

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name: **Angioplasty and/or stenting to treat peripheral arterial disease causing refractory erectile dysfunction (1138/1)**

Name of Specialist Advisor: **Alexander Chapman**

Specialist Society: **British Society of Interventional Radiology**

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:

Although I have not performed the procedure myself I perform Interventional procedures within the pelvis and internal iliac arteries. From my previous urology training I am familiar with Erectile dysfunction and the pt questionnaires used to assess this.

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

Yes.

No 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:

This procedure can be performed by endovascular interventionalists familiar with internal iliac artery interventions and would in the UK be predominantly Vascular Interventional radiologists and possibly interventional Cardiologists (as seen in US)

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:

N/A

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 an interest in this field due to my previous urological experience (3yrs) and career as a Vascular Interventional Radiologist and have reviewed some of the relevant medical literature.

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:

Percutaneous angioplasty and stenting is well established. The published safety data is in small studies however there are no proven safety concerns particularly. Efficacy data is limited by small patient numbers in few studies with limited follow up.

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

Medical treatment (which predominantly involves phosphodiesterase 5 inhibitors)

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:

Far less than 10%. I am not aware of any Interventional radiologists in the UK with significant experience in this field but small numbers of cases may well be being performed.

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

Puncture site complication. Haemorrhage, pseudoaneurysm formation (2%)

Vascular injury. Dissection of artery. (<5%)

Distal embolization leading to pelvic or buttock ischaemia (1%)

Vessel perforation and pelvic haematoma (<5%)

2. Anecdotal adverse events (known from experience)

As above

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

Very little complication data is evident in the literature. In the PERFECT-1 trial (wang et al) which only treated 16 patients, no adverse events were reported. Similarly the ZEN trial (Rogers et al) did not report any procedural complications in the 30 patients they stented. Although the generic complications related to percutaneous angioplasty / stent would be expected to also apply to this procedure and would include puncture related complications (haemorrhage, pseudo-aneurysm formation), vascular injury (dissection) and distal embolization) although the rates for these are low.

4.2 What are the key efficacy outcomes for this procedure?

Improvement in the patients erectile dysfunction normally assessed via the International Index of Erectile Function questionnaire (IIEF-5).

Objective measures such as Doppler ultrasound or fractional flow reserve (FFR) could be used.

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

The previously published data reports efficacy from 60-80%

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

Skills in interpretation of vascular imaging (CT angio and Doppler Ultrasound) and good experience in endovascular intervention particularly of the internal iliac arteries as well as ballon angioplasty and stent placement are required.

Modern CT equipment and fixed angiography suite with appropriate radiology, nursing and radiography staff.

Urological input and a MDT meeting to select cases is advisable.

Consultation with the Interventionalist carrier out the procedure and facilities for clinical follow up

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

There are small, feasibility and safety studies eg Zen trial and PERFECT – 1 trial but no major trials or registries that I am aware of

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?

No

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):

**IIEF-5 questionnaires
Penile Doppler ultrasound
Fractional flow reserve
Angiographic follow up (catheter / CT)**

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

**Puncture site complications
Restenosis / occlusion rates. (primary patency)
Re-intervention rate (secondary patency)
IIEF-5 questionnaire – (deterioration in erectile function)
Internal Iliac artery injury – pelvic ischaemia / buttock claudication**

6 Trajectory of the procedure

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

Interventional radiology is a small specialty with not all performing endovascular interventions. Similarly the patient selection will keep the volume of work relatively low initially until the technique has better efficacy data. As a result I suspect there will be a small numbers of centres wishing to start this under the normal Research and audit conditions contributing to a registry. Maybe 15-20 centres over next 1-2yrs with small volumes

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:

As above

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:

Only a small proportion of the large number of patients with erectile dysfunction not responsive to medical treatment will be considered. Only a small proportion of these will have the anatomical configuration of atherosclerotic disease to be considered for this procedure.

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

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: **Angioplasty and/or stenting to treat peripheral arterial disease causing refractory erectile dysfunction (1138/1)**

Name of Specialist Advisor: **Arun Sebastian**

Specialist Society: **British Society of Interventional Radiology**

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:

Though I have not yet been referred patients for this procedure, I have extensive experience in peripheral arterial angioplasty and stent insertion. I also have experience of working in the pelvic vasculature performing embolization.

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:

Interventional Radiologists have extensive experience in angioplasty. This procedure will involve angioplasty of the pudental artery.

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

None. This would be for patients who fail medical treatment and have pudental arterial stenosis.

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

Arterial dissection, end organ ischaemia/infarction.

2. Anecdotal adverse events (known from experience)

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

Recurrence

4.2 What are the key efficacy outcomes for this procedure?

Improvement in IIEF score

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

Recurrence rate. Patient selection.

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

Minimal. Would be mainly around patient selection and pre-procedure work up.

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

I am 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, e.g. PUBMED? (This can include your own work). If yes, please list.

Small studies in literature

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

I am not aware.

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):

IIEF score.

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

Target organ ischaemia, recurrence, failure.

6 Trajectory of the procedure

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

Difficult to be certain as I feel that there may be many suitable patients who are not fully assessed to determine suitability for this procedure. I donot know if this procedure is performed in significant numbers in the UK at present.

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:

Could be part of a national registry initially (like the UK-ROPE registry), limiting the number of hospitals performing the procedure initially.

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:

Difficult to be certain.

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

8.1 Data protection statement

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Consultancies or directorships attracting regular or occasional payments in cash or kind YES
 NO

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 NO

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Investments – any funds which include investments in the healthcare industry YES
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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
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February 2010

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

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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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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.

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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)

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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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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: **Angioplasty and/or stenting to treat peripheral arterial disease causing refractory erectile dysfunction (1138/1)**

Name of Specialist Advisor: **Mr Asif Muneer**

Specialist Society: **British Association of Urological Surgeons**

Please complete and return to: aazeem.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:

I would suggest adding internal iliac and internal pudendal artery stenting

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:

I do not perform this within urology

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 looked into the topic when searching for treatments for ED as part of a BMJ review

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 pharmacotherpies and penile prosthesis surgery

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

As this is a percutaneous procedure the risks are the same as for coronary stenting or vascular stenting which include bleeding from the puncture site and false aneurysm formation and pain related to the injection site. There is also the risk of AV fistual

2. Anecdotal adverse events (known from experience)

This is a procedure that I do not perform

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

The literature is based on case series which are small with very little outcome data.

4.2 What are the key efficacy outcomes for this procedure?

1. Erectile function which needs to be assessed objectively with a validated questionnaire IIEF and SHIM.
2. Long term complications related to angioplasty
3. Stent migration

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

The main concern is that this was initially developed in the 1980s and hasn't really become standard of care. The erectile dysfunction in refractory cases is normally due to a combination of smooth muscle dysfunction and endothelial dysfunction as a result of diabetes or vasculopathy at the level of the penis. Therefore in these situations it is unlikely that any procedure to increase the blood flow through angioplasty or stenting is likely to improve the erectile function. In these cases the option if pharmacotherapy fails is a penile prosthesis.

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

Interventional radiologists and cardiologists are the main clinicians who would be able to perform this

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

None at the moment

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.

The literature has a low evidence base mainly level 4 as it relates to case reports and small case series some of which are only 2-3 patients.

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

This is controversial as the patient selection needs to be strict. If there is a definite traumatic injury or stenosis then it is likely that patients will also have buttock claudication (LeRiche's) if the internal iliac artery is involved. If patients are end stage due to injury to the cavernosal nerves secondary to prostate surgery or pelvic surgery or have vasculopathy or neuropathy due to diabetes then it is unlikely that any increase in blood flow from stenting is going to reverse this.

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):

IIEF

SHIM
Any QoL patient and partner questionnaire

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

Aneurysm or AV fistula of the artery. Bleeding. No change in symptoms.

6 Trajectory of the procedure

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

This is difficult to quantify as the technique is not used widespread

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:

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

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: **Angioplasty and/or stenting to treat peripheral arterial disease causing refractory erectile dysfunction (1138/1)**

Name of Specialist Advisor: **James Lenton**

Specialist Society: **British Society of Interventional Radiology**

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:

I have limited knowledge of the procedure - I agreed to respond as one advised was supposed to have little knowledge - so I will answer the below questions

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?

Unknown

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:

Many would be able to perform but numbers are very low so only few will have done

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

Bleeding and vascular damage

Embolisation and end organ ischemia

Contrast reactions

Incidence in this indication is unknown

2. Anecdotal adverse events (known from experience)

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

4.2 What are the key efficacy outcomes for this procedure?

Resolution of erectile dysfunction

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

Erectile dysfunction is multifactorial and although the procedure may be a technical success there is a significant risk that symptoms may not improve.

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

Vascular interventional training

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

Unknown

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?

Unknown - most controversy I suspect relates to the likelihood of success

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):

Return to normal sexual function

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

Bleeding and vascular damage

Embolisation and end organ ischemia

Contrast reactions

6 Trajectory of the procedure

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

Slow

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:

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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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

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: **Angioplasty and/or stenting to treat peripheral arterial disease causing refractory erectile dysfunction (1138/1)**

Name of Specialist Advisor: **Mr Majid Shabbir**

Specialist Society: **British Association of Urological Surgeons**

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:

Procedure is best performed by interventional radiologist, but case selection will be done by urologist/ specialist andrologist. Exact role of this therapy in erectile dysfunction is not yet clearly defined or established. Who should undergo the procedure, whom should be excluded, and what constitutes a stentable lesion needs to be clarified.

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:

I am a Specialist Andrologist

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:

Angioplasty/ Stenting has well established safety and efficacy in coronary artery disease, but its role in refractory ED is still not clearly defined or established therapy

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

Safety: as compared to angioplasty/ stenting of other areas of vascular disease (such as coronary arteries). Device related or procedure related adverse outcomes

Efficacy: improvements in sexual function / IIEF /SEP 3 scores.

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

Vascular injury or event related to procedure or device, including vessel dissection/ rupture, haemorrhage, subsequent ischemia (causing glans, penile, or perineal necrosis), failure of procedure. Re stenosis/ occlusion of stent.

2. Anecdotal adverse events (known from experience)

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

None reported in limited literature

4.2 What are the key efficacy outcomes for this procedure?

Long term improvements in unassisted sexual function, as assessed by the IIEF questionnaire, and the SEP 3 questionnaire. Improved sustained response to medical therapy for erectile dysfunction (PDE5i), making patients who were refractory to treatment responsive again.

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

To date efficacy data presented is only at 6 months, and long term outcome remains uncertain

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

Technique is same as endovascular stenting elsewhere in the body, although small vessel size, and unfamiliar pelvic anatomy will make this procedure more

challenging. Should be undertaken in specialist centres with higher throughput of pelvic endovascular cases.

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

I am not aware of any current trials

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.

Babaev A, Jhaveri RR. Angiography and endovascular revascularization of pudendal artery atherosclerotic disease in patients with medically refractory erectile dysfunction. J Invasive Cardiol. 2012 May;24(5):236-40.

Rogers JH, Goldstein I, Kandzari DE, Köhler TS, Stinis CT, Wagner PJ, Popma JJ, Jaff MR, Rocha-Singh KJ. Zotarolimus-eluting peripheral stents for the treatment of erectile dysfunction in subjects with suboptimal response to phosphodiesterase-5 inhibitors. J Am Coll Cardiol. 2012 Dec 25;60(25):2618-27.

Wang TD, Lee WJ, Yang SC, Lin PC, Tai HC, Hsieh JT, Liu SP, Huang CH, Chen WJ, Chen MF. Safety and six-month durability of angioplasty for isolated penile artery stenoses in patients with erectile dysfunction: a first-in-man study. EuroIntervention. 2014 May;10(1):147-56.

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

Long term outcome remains uncertain

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):

Improvements in IIEF scores (% patients with improvement in score \geq 4)

Improvements in SEP 3 score

Improvement in un-assisted erections

Improvement in response to PDE5i

Improvements in Doppler flow results (PSV)

Angiographic appearance of stenotic region

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

restenosis rate

vascular injury or haemorrhage requiring re-intervention

clinical assessment of distal ischaemia (glans/ penile/ scrotal/ perineal)

6 Trajectory of the procedure

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

If shown to be safe and efficacious in the long term, could become more established approach for arteriogenic erectile dysfunction. Will need minimum 1 year long term follow up data in the first instance, and currently follow up data is only available at 6 months.

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:

The potential number of patients with arteriogenic ED is significant, but the number of patients with treatable/ stentable lesions may be significantly less. Only those with a clearly defined short segment of stenosis would be most suitable for this treatment, and it remains to be seen how many suitable patients there will be. In one study of 383 potential candidates, only 30 met the inclusion criteria. As experience with this technique improves, more complex cases initially considered unsuitable for therapy, may become amenable to treatment with this technique, but in the initial phase numbers will be low.

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 received payments from Lilly UK for talks/ educational events on erectile dysfunction and PDE5i, but this does not and has not related to the role of interventional procedures for refractory erectile dysfunction.

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

- 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: **Angioplasty and/or stenting to treat peripheral arterial disease causing refractory erectile dysfunction (1138/1)**

Name of Specialist Advisor: **Paul Crowe**

Specialist Society: **British Society of Interventional Radiology**

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 procedure is and will be primarily performed by interventional radiologists but could also be performed by vascular surgeons with appropriate endovascular training. In other parts of Europe interventional cardiologists may also undertake the procedure (in these countries cardiologists have traditionally undertaken intervention in organs other than the heart).

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:

I regularly perform angioplasty and stenting for a wide variety of indications but only a very small number on an ad hoc basis for this specific indication. The technical procedure and skills are however virtually identical to those used on a daily basis for multiple other angioplasty and stenting procedures in various arteries.

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:

I have selected patients as part of a multidisciplinary meeting process or have agreed to procedure following discussion with the referring clinician (usually a vascular surgeon or a urologist)

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:

The procedure is essentially the application of standard arterial angioplasty and stenting techniques to the clinical setting of erectile dysfunction secondary to narrowing of either the internal iliac artery itself or more distal narrowing of the pudendal or penile arteries. Angioplasty of the larger more proximal internal iliac artery is within the remit and day to day practice of most vascular interventional radiologists. Angioplasty and stenting of the more distal branches is more superspecialised being akin to distal below knee angioplasty and stenting into smaller arteries or even coronary stenting but appropriate expertise is already present in any large interventional radiology department supporting a vascular unit.

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

No direct interventional radiology comparator. It is possible that many cases of refractory erectile dysfunction that may benefit from the procedure are unrecognised. It must also be remembered that erectile dysfunction has multifactorial aetiology including neurological, hormonal and psychological factors and it is very difficult to standardise studies. Additionally, vascular disease of the internal iliac artery and its branches is often just a local manifestation or more generalised widespread vascular disease often with associated contributory co-morbidities such as diabetes. Surgical arterial by-pass documented in literature.

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:

* See comments in section 3.1 above. Most doctors in the speciality are performing angioplasty and stenting and many will have experience of superselectively treating smaller arteries. Some will have done so for this condition on an ad hoc basis. Very few will have a formal treatment programmes or specific treatment algorithms for refractory erectile dysfunction.

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

- The standard risks of any angiography procedure including puncture site haematoma or pseudoaneurysm formation.
- Standard risk of anaphylactic reaction to iodinated intravenous contrast used in any angiographic procedure.
- Theoretical risk of vessel rupture or occlusion on angioplasty resulting in ischaemia.
- Theoretical risk of damage or occlusion to other pelvic organs such as bladder or prostate (though such organs may also benefit from angioplasty of more proximal stenosis).

2. Anecdotal adverse events (known from experience)

None of note.

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

None of note.

4.2 What are the key efficacy outcomes for this procedure

-Immediate angiographic evidence of opening of a stenosis at the time of the procedure.

-Subjective symptomatic improvement ideally backed by some objective evidence of at least a standardised score (e.g. Erectile Function 5 score, IIEF-5)

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

- No uncertainties about the ability of an interventional radiologist to reopen and if necessary stent a narrowed artery.
- Uncertainties are more around the multifactorial aetiology of erectile dysfunction and contribution of other factors and co-morbidities.
- In the subset of patients whose erectile dysfunction is due solely or primarily to narrowing of the supplying internal iliac arteries there are no concerns.

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

- Standard interventional radiology specialist registrar training and fellowship with appropriate specialist accreditation.
- If doing superselective pudendal and penile angioplasty for the first time may elect to have a proctor or more experienced colleague in attendance.
- Standard interventional radiology or hybrid theatre facilities as should already be present in any vascular unit.

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

PERFECT-2 study (presented at EuroPCR May 2015)

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.

See 4.5

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 that I am aware of.

5 Audit Criteria

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

- Symptoms at presentation, baseline Doppler ultrasound and arteriography.
- Baseline symptom score, e.g. IIEF-5 (see 4.2)
- Documentation of procedure, materials.
- Technical success and immediate complications.
- Follow up symptom scores and imaging (if any)

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

- As for 5, above.
- Symptom scores
- Re-intervention rates
- Documentation of imaging of restenosis in reinterventions.

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

- Documentation of immediate periprocedural complications generic to any angiographic procedure.
- Documentation of any late complications that may be deemed related to the procedure.
- Documentation of recurrent stenosis requiring re-intervention.

6 Trajectory of the procedure

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

Even allowing for underdiagnosis the overall numbers are likely to be relatively small and speed of diffusion is likely to be gradual and organic. Many cases will continue to be done on an ad hoc basis.

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:

*Straight-forward proximal internal iliac stenosis can be treated in any DGH with a vascular interventional service. The more specialised and distal angioplasty and stenting of pudendal or penile arteries would be best undertaken in larger units with more expertise in and regular practice of intervention in smaller vessels. This would still be significantly more than 10 units, probably one or two units in each major city. The unit should have access to Doppler ultrasound and CT angiography for work up and have multidisciplinary input from other specialities.

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:

Overall numbers are likely to be small but interventional radiology is already an overstretched speciality with considerable manpower shortages at consultant level and underprovision of interventional radiology theatres within the NHS. What services are available are often stretched to deliver urgent intervention for life or limb threatening conditions across many referring specialities. Undertaking the type of superspecialist distal angioplasty and stenting envisaged in this proposal will require resource in terms of ring-fencing elective time for what may potentially be lengthy procedures.

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:

Consultancies or directorships attracting regular or occasional payments in cash or kind YES
 NO

Fee-paid work – any work commissioned by the healthcare 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).

- industry – **this includes income earned in the course of private practice** **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 hold shares in Spire Healthcare Limited, declared in my entry on Spire Parkway Hospital as less than 0.1% of share capital. I do not undertake angioplasty or stenting in any Spire facility and do not see this investment as a material conflict in my commentary on the procedure in question.

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

- 1 **Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee**
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 - 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).
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 - 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.