NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

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

Please respond in the boxes provided.

Please complete and return to: Deonee.Stanislaus@nice.org.uk

Procedure Name:	**Prostate Artery Embolisation for Benign Prostatic Hyperplasia**
Name of Specialist Advisor:	Dr Mark W. Little
Specialist Society:	British Society of Interventional Radiology

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

X Yes.

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

1.1 Does the title used above describe the procedure adequately?

X Yes.

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

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

X Yes.

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

X 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:

Patients with symptomatic benign prostatic hyperplasia (BPH) deemed appropriate for prostate artery embolization (PAE) will require collaborative clinical and radiological assessment from an interventional radiologist and urologist. All suitable patients will have PAE performed by an interventional radiologist.

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

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

☐ I have never done this procedure.

☐ I have done this procedure at least once.

X I do this procedure regularly.

Comments:

I have performed approximately 50 cases of PAE

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

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

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

Comments:

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

☐ I have done bibliographic research on this procedure.

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

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

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

☐ Other (please comment)

Comments:

I am a researcher and study author on the proSTatic aRtery EmbolizAtion for the treatMent of Benign Prostatic Hypertrophy (STREAM) trial (Ethics Ref**:** 14/SC/0122, REC reference 14/SC/0122). This is a prospective cohort study investigating the clinical outcome of PAE. I have presented data from this study internationally (CIRSE annual scientific meeting, September 17), and locally (Nuffield Department of Surgery, Oxford). I am also first and corresponding author of the following paper arising from the STREAM study: Little MW et al. Adenomatous-dominant Benign Prostatic Hyperplasia (AdBPH) as a Predictor for Clinical Success Following Prostate Artery Embolisation: An Age-Matched Case-Control Study. Cardiovasc Intervent Radiol 2017 May;40(5):682-689.

3 Status of the procedure

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

X Established practice and no longer new.

☐ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

☐ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

Prostate artery embolization is a long established treatment for control of prostatic bleeding, with the first case described in 1977. PAE for BPH was first described in 2000 by DeMerritt et al (DeMeritt JS, Elmasri FF, Esposito MP, Rosenberg GS. Relief of benign prostatic hyperplasia-related bladder outlet obstruction after transarterial polyvinyl alcohol prostate embolization. J Vasc Interv Radiol. 2000;11(6):767–770). Since this publication, there have been numerous studies investigating the clinical outcome of PAE, with more than one thousand individual patient outcomes reported worldwide. The largest single series to date was presented in Feb 2017 at the SIR annual scientific meeting. In this, Pisco et al reported the long term follow up of 1000 men following PAE elucidating good efficacy and safety profile; in this study, bilateral PAE was performed in 91% of patients. The cumulative clinical success rates at short, medium and long-term follow up were 89% (95% CI, 79-93.2%), 82.2% (95% CI 72.4-89.3%) and 78.1% (95% CI 72.4-89.3%) respectively. There were two major complications, a patch of bladder ischemia and perineal pain. There were no cases of sexual or urinary dysfunction. (Pisco et al Short, medium, and long-term outcome of prostate artery embolization for patients with benign prostatic hyperplasia: 1000 patients).

The efficacy, safety, and use of PAE in the management of BPH has led to it being included in the European Curriculum and Syllabus for Interventional Radiology Second Edition issued by CIRSE, February 2017. This document sets out a detailed

curriculum to ensure the highest quality training standard is achieved for all those performing interventional radiology procedures within Europe. The PAE section (2.2.1.2) includes guidance on knowledge, clinical and technical skills pertinent to PAE in the management of BPH.

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

Transurethral resection of the prostate (TURP) remains the gold standard intervention for men requiring invasive therapy for BPH.

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

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

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

☐ Cannot give an estimate.

Comments:

It is difficult to be certain. As it currently remains in the domain of research, I imagine that the number of interventional radiologists performing PAE for BPH to be small. However, the number of interventional radiologists with experience of performing PAE for prostate-mediated haematuria is likely to be higher. The technical procedure of PAE for BPH and haematuria is identical.

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

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

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

In a systematic review of 788 patients, the authors report the following complications

Complication	Number of patients	Incidence (%)
Major complications		
Vesicular artery dissection	1	0.13
Persistent UTI requiring hospitalization	1	0.13
Focal bladder wall ischemia	1	0.13
Minor complications		
Acute urinary retention	60	7.61
Rectal bleeding	45	5.71
Hematospermia	40	5.08
Hematuria	39	4.95
Dysuria	36	4.57
Urinary tract infection	34	4.30
Irritative voiding	28	3.55
Inguinal hematoma	16	2.03
Balanoposthitis	6	0.76
Post-embolization syndrome	6	0.76
Diarrhea	4	0.51

Ref: Kuang M, Vu A, Athreya S . A systematic Review of Prostatic Artery Embolization in the Treatment of Symptomatic Benign Prostatic Hyperplasia. Cardiovasc Intervent Radiol. 2017 May;40(5):655-663.

2. Anecdotal adverse events (known from experience)

From my experience, the procedure is well tolerated. In approximately half of patients, they will experience retro-pubic pain that peaks at day 2 post procedure and resolves within a week. The pain is controlled by standard analgesia within the outpatient setting. Two patients whom I have treated were diagnosed with post procedural UTI requiring oral antibiotics. Two further patients required a urinary catheter for a couple of days as a result of retention post procedure.

I am not directly aware of any sexual dysfunction reported following PAE.

3. Theoretical adverse events

The primary theoretical risk is non-target embolization- That is, the particles used to embolise the prostate arteries entering other adjacent arteries. The arterial anatomy of the male pelvis is complicated and requires sound knowledge to assess accurately; the prostate artery can share blood supply with the arteries supplying the urinary bladder, the rectum, skin and or penis. This may result in ischemia within these organs-a potentially very serious complication. In addition to a sound knowledge of the pelvic arterial anatomy, careful pre-procedural planning with CT angiography and use of intra-procedural cone-beam CT can all help to minimise the incidence of non-target embolization.

4.2 What are the key efficacy outcomes for this procedure?

The key efficacy outcome for the procedure is patient reported symptom score, which is assessed using the international prostate symptom score (IPSS). Secondary outcome measures include assessment of sexual function (international index for erectile function), quality of life score, and uroflowmetry/urodynamics.

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

There is data assessing the efficacy of PAE, with over 1000 patient outcomes reported. A review of the literature reveals two randomised controlled trials (RCTs) comparing the technique against the surgical gold standard of trans-urethral resection of the prostate (TURP). With regard to urinary symptoms, both RCTs reported significant improvements in IPSS in both the PAE and TURP groups at 12 months. Gao et al (2014) reported no significant difference between PAE and TURP in relation to the change in mean IPSS score at 12 months (-13.8 vs. - 14.1, $P > 0.05$) or 24 months (-15.6 vs. -16.3 $P > 0.05$). Carnevale et al (2016) found that TURP and PErFecTED PAE both resulted in significantly lower IPSS than original PAE but were not significantly different from one another. The authors also found that TURP is associated with both better urodynamic results, but more adverse events. Criticism of the PAE literature is the paucity of multicentre RCTs, and long-term follow up data. The longest follow-up data comes from Pisco et al, which was reported at SIR, 2017. They presented data on 406 patients undergoing PAE with over 3 years follow-up. Given the array of symptoms that patients with BPH present with, there has been debate about which groups of patients PAE is most efficacious in. The literature suggests that patients with large prostates (>80cm^3) will achieve the best clinical outcomes following PAE. It is important that there is collaborative assessment of patients between interventional radiologists and urologists to assess patients on clinical and radiological grounds, ensuring appropriate patient selection to maximise procedural efficacy.

RCT references:

Carnevale FC, Iscaife A, Yoshinaga EM, Moreira AM, Antunes AA, Srougi M. Transurethral Resection of the Prostate (TURP) Versus Original and PErFecTED Prostate Artery Embolization (PAE) Due to Benign Prostatic Hyperplasia (BPH): Preliminary Results of a Single Center, Prospective, Urodynamic- Controlled Analysis. *Cardiovascular & Interventional Radiology* 2016; 39: 44-52.

Gao Y-a, Huang Y, Zhang R, Yang Y-d, Zhang Q, Hou M, et al. Benign prostatic hyperplasia: prostatic arterial embolization versus transurethral resection of the prostate--a prospective, randomized, and controlled clinical trial. *Radiology* 2014; 270: 920-8.

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

At least two consultant interventional radiologists should undertake the procedure for the first 5-10 cases as there is a learning curve with regards to confidently identifying the pelvic arterial anatomy, and this will increase the safety of the procedure. Furthermore, the team undertaking the procedure should have access to CT angiography, prostate MRI and intra-procedural cone-beam CT (this will aid procedural planning, patient selection, and help to minimize non-target embolization). There are several established training opportunities available for PAE in Europe and North America. I would advocate attending a relevant course, and having a proctor for the first few cases to support centres starting to offer PAE for patients with BPH. Centres should also have a urology service, enabling appropriate patient selection, and collaborative discussion of cases referred for PAE.

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

The UK registry of prostate artery embolization (UK-ROPE)-I understand that the results are being reported from CEDAR to NICE.

There are a number of small prospective cohort studies listed on clinicaltrials.gov. In addition there are four randomised controlled trials under way:

1. Prostatic Artery Embolization Versus Medical Treatment in Symptomatic Benign Prostatic Hyperplasia (PARTEM)

Estimated completion date Feb 2021
Estimated enrolment: 90
Centre: Paris, France

2. Prostatic Artery Embolization vs. Conventional Transurethral Prostatectomy in the Treatment of Benign Prostatic Hyperplasia: A Prospective Randomized Trial
Estimated completion date Dec 2022
Estimated enrolment: 101
Centre: Gallen, Switzerland

3. Prospective Controlled Randomized Study of PAE vs TURP for BPH Treatment.

Estimated completion date May 2019
Estimated enrolment: 100
Centre: Zaragoza, Spain

4. Clinical Trial of Prostatic Arterial Embolization Versus a Sham Procedure to Treat Benign Prostatic Hyperplasia

Estimated completion date December 2018
Estimated enrolment: 80
Centre: Lisbon, Portugal

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

Yes. There was a presentation of the preliminary results from the UK-ROPE study, presented at the CIRSE annual scientific meeting in Copenhagen September 2017. I understand Cedar are feeding the results of this study directly back to NICE.

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

Not to my knowledge.

5 Audit Criteria

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

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

International prostate symptom score (IPSS), International index of erectile function (IIEF), and quality of life scores (QOL) (a score is included within the IPSS) should be assessed pre procedure and at 6 weeks, 3 months, and 1 year. Uroflowmetry is often used in the literature with Qmax a common outcome measure of clinical success. Finally the post-void residual urine volume (PVR) can be assessed with ultrasound, and gives a quantitative measure of bladder emptying pre and post PAE.

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

A common early complication is retro-pubic pain, which could be assessed with a telephone consultation at 1 week. If pain is severe, not abating, or extends beyond a week, patients should attend for clinical and radiological assessment to exclude non-target embolization.

Groin haematoma can occur following arterial access. Patients need to have the puncture site monitored for up to 4-hours post procedure within hospital to look for signs of bleeding. Patients should be given advice to look for painful swelling over the first week following the procedure, and seek medical attention if any adverse features occur.

Patients should also be given advice to seek medical attention if signs and symptoms of a UTI are encountered. This occurs early within weeks following PAE.

Patients should be given advice to look for features of non-target embolization. This includes haematuria, per-rectal bleeding, skin ulceration and persistent/worsening pain. The timescale for the clinical manifestations of non-target embolization is variable depending on the anatomy involved but should be monitored over the first month following PAE.

Patients should be warned about the risk of experiencing urinary retention. This is an early complication experienced days following PAE. Patients should be advised to seek medical attention if urinary retention is experienced.

6 Trajectory of the procedure

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

The incidence of BPH is high and increases with age, with some 70% of men symptomatic by 70 years of age. As such I believe the demand for PAE will be high and the procedure will spread quickly.

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

X 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:

Given the fact that PAE is a minimally invasive day case procedure performed under local anaesthetic, the cost is low. It therefore has the potential to benefit local populations and alleviate the pressure on waiting lists for current approved interventions for BPH. Whilst I believe the potential demand for PAE will be high and require provision nationwide, I must stress that units must have appropriately trained/proctored interventional radiologists with access to CT angiography, MRI, and conebeam CT. Units offering the procedure should also have urologists already managing patients with BPH. The correct way to proceed with setting up a PAE service is one of collaboration between urology and interventional radiology.

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:

X Major.

☐ Moderate.

☐ Minor.

Comments:
BPH is a very common condition, with over 50% of men in their 60's and approximately 70% of men in their 70's thought to suffer some symptoms of an enlarged prostate. As commented above, PAE is a day case procedure that is minimally invasive, requiring a tiny incision in the groin or wrist. The procedure is relatively quick once the learning curve has been overcome-with procedural times ranging between 1-1.5 hours. The consumables used for PAE are standard for embolization procedures, requiring no additional special equipment.

Not all patients presenting for an intervention for symptoms pertaining to their BPH will be suitable for PAE (e.g. unable to lie flat or have inappropriate arterial anatomy). There must therefore be good cross-discipline collaboration between urologists and interventional radiologists to offer the best treatment to each patient on an individual

basis. This must be based on patient preference and choice, as well as anatomical and pathophysiological considerations.

7 Other information

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

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

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

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

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

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

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

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

[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	**X**	**YES**
	☐	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	**X**	**YES**
	☐	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	X	**NO**
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☐	**YES**
	X	**NO**
Investments – any funds that include investments in the healthcare industry	☐	**YES**
	X	**NO**
Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	**X**	**YES**
	☐	**NO**

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

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

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

Comments:
I am an adviser for Merit Medical, I have received no payment for this role, and given no specific advice on PAE.
I am a researcher on a study investigating the clinical outcomes of PAE. I have presented data from the study within the UK and internationally, and authored a number of peer-reviewed journal articles on PAE.

September 2017.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

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

Jan 2016

Conflicts of Interest for Specialist Advisers

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

1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.

1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

2 Personal pecuniary interests

2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'** or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples are as follows.

2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.

2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place.

2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

2.2 No personal interest exists in the case of:

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

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

3 **Personal family interest**

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

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

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

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

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

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

3.2 No personal family interest exists in the case of:

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

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

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

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

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

4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration

4.4 other reputational risks in relation to an intervention under review.

5 Non-personal interests

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

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

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

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

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

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

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

Please respond in the boxes provided.

Please complete and return to: Deonee.Stanislaus@nice.org.uk

Procedure Name:	**Prostate Artery Embolisation for Benign Prostatic Hyperplasia**
Name of Specialist Advisor:	Dr Nadeem Shaida
Specialist Society:	British Society of Interventional Radiology

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

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

☒ I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

I have received formal training in how to perform this procedure from a European centre and have performed it very occasionally for a different indication which was intractable bleeding.

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

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

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

Comments:

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

☒ I have done bibliographic research on this procedure.

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

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

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

☐ Other (please comment)

Comments:

3 Status of the procedure

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

☐ Established practice and no longer new.

☐ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

☐ Definitely novel and of uncertain safety and efficacy.

☒ The first in a new class of procedure.

Comments:

The procedure has been performed for >5 years now although the number of centres performing it has been limited in the UK. The literature from numerous case series suggests the procedure to be safe and efficacious although there are only limited (currently 2 to my knowledge) published randomised trials comparing PAE head to head with the surgical equivalent of TURP.

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

Urological surgical equivalents – These include standard TURP, greenlight and other forms of laser TURP, the Holep procedure and more recently the urolift procedure. Other potential treatments for BPH include medical therapy although this is generally recognised as first line treatment and intervention/surgery generally used for those refractory to medical treatment.

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

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

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

☐ Cannot give an estimate.

Comments:

In the Uk mainly limited to those centres who were involved in the ROPE registry.

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

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

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

Mainly related to non-target embolization. Very low risk of bladder ischaemia (case report) which settled transiently. Small rate (<5%) of transient rectal bleeding which settles spontaneously. Case report of sloughing of the skin of the glans penis (Kisilevsky 2016 JVIR).

2. Anecdotal adverse events (known from experience)

n/a

3. Theoretical adverse events

Non-target embolization to rectum causing significant bowel ischaemia.

Procedure causes PSA reduction so caution required in assessment of PSA if future prostate ca. suspected.

4.2 What are the key efficacy outcomes for this procedure?

IPSS scores
Flow rate (uroflowmetry)
QOL scores
IIEF (ejaculatory function scores)

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

No

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

Technically demanding procedure with long flouro times initially.
Although no guidelines as yet most people suggest a visit to a training centre initially followed by proctoring of the first few cases would be helpful.
Most experienced operators suggest that cone beam CT is useful particularly early on in the learning curve.

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

UK ROPE registry – has just reported at CIRSE 2017.

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

As above UK ROPE

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

IPSS score, IEEF score, Flow rates

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

Non –target embolization usually obvious within 2/52.

6 Trajectory of the procedure

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

Quickly – huge interest amongst IR community. Urology community aware but a little concerned about a new treatment impacing on their workload. It may be that PAE v surgery ends up as complementary therapy eg.
PAE easier in big glands – Surgery (excepting Holep) easier in moderate size glands.
PAE easier in elderly/infirm patients (assuming iliac vessels not occluded)
Younger patients keen to preserve ejaculatory function – surgical treatments all compromise this with the exception of Urolift – but this cannot be done in big glands.
So the target subset might be young patients with big glands keen to preserve sexual function.

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:

Depends a lot on local interest – it is already done in some smaller centres. A lot depends on whether the urologists who see the patient are aware of this procedure and prepared to refer for it.

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

☐ Major.

☐ Moderate.

☒ Minor.

Comments:
This will still be a specialised treatment requiring specific expertise. The overall number of patients is not likely to be very high initially.

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?

n/a

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

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

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

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

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

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

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

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐	**YES**
	☒	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☐	**YES**
	☒	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	☒	**NO**
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☐	**YES**
	☒	**NO**
Investments – any funds that include investments in the healthcare industry	☐	**YES**
	☒	**NO**
Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	☐	**YES**
	☒	**NO**

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

Fellowships endowed by the healthcare industry	☐	**YES**
	☒	**NO**

[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).

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

☐ **YES**

☒ **NO**

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

Comments:

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

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

Jan 2016

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.