NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to:azad.hussain@nice.org.uk

Procedure Name: **Laparoscopic cerclage for cervical incompetence to prevent late miscarriage or preterm birth**

Name of Specialist Advisor: Professor Andrew Shennan

Specialist Society: Royal College of Obstetricians and Gynaecologists (RCOG)

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

Yes.

1.1 **Does the title used above describe the procedure adequately?**

Yes.

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?

not sure what this means. The abdominal route works. Whether lararoscopic is as good is not known. So yes I think.

Comments:

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If youare 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 referspatients for the procedure, please answer question 2.2.2.

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

I have never done this procedure.

I have done this procedure at least once.

I do this procedure regularly.

I do the abdominal procedure weekly but not laparoscopically

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 take part in patient selection or refer patients for this procedure regularly.

Comments:

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

I have done bibliographic research on this procedure.

I have done clinical research on this procedure involving patients or healthy volunteers.

Comments:

3 **Status of the procedure**

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

Established practice and no longer new.

Comments:

Although not fully established if beneficial

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

Abdominal cerclage open procedure

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

Fewer than 10% of specialists engaged in this area of work.

Cannot give an estimate.

Comments:

4 Safety and efficacy

4.1 **What is the potential harm of the procedure?**

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

3. Theoretical adverse events

4.2 **What are the key efficacy outcomes for this procedure?**

Preterm birth or late miscarriage

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

Not sure if as good as an open procedure

4.4 **What training and facilities are needed to do this procedure safely?**

Normal gynae practice

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

Not aware

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, for example PUBMED? (This can include your own work). If yes, please list.**
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

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?**

Not sure if procedure efficacious

5Audit Criteria
Please suggest a minimum dataset of criteria by which this procedure could be audited.

Would need large numbers to show equivalence to abdo procedure. Would take a long time. Maybe not possible. Could do formal stats if required

5.1Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

Can send you our last trial outcomes (Mavric) if you wish?

5.2Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

As above

6Trajectory of the procedure

6.1In your opinion, how quickly do you think use of this procedure will spread?

Already used

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

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

Cannot predict at present.

Comments:

The same goes for abdominal procedure

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

Minor.

Comments:

I do about 40 abdominal per year but am a national r feral centre. These could all be laparoscopic if better

7Other information

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

8Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

Tick I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

I have no conflicts in regard o this subject matter

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

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

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

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 that include investments in the healthcare industry	**YES**
	NO
Do you have a **personal non-pecuniary** interest – for example 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.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mark Campbell
Acting Programme Director
Devices and Diagnostics

June 2018

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.

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Interventional Procedures Programme

Specialist Adviser questionnaire

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Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk

Procedure Name:	**Laparoscopic cerclage for cervical incompetence to prevent late miscarriage or preterm birth**
Name of Specialist Advisor:	Mr Oliver O'Donovan
Specialist Society:	British Society for Gynaecological Endoscopy

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:

BUT

1) Ideally should be referred to as "laparoscopic transabdominal cervical cerclage"
2) Many patients/clinicians prefer to use "cervical insufficiency" rather than "incompetence"- they think that it is more accurate (most women are somewhere on a continuum between a competent and incompetent) and they think it feels less like the women is being blamed for the problem.
3) Consider using "second trimester miscarriage" rather than late miscarriage.

So perhaps:

"Laparoscopic transabdominal cervical cerclage for cervical insufficiency", plus/minus "to prevent second trimester miscarriage and preterm birth".

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:

Generally patient selection and counselling is carried out jointly by the pre-term birth specialist and specialist laparoscopic gynaecologist, but the procedure is carried out by the gynaecologist.

The next 2 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 that does this procedure, please indicate your experience with it:

I have never done this procedure.

I have done this procedure at least once.

I do this procedure regularly.

Comments:

I have assisted on many more.

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 done bibliographic research on this procedure.

I have done research on this procedure in laboratory settings (e.g. device-related research).

I have done clinical research on this procedure involving patients or healthy volunteers.

I have had no involvement in research on this procedure.

Other (please comment)

Comments:

We have a paper at submission stage with the outcomes of our case series. I have presented the results locally, nationally and internationally and have done the appropriate background literature searches etc.

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 the procedure's safety and efficacy.

Definitely novel and of uncertain safety and efficacy.

The first in a new class of procedure.

Comments:

Although open transabdominal cervical cerclage is widely performed, the laparoscopic approach has not been widely practiced (despite it being first described in the '90s). This is because of the perceived difficulty and specialist skills required; although actually it is not that hard and the skills needed are possessed quite widely. Due to the difficulty in placing the cerclage laparoscopically in a gravid uterus and also the decreased risk for mother and foetus laparocsopic cerclage tends to be performed pre-conception, whereas open cerclage tends to be performed after about 12 weeks gestation. The laparoscopic approach certainly holds all the advantages of laparoscopic over open surgery (decreased pain, shorted

recovery time, better cosmetics etc) and less morbidity for the mother. Complication rates are low in the literature.

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

Open transabdominal cervical cerclage

3.3. Please estimate the proportion of doctors in your specialty who are doing 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:

There are only a handful of specialists doing this procedure regularly.

4. Safety and efficacy

4.1. What is the potential harm of the procedure?

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

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

Post-op wound infection, bladder injury and uterine fundal perforation (Laparoscopic transabdominal cerclage: Outcomes of 121 pregnancies, Ades 2018, ANZOG)

Perforation on uterus, pelvic infection, small bowel injury, perforation of bladder, laceration of uterine vein, insufficient tightening off cerclage, perioperative miscarriage (only if post-conception operation). (Systematic Review of Transabdominal Cerclage Placed via Laparoscopy for the Prevention of Preterm Birth, Mowad et al 2017/18, JMIG)

Perforation of uterus (Simplified laparoscopic cervical cerclage after failure of vaginal suture: technique and results of a consecutive series of 100 cases, Huang et al 2016, European Journal of O&G and reproductive medicine)

2. Anecdotal adverse events (known from experience)

None in our series.

3. Theoretical adverse events

All those general anaesthetic complications and complications of laparoscopic surgery (ie pain, bleeding, infection, thrombosis, damage to bladder/bowel/internal structures etc).

Damage to uterine artery; bleeding plus/minus effects on foetus in future pregnancies (growth restriction?).

Theoretical risk of mesh-type complications with Merciline tape (ie chronic pain, infected tape etc).

Damage to cervix if labours with cerclage in situ.

Need for hysterotomy/classical Caesarean section if miscarriage and unable to deliver vaginally (despite removal/cutting of suture).

Increased rate of chorioamnionitis?

4.2. What are the key efficacy outcomes for this procedure?

"Take home baby" rate
Rates of delivery at term (>37/40), after 34/40, after 28/40.
Second trimester miscarriage rate
Neonatal survival rate
Mean gestational age at delivery
Increase in gestational age at delivery
Fertility rate

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

Generally accepted to be efficacious

4.4. What training and facilities are needed to do this procedure safely?

Advanced laparoscopic skills, particularly bladder dissection and laparoscopic suturing. No special facilities

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

Not aware of any currently

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, for example PUBMED? (This can include your own work). If yes, please list.

Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

Most important are probably those listed above under complications, as well as our as yet unpublished series of 54 cases with 36 pregnancies (we would be more than happy to share results with you as already widely presented).

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

Some controversy over type of suture used (monofilament vs tape). I understand there is an ongoing trial into this in transvaginal cerclage which may effect choice.

Some controversy over indication, but generallly accepted should be offered where transvaginal cerclage has failed or is impossible (eg post cervical surgery).

5 Audit Criteria

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

"Take home baby" rate
Rates of delivery at term (>37/40) and after 34/40
Second trimester miscarriage rate
Neonatal survival rate
Procedural complication rates

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

"Take home baby"
Delivery at term (>37/40), after 34/40, after 28/40.
Avoidance of second trimester miscarriage
Neonatal survival
Mean gestational age at delivery
Increase in gestational age at delivery

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

Operative bladder injury
Operative bowel injury

Operative uterine perforation

Pelvic infection rate (up to 6 weeks post-procedure)

Peri-operative bleeding (intra-operative and up to 6 weeks post-operative)

Failure to place cerclage at operation (eg due to severe endometriosis/ adhesions secondary to trachelectomy or other surgery)

Failure of procedure (ie does not result in live birth/take home baby or prevent second trimester miscarriage or pre-term birth)

Chronic pelvic pain (with cerclage or complication of cerclage being presumed cause)

Need for potentially complex procedure to remove cerclage or deliver baby in event of miscarriage

Chorioamnionitis in pregnancy (there is theoretical increased risk)

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

Potentially pretty quickly. The favourable outcomes in this high risk group are remarkable. The skill set required is possessed by many gynaecologists and the complication rate/risk relatively low. The thing holding it back is that the numerical requirement for cases is low, so I expect it will concentrate into specialist centres where they will be done regularly. However, awareness of the procedure and referrals has increased significantly over the last few years.

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:

See 6.1

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:

We have done largest number in UK, and only do about 10 per year.

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. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

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I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

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

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

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

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 that include investments in the healthcare industry	**YES** **NO**
Do you have a **personal non-pecuniary** interest – for example 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.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mark Campbell
Acting Programme Director
Devices and Diagnostics

June 2018

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

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk

Procedure Name:	**Laparoscopic cerclage for cervical incompetence to prevent late miscarriage or preterm birth**
Name of Specialist Advisor:	Dr Nigel Simpson
Specialist Society:	Royal College of Obstetricians and Gynaecologists (RCOG)

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:

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*

☐ 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 2 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 that does this procedure, please indicate your experience with it:

x I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

In UK practice is usually undertaken by minimal access (sub)specialists (usually gynaecologists) and women are then cared for by high-risk obstetricians

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 done bibliographic research on this procedure.

☐ I have done research on this procedure in laboratory settings (e.g. device-related research).

☐ I have done clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

x Other (please comment)

Comments:

I have read the literature on this procedure

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 the procedure's safety and efficacy.

x Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

The conventional approach is by open surgery through a transverse suprapubic approach, the laparoscopic cerclage offers potential benefits in terms of a quicker recovery, accompanied by lower morbidity and comparable success rates

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

The open procedure (as above), or the Shirodkar (aka supravaginal or high vaginal approach)

3.3 Please estimate the proportion of doctors in your specialty who are doing 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.

x Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

Only a handful of centres/specialists offering this procedure in the UK

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

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

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

Since the last IP review in 2007 there have been plenty of observational cohorts reported from around the world citing the same AEs listed in that report. This applies to 4.1.2 and 4.1.3

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

4.2 What are the key efficacy outcomes for this procedure?

As in last IP review

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

None new

4.4 What training and facilities are needed to do this procedure safely?

Skills in minimal access surgery (usually confined to gynaecologists) – and the obstetric specialist experience/ability to care for the woman in the subsequent pregnancy/ies

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

No

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, for example PUBMED? (This can include your own work). If yes,

please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

No – PUBMED is replete with single centre observational studies with one systematic review (https://www.ncbi.nlm.nih.gov/pubmed/28797657) - none of these have emerged from UK-based groups since the last IP review.

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

No – I think clinicians recognise that appropriate skills in minimal access surgery are required, which I think has limited its adoption into UK obstetric practice

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). Please suggest the most appropriate method of measurement for each:

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

See 4.7…it will remain confined to one or two centres and depend on the enthusiasm of the gynaecologists who offer it.

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.

x Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

As 6.1

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.

x Minor.

Comments:
The number of women in the UK likely to require the procedure each year (typically those with probable cervical weakness leading to midtrimester loss or preterm birth <32 weeks AND who have had a failed vaginal cerclage) will be low – and the necessary skills to carry out the procedure with greatest efficacy and safety will limit the number of centres offering the procedure. I do not think the landscape within the NHS has changed much since 2007.

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?

No

8 Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

x ☐ I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

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

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐	**YES**
	x	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☐	**YES**
	x	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	x	**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**
	x	**NO**
Investments – any funds that include investments in the healthcare industry	☐	**YES**
	x	**NO**
Do you have a **personal non-pecuniary** interest – for example 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**
	x	**NO**

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

Fellowships endowed by the healthcare industry	☐	**YES**

[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).

	x	**NO**
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	☐	**YES**
	x	**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.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mark Campbell
Acting Programme Director
Devices and Diagnostics

June 2018

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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