

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name: **Insertion of a double balloon catheter for induction of labour in pregnant women without previous caesarean section (1278/1)**

Name of Specialist Advisor: **Prof Gordon Smith**

Specialist Society: **Royal College of Obstetricians and Gynaecologists**

Please complete and return to: azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

1 Do you have adequate knowledge of this procedure to provide advice?

Yes.

No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

Yes.

No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

Yes.

Is there any kind of inter-specialty controversy over the procedure?

No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

The next two questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure please answer question 2.2.2.

2.2.1 If you are in a specialty which does this procedure, please indicate your experience with it:

- I have never performed this procedure.
- I have performed this procedure at least once.
- I perform this procedure regularly.

Comments:

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

- I have never taken part in the selection or referral of a patient for this procedure.
- I have taken part in patient selection or referred a patient for this procedure at least once.
- I take part in patient selection or refer patients for this procedure regularly.

Comments:

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- I have undertaken bibliographic research on this procedure.
- I have undertaken research on this procedure in laboratory settings (e.g. device-related research).
- I have undertaken clinical research on this procedure involving patients or healthy volunteers.
- I have had no involvement in research on this procedure.
- Other (please comment)

Comments:

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

- Established practice and no longer new.
- A minor variation on an existing procedure, which is unlikely to alter that procedure's safety and efficacy.
- Definitely novel and of uncertain safety and efficacy.
- The first in a new class of procedure.

Comments:

3.2 What would be the comparator (standard practice) to this procedure?

Use of prostaglandin priming (PGE2 or misoprostol)

3.3 Please estimate the proportion of doctors in your specialty who are performing this procedure (choose one):

- More than 50% of specialists engaged in this area of work.
- 10% to 50% of specialists engaged in this area of work.
- Fewer than 10% of specialists engaged in this area of work.
- Cannot give an estimate.

Comments:

Do you mean performing induction of labour? If so >50%
Do you mean using a double balloon. If so <10%

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Theoretical adverse events

2. Anecdotal adverse events (known from experience)

Failed induction of labour

Prolonged interval from commencement of induction to delivery

3. Adverse events reported in the literature (if possible please cite literature)

4.2 What are the key efficacy outcomes for this procedure?

Proportion of women achieving vaginal birth

Interval from commencement of induction to delivery

**4.3 Are there uncertainties or concerns about the efficacy of this procedure?
If so, what are they?**

Not clear whether it works better than prostaglandins

4.4 What training and facilities are required to undertake this procedure safely?

Should be within the competence of any doctor working on a Delivery Unit. However, in many units, midwives might administer prostaglandins, and they are less used to using a speculum. So there may be a requirement for midwife training if the procedure was introduced.

4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

Don't know.

- 4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, e.g. PUBMED? (This can include your own work). If yes, please list.**

Not to my knowledge

- 4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?**

Not to my knowledge

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

- 5.1 Outcome measures of benefit (including commonly used clinical outcomes – both short and long-term; and quality of life measures):**

Vaginal birth

Interval from onset of induction to delivery

Proportion women delivered within 48 hours

Maternal satisfaction

Reduced requirement for analgesia

Lack of hyperstimulation (complication of prostaglandins)

Neonatal morbidity (fetal distress could be less common than with prostaglandins)

Postpartum haemorrhage

Need for blood transfusion

Use of procedure as outpatient (women generally admitted with PGs – this method might be suitable for out patient induction – I don't know)

Length of stay

- 5.2 Adverse outcomes (including potential early and late complications):**

Cervical tear

Cord prolapse

Maternal pain and discomfort

6 Trajectory of the procedure

6.1 In your opinion, what is the likely speed of diffusion of this procedure?

Depends on whether strongly positive trial. If a trial showed superiority to PGs, then it could be quickly taken up.

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

- Most or all district general hospitals.
- A minority of hospitals, but at least 10 in the UK.
- Fewer than 10 specialist centres in the UK.
- Cannot predict at present.

Comments:

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

- Major.
- Moderate.
- Minor.

Comments:

This would particularly be the case if it could be safely used for outpatient cervical priming.

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

8 Data protection and conflicts of interest

8.1 Data protection statement

The Institute is committed to transparency. As part of this commitment your name and specialist society will be placed in the public domain, in future publications and on our website (www.nice.org.uk) and therefore viewable worldwide. This information may be passed to third parties connected with the work on interventional procedures.

A copy of the completed Specialist Adviser advice will be sent to the Specialist Society who nominated the Specialist Adviser.

Specialist Advisers should be aware that full implementation of the Freedom of Information Act 2000 may oblige us to release Specialist Advice from 2005. The Freedom of Information Act 2000 favours the disclosure of information however requests will be considered on a case by case basis. If information is made available, personal information will be removed in accordance with the Data Protection Act 1998. In light of this please ensure that you have not named or identified individuals in your comments.

8.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Please state any potential conflicts of interest, or any involvements in disputes or complaints, relevant to this procedure. Please use the “Conflicts of Interest for Specialist Advisers” policy (attached) as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

Do you or a member of your family¹ have a **personal pecuniary** interest?
The main examples are as follows:

¹ ‘Family members’ refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

- Consultancies or directorships** attracting regular or occasional payments in cash or kind YES
 NO
- Fee-paid work** – any work commissioned by the healthcare industry – **this includes income earned in the course of private practice** YES
 NO
- Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry YES
 NO
- Expenses and hospitality** – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences YES
 NO
- Investments** – any funds which include investments in the healthcare industry YES
 NO
- Do you have a **personal non-pecuniary** interest – eg have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic? YES
 NO
- Do you have a **non-personal** interest? The main examples are as follows:
- Fellowships** endowed by the healthcare industry YES
 NO
- Support by the healthcare industry or NICE** that benefits his/her position or department, eg grants, sponsorship of posts YES
 NO

If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.

Comments:

I have commercial interests, but they are not relevant for this procedure. But for full disclosure they are listed here:

GS receives/has received research support from GE (supply of two diagnostic ultrasound systems) and Roche (supply of equipment and reagents for biomarker studies). GS has been paid to attend advisory boards by GSK and Roche. GS has acted as a paid consultant to GSK. GS has received support to attend a scientific meeting from Chiesi. GS is named as co-inventor in a patent submitted by Cambridge Enterprise (UK) in the national phase, for a novel treatment for preterm infants (US61/253936). GS is named inventor in a patent submitted by GSK (UK), for novel application of an existing GSK compound for the prevention of preterm birth (PCT/EP2014/062602).

Thank you very much for your help.

**Professor Bruce Campbell, Chairman,
Interventional Procedures Advisory
Committee**

**Professor Carole Longson, Director,
Centre for Health Technology
Evaluation.**

February 2010

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Conflicts of Interest for Specialist Advisers

- 1 **Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee**
 - 1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.
 - 1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.
- 2 **Personal pecuniary interests**
 - 2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**' or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples are as follows.
 - 2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
 - 2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
 - 2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.
 - 2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
 - 2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
 - 2.2 No personal interest exists in the case of:
 - 2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where

the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 **Personal family interest**

3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.

3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.

3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).

3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)

3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

3.2 No personal family interest exists in the case of:

3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

3.2.2 accrued pension rights from earlier employment in the healthcare industry.

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

- 4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration
- 4.4 other reputational risks in relation to an intervention under review.

5 Non-personal interests

5.1 A non-personal interest involves payment that benefits a department or organisation for which a Specialist Advisor is responsible, but that is not received by the Specialist Advisor personally. This may either relate to the product or service being evaluated, in which case it is regarded as '**specific,**' or to the manufacturer or owner of the product or service, but is unrelated to the matter under consideration, in which case it is regarded as '**non-specific**'. The main examples are as follows.

5.1.1 **Fellowships** – the holding of a fellowship endowed by the healthcare industry.

5.1.2 **Support by the healthcare industry or NICE** – any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:

- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name: **Insertion of a double balloon catheter for induction of labour in pregnant women without previous caesarean section (1278/1)**

Name of Specialist Advisor: **Jan Butler**

Specialist Society: **Royal College of Midwives**

Please complete and return to: azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

1 Do you have adequate knowledge of this procedure to provide advice?

X Yes.

No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

X Yes.

No. If no, please enter any other titles below.

Comments:

However, we are not currently using them in our trust

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

X Yes.

Is there any kind of inter-specialty controversy over the procedure?

No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

The next two questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure please answer question 2.2.2.

2.2.1 If you are in a specialty which does this procedure, please indicate your experience with it:

- I have never performed this procedure.
- I have performed this procedure at least once.
- I perform this procedure regularly.

Comments:

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

- I have never taken part in the selection or referral of a patient for this procedure.
- I have taken part in patient selection or referred a patient for this procedure at least once.
- I take part in patient selection or refer patients for this procedure regularly.

Comments:

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- I have undertaken bibliographic research on this procedure.
- I have undertaken research on this procedure in laboratory settings (e.g. device-related research).
- I have undertaken clinical research on this procedure involving patients or healthy volunteers.
- I have had no involvement in research on this procedure.
- Other (please comment)

Comments:

I have carried out my own literature search and review in preparation

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

- Established practice and no longer new.
- A minor variation on an existing procedure, which is unlikely to alter that procedure's safety and efficacy.
- Definitely novel and of uncertain safety and efficacy.
- The first in a new class of procedure.

Comments:

Non of the above. Cochrane review of 71 RCTs, but mostly small sample sizes.

3.2 What would be the comparator (standard practice) to this procedure?

Prostaglandins

3.3 Please estimate the proportion of doctors in your specialty who are performing this procedure (choose one):

- More than 50% of specialists engaged in this area of work.
- 10% to 50% of specialists engaged in this area of work.
- Fewer than 10% of specialists engaged in this area of work.
- X Cannot give an estimate.

Comments:

This is not currently offered as a method of IoL in our Trust.

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

Theoretical adverse events; Cochrane Review summary
Jozwiak M, Bloemenkamp KWM, Kelly AJ, Mol BWJ, Irion O, Bouvain M
Published Online:
14 March 2012

Mechanical methods of induction were developed to promote cervical ripening and the onset of labour by stretching the cervix. They are amongst the oldest methods to initiate labour. More recently pharmacological prostaglandins (vaginal and intracervical prostaglandin E2, vaginal and oral misoprostol) and oxytocin have partly replaced mechanical methods.

This review of 71 randomised controlled trials (9722 women) was to determine the effects of mechanical methods for cervical ripening or induction of labour in comparison with no treatment, prostaglandins and oxytocin for women in the third trimester of pregnancy.

The review includes 71 randomised controlled trials (total of 9722 women), ranging from 39 to 588 women per study. Most studies reported on caesarean section; all other outcomes are based on substantially fewer women. Mechanical methods were as effective as prostaglandins in achieving delivery within 24 hours of the start of the intervention, with fewer episodes of excessive uterine contractions. The risk of caesarean section did not differ. Few studies addressed the issue of infection, which appeared not to be higher when using mechanical methods. Thus mechanical methods can be considered to have less side effects compared with prostaglandins. The one study that reported on maternal discomfort showed more discomfort during ripening with prostaglandins compared with Foley catheter insertion, and with double balloon devices compared with Foley catheters. This outcome may influence the choice of method and is an important issue to be addressed in future studies. Mechanical methods were more effective than induction with oxytocin. Serious neonatal and maternal ill effects were not often reported and did not differ between the interventions.

1. Anecdotal adverse events (known from experience)

none

2. Adverse events reported in the literature (if possible please cite literature)

Cochrane review 2012 A/A

4.2 What are the key efficacy outcomes for this procedure?

A/A

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

A/A

4.4 What training and facilities are required to undertake this procedure safely?

A/A

4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

Not that I can find

4.6 Are you aware of any abstracts that have been *recently* presented/published on this procedure that may not be listed in a standard literature search, e.g. PUBMED? (This can include your own work). If yes, please list.

A/A

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

Variations in usage in developed countries where IoL accounts for approx. 25% of all deliveries. In developing countries mechanical methods of induction of labour are among the oldest and most important approaches to induction of labour.

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

Unable to answer

5.1 Outcome measures of benefit (including commonly used clinical outcomes – both short and long-term; and quality of life measures):

Induction of labour using mechanical methods results in similar caesarean section rates as prostaglandins, for a lower risk of hyperstimulation. Mechanical methods do not increase the overall number of women not delivered within 24 hours, however the proportion of multiparous women who did not achieve vaginal delivery within 24 hours was higher when compared with vaginal PGE2. Compared with oxytocin, mechanical methods reduce the risk of caesarean section.

Health services should implement a strategy to improve the quality of care for pregnant women undergoing induction of labour, including early detection and appropriate management of complications

5.2 Adverse outcomes (including potential early and late complications):

A/A

6 Trajectory of the procedure

6.1 In your opinion, what is the likely speed of diffusion of this procedure?

Further studies on mechanical methods involving large sample sizes should be considered as a matter of urgency to obtain more robust evidence. A comparative study of balloon with a placebo is recommended to confirm the recommendation of IoL with balloon catheters.

Cost effectiveness analytical methods comparing mechanical methods with prostaglandins for cervical ripening is another area of research to be undertaken.

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

Most or all district general hospitals.

A minority of hospitals, but at least 10 in the UK.

Fewer than 10 specialist centres in the UK.

Cannot predict at present.

Comments:

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

Major.

Moderate. Potentially

Minor.

Comments:

Although difficult to quantify without robust research data.

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7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

8 Data protection and conflicts of interest

8.1 Data protection statement

The Institute is committed to transparency. As part of this commitment your name and specialist society will be placed in the public domain, in future publications and on our website (www.nice.org.uk) and therefore viewable worldwide. This information may be passed to third parties connected with the work on interventional procedures.

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Do you or a member of your family¹ have a **personal pecuniary** interest?
The main examples are as follows:

¹ ‘Family members’ refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

Consultancies or directorships attracting regular or occasional payments in cash or kind YES

NO

Fee-paid work – any work commissioned by the healthcare industry – **this includes income earned in the course of private practice** YES

NO

Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry YES

NO

Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences YES

NO

Investments – any funds which include investments in the healthcare industry YES

NO

Do you have a **personal non-pecuniary** interest – eg have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic? YES

NO

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry YES

NO

Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts YES

NO

If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.

Comments:

Thank you very much for your help.

**Professor Bruce Campbell, Chairman,
Interventional Procedures Advisory
Committee**

**Professor Carole Longson, Director,
Centre for Health Technology
Evaluation.**

February 2010

Conflicts of Interest for Specialist Advisers

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 - 2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where

the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 **Personal family interest**

3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.

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4 **Personal non-pecuniary interests**

These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

- 4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration
- 4.4 other reputational risks in relation to an intervention under review.

5 Non-personal interests

5.1 A non-personal interest involves payment that benefits a department or organisation for which a Specialist Advisor is responsible, but that is not received by the Specialist Advisor personally. This may either relate to the product or service being evaluated, in which case it is regarded as '**specific,**' or to the manufacturer or owner of the product or service, but is unrelated to the matter under consideration, in which case it is regarded as '**non-specific**'. The main examples are as follows.

5.1.1 **Fellowships** – the holding of a fellowship endowed by the healthcare industry.

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- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name: **Insertion of a double balloon catheter for induction of labour in pregnant women without previous caesarean section (1278/1)**

Name of Specialist Advisor: **Dr Sikhar Sircar**

Specialist Society: **Royal College of Obstetricians and Gynaecologists**

Please complete and return to: azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

1 Do you have adequate knowledge of this procedure to provide advice?

Yes.

No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

Yes.

No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

Yes.

Is there any kind of inter-specialty controversy over the procedure?

No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

The next two questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure please answer question 2.2.2.

2.2.1 If you are in a specialty which does this procedure, please indicate your experience with it:

- I have never performed this procedure.
- I have performed this procedure at least once.
- I perform this procedure regularly.

Comments:

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

- I have never taken part in the selection or referral of a patient for this procedure.
- I have taken part in patient selection or referred a patient for this procedure at least once.
- I take part in patient selection or refer patients for this procedure regularly.

Comments:

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- I have undertaken bibliographic research on this procedure.
- I have undertaken research on this procedure in laboratory settings (e.g. device-related research).
- I have undertaken clinical research on this procedure involving patients or healthy volunteers.
- I have had no involvement in research on this procedure.
- Other (please comment)

Comments:

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

- Established practice and no longer new.
- A minor variation on an existing procedure, which is unlikely to alter that procedure's safety and efficacy.
- Definitely novel and of uncertain safety and efficacy.
- The first in a new class of procedure.

Comments:

3.2 What would be the comparator (standard practice) to this procedure?

The use of Foley catheter (Bladder catheter) for extra-amniotic insertion as an agent for IOL is well established, though not commonly performed. This is also one available option at our institution.

3.3 Please estimate the proportion of doctors in your specialty who are performing this procedure (choose one):

- More than 50% of specialists engaged in this area of work.
- 10% to 50% of specialists engaged in this area of work.
- Fewer than 10% of specialists engaged in this area of work.
- Cannot give an estimate.

Comments:

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Theoretical adverse events

Rupture of membrane, scar rupture (if used in woman with previous CS), infection, procedural pain and pain after insertion, bleeding, placental abruption

2. Anecdotal adverse events (known from experience)

3. Adverse events reported in the literature (if possible please cite literature)

Pennell, C., Henderson, J., O'Neill, M., McCleery, S., Doherty, D. and Dickinson, J. (2009), Induction of labour in nulliparous women with an unfavourable cervix: a randomised controlled trial comparing double and single balloon catheters and PGE₂ gel. *BJOG: An International Journal of Obstetrics & Gynaecology*, 116: 1443–1452. doi: 10.1111/j.1471-0528.2009.02279.x

Atad, J., Hallak, M., Ben-David, Y., Auslender, R. and Abramovici, H. (1997), Ripening and dilatation of the unfavourable cervix for induction of labour by a double balloon device: experience with 250 cases. *BJOG: An International Journal of Obstetrics & Gynaecology*, 104: 29–32. doi: 10.1111/j.1471-0528.1997.tb10644.x

4.2 What are the key efficacy outcomes for this procedure?

Change in Bishop's score to enable ARM

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

The use of mechanical device to induce labour is well established. Theoretically, the extra-amniotic production of prostaglandin will help in changing the Bishop's score to a more favourable one.

4.4 What training and facilities are required to undertake this procedure safely?

will need the experience and expertise of a Registrar (ST3 and above) in Obstetrics to do the procedure.

4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

US Trial: ClinicalTrials.gov Identifier:

NCT01091285

ClinicalTrials.gov Identifier:

NCT00690040

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, e.g. PUBMED? (This can include your own work). If yes, please list.

no

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

use in patients with previous CS

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

5.1 Outcome measures of benefit (including commonly used clinical outcomes – both short and long-term; and quality of life measures):

Change in Bishop Score
Mean duration of Induction
Induction delivery duration
Syntocinon use

5.2 Adverse outcomes (including potential early and late complications):

maternal pain
Bleeding
Hyperstimulation

Foetal outcome- apgar score, need of neonatal admission

6 Trajectory of the procedure

6.1 In your opinion, what is the likely speed of diffusion of this procedure?

One to two years if safety profile and efficacy is well established

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

- Most or all district general hospitals.
- A minority of hospitals, but at least 10 in the UK.
- Fewer than 10 specialist centres in the UK.
- Cannot predict at present.

Comments:

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

Major.

Moderate.

Minor.

Comments:

One has to justify the use of such device over Foley catheter, in view of marginal benefit is efficacy with major difference in cost

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7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

8 Data protection and conflicts of interest

8.1 Data protection statement

The Institute is committed to transparency. As part of this commitment your name and specialist society will be placed in the public domain, in future publications and on our website (www.nice.org.uk) and therefore viewable worldwide. This information may be passed to third parties connected with the work on interventional procedures.

A copy of the completed Specialist Adviser advice will be sent to the Specialist Society who nominated the Specialist Adviser.

Specialist Advisers should be aware that full implementation of the Freedom of Information Act 2000 may oblige us to release Specialist Advice from 2005. The Freedom of Information Act 2000 favours the disclosure of information however requests will be considered on a case by case basis. If information is made available, personal information will be removed in accordance with the Data Protection Act 1998. In light of this please ensure that you have not named or identified individuals in your comments.

8.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Please state any potential conflicts of interest, or any involvements in disputes or complaints, relevant to this procedure. Please use the “Conflicts of Interest for Specialist Advisers” policy (attached) as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

Do you or a member of your family¹ have a **personal pecuniary** interest?
The main examples are as follows:

¹ ‘Family members’ refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

Consultancies or directorships attracting regular or occasional payments in cash or kind YES

NO

Fee-paid work – any work commissioned by the healthcare industry – **this includes income earned in the course of private practice** YES

NO

Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry YES

NO

Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences YES

NO

Investments – any funds which include investments in the healthcare industry YES

NO

Do you have a **personal non-pecuniary** interest – eg have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic? YES

NO

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry YES

NO

Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts YES

NO

If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.

Comments:

Thank you very much for your help.

**Professor Bruce Campbell, Chairman,
Interventional Procedures Advisory
Committee**

**Professor Carole Longson, Director,
Centre for Health Technology
Evaluation.**

February 2010

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Conflicts of Interest for Specialist Advisers

- 1 **Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee**
 - 1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.
 - 1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.
- 2 **Personal pecuniary interests**
 - 2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**' or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples are as follows.
 - 2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
 - 2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
 - 2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.
 - 2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
 - 2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
 - 2.2 No personal interest exists in the case of:
 - 2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where

the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 **Personal family interest**

3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.

3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.

3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).

3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)

3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

3.2 No personal family interest exists in the case of:

3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

3.2.2 accrued pension rights from earlier employment in the healthcare industry.

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

- 4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration
- 4.4 other reputational risks in relation to an intervention under review.

5 Non-personal interests

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