3. Delay in the first stage of labour**

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.

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

### **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?

### **Maternal request for CS**

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

### **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?
- 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.
- c) Repeat of the National Caesarean Section Sentinel Audit



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

### **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 to 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 Intrapartum Care**

### **1. Planning place of birth**

There is a need to establish a single generic health-related quality of life index value for the multiattribute perinatal and maternal outcomes of intrapartum care.

### **2. 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) 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.

c) 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.

d) Hygiene rituals around the time of vaginal examination and birth would benefit from further research.

### **3. 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).

### **4. Pain relief in labour: regional analgesia**

There is a need for studies:

a) 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

b) to explore the optimum duration of the passive and active second stage of labour, for women with an epidural

c) to assess the impact of low-dose epidurals with opioids (fentanyl) on neonatal outcomes, including resuscitation and breastfeeding.



**5. Normal labour: first stage**

- a) A prospective cohort study on impact of length of labour on outcomes is needed.
- b) Studies to examine the clinical efficacy of the initial contact observations/examination.
- c) 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.
- d) Further studies are required to investigate methods of assessing pain relief, attitudes to pain, effects of labour pain, and long-term outcomes.

**6. Normal labour: second stage**

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

**7. 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.

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

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

**9. 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.

**10. Meconium-stained liquor**

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

**11. 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.

**12. Complicated labour: first stage**

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

**13. 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 DRAFT Caesarean Section Guideline**

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

Further evaluation is needed to determine the impact of demographic and clinical factors (such as ethnic group, increase in body mass index) and attitudinal factors on CS rates. 4.2

### **2. 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

### **3. Multiple pregnancy**

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

### **4. Preterm birth and CS**

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

### **5. 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.

### **6. 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?

### **7. 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.

#### **8. Maternal request for CS**

- a) Medium to long term quality of life study comparing psychological and physical outcomes in women who have had a requested and given birth by CS compared with women who plan a vaginal birth.
- b) Qualitative and quantitative research should be carried out to look at the reasons that lead to pregnant women's request for CS
- c) The effect of counselling and other interventions such as second opinion and provision of support on the likelihood of CS for women who express a preference for CS need further evaluation.

#### **9. 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.

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

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

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

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

#### **12. '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.

#### **13. 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.



#### **14. 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.

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.

#### **15. 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.

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

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

#### **17. 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.

#### **18. Respiratory physiotherapy after CS**

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



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

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

### **20. 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.

### **References**

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<sup>1</sup> National Institute for Health and Clinical Excellence (2008) Induction of Labour.CG70.  
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<sup>2</sup> National Institute for Health and Clinical Excellence (2007) Intrapartum Care.CG55.  
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<sup>3</sup> National Institute for Health and Clinical Excellence (2011) Caesarean Section (update).  
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