NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

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

Please respond in the boxes provided.

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

Procedure Name:	**Prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia**
Name of Specialist Advisor:	Mark Rochester
Specialist Society:	British Association of Urological Surgeons (BAUS)

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?

☐ Yes.

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

Comments:

May be best to define it as temporary implantable nitinol device (TIND) to be sure to distinguish it from prostatic urethral lift implant

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

X☐ Yes.

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

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

Comments:

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

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

X☐ I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

This is not a procedure which is currently widely adopted in the UK

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.

X☐ 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):

☐**X** 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.

☐**X** 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?

Gold standard for bladder outflow surgery is TURP or HoLEP. There is an established NICE-approved minimally invasive comparator – Prostatic urethral lift implant, this is best comparator

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

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

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

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

☐ Cannot give an estimate.

Comments:

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)

UTI 3%, transient incontinence 3%, retention 3%, prostate abscess 3%

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

Infection, bleeding, transient worsening LUTS, retrograde ejaculation, erectile dysfunction, retention, failure to improve, need for further treatment.

4.2 What are the key efficacy outcomes for this procedure?

Changes in IPSS score, Quality of life score, sexual function, flow rate/post void residual volume, re-operation rate over 5 years

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

Long term data lacking. Only one published cohort followed up at 3 years (porpiglia, BJU 2015, BJU 2018)

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

Any urologist with adequate mentoring from a trained surgeon should be able to perform. Exact number of cases needed to be done supervised before independent proactive unclear, but I expect 5-10

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

5 ongoing studies- these are listed in the review article published in Current Urol Rep 2018 (Bertolo 2018)

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).

TIND vs sham n=40 presented at AUA 2017 (Porpiglia, Bertoli J Urol 2017;197 (4 Supple, E512)

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 medium or long term data, just one published study

5 Audit Criteria

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

Baseline IPSS and QoL, sexual function, flow rate/residual baseline and follow up, complications by Clavien classifications and reoperation rate at 5 years Some assessment of the short term storage symptoms and pain experienced should be documented too

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:

As above

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:

Post op, 3 months/ 6 months

6 Trajectory of the procedure

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

I expect slowly as alternatives such as Rezum or urolift more widely adopted already and this needs to show a benefit to prove why it should be adopted

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:

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

☐ Major.

☐ Moderate.

X☐ Minor.

Comments:

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.

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

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

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

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

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

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

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐	**YES**
	X	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	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?	☐	**YES**
	X	**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:
Private practice in urology
Have been paid consultant for neotract
Thank you very much for your help.

[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).

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mark Campbell
Acting Programme Director
Devices and Diagnostics

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

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Please respond in the boxes provided.

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

Procedure Name:	**Prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia**
Name of Specialist Advisor:	Neil Barber
Specialist Society:	British Association of Urological Surgeons (BAUS)

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?

☐ Yes.

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

Comments:

Temporary prostatic urethral device for lower urinary tract symptoms related to benign prostatic hyperplasia

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

x☐ Yes.

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.

x☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

I have performed the procedure within study MT02 – a prospective pan European study

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):

x☐ 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.

x☐ 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 concept of incisions through the bladder neck and prostatic urethra to relieve bladder outlet obstruction is not novel. A device that achieves this after it is placed under sedation/ local anaesthesia and removed similarly 5 or so days later, is novel

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

I cross between bladder neck incision or TUIP, prostatic stents and Urolift

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

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

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

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

☐ Cannot give an estimate.

Comments:

Less than 10 in England and Wales

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)

Haematuria, pain, urosepsis, failure to void/ catheterisation

Follow-up of Temporary Implantable Nitinol Device (TIND) Implantation for the Treatment of BPH: a Systematic Review.
Bertolo R, Fiori C, Amparore D, Porpiglia F.
Curr Urol Rep. 2018 Apr 26;19(6):44.

3-Year follow-up of temporary implantable nitinol device implantation for the treatment of benign prostatic obstruction.
Porpiglia F, Fiori C, Bertolo R, Giordano A, Checcucci E, Garrou D, Cattaneo G, De Luca S, Amparore D.
BJU Int. 2018 Jul;122(1):106-112.

Temporary implantable nitinol device (TIND): a novel, minimally invasive treatment for relief of lower urinary tract symptoms (LUTS) related to benign prostatic hyperplasia (BPH): feasibility, safety and functional results at 1 year of follow-up.
Porpiglia F, Fiori C, Bertolo R, Garrou D, Cattaneo G, Amparore D.
BJU Int. 2015 Aug;116(2):278-87

2. Anecdotal adverse events (known from experience)

As above

3. Theoretical adverse events

Retrograde ejaculation, impotence, incontinence – not reported though in any of the literature published or indeed in MT02 in which I was involved

4.2 What are the key efficacy outcomes for this procedure?

Symptom improvement as measured by IPSS/ Quality of life score
Improvement in urinary stream – as measured by improvement in maximum flow rate Qmax

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?

Minimum – standard urological equipment and skill set required only

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

MTO2 – prospective multi centred pan European evaluation study
Trial vs sham procedure in US
MT04 - prospective randomised trial for iTIND in acute urinary retention

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).

MT02 has been presented at AUA/ EAU annual meetings

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/ Qmax/ IIEF – 5/ MSHQ-EjD

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:

pain and bleeding/ urosepsis on insertion and through duration of implant placement
pain and bleeding/ urosepsis on removal
pain and bleeding/ urosepsis after device removal

6 Trajectory of the procedure

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

slowly

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

☐ Most or all district general hospitals.

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

☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

However, this is a busy field with many minimally invasive options

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

☐ Major.

☐ Moderate.

x☐ Minor.

Comments:

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?

My general feeling is that this will be quite a niche procedure – potentially the best option for a minority of patients

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

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

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

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

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

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

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐	**YES**
	x ☐	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	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:

---

[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).

Fellowships endowed by the healthcare industry

x ☐ **YES**

☐ **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 have lectured widely on BPH and minimally invasive surgeries – some have been open to the public
I do have a private practice
I have received expenses by companies to attend training, provide training and to attend conferences
I have received occasional consultancy fees from companies usually for training other urologists – and am/ have been a Key Opinion Leader for Olympus, Intuitive Surgical, Neotract, Boston Scientific
I have a BPH fellow post at Frimley Park Hospital, Frimley Health NHS Foundation Trust, sponsored by industry (not this company)

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mark Campbell
Acting Programme Director
Devices and Diagnostics

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: azad.hussain@nice.org.uk

Procedure Name:	**Prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia**
Name of Specialist Advisor:	Professor Prokar Dasgupta
Specialist Society:	British Association of Urological Surgeons (BAUS)

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

Yes.

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

Yes.

Comments: I have used sedation for both insertion and removal of iTIND

2. Your involvement in the procedure

2.1. Is this procedure relevant to your specialty?

Yes it is

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 is one of many new treatments available for BPH which does not affect ejaculatory function

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

Comments: The patients are selected and treated by the urologist. In this case it is myself so I have not referred anyone yet

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 - Yes

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) - I have also audited my own patients with symptom scores and flow rates before and after the procedure

Comments:

3. Status of the procedure

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

The first in a new class of procedure.

Comments: The device creates grooves in the prostate while in situ. Ejaculation is preserved unlike in bladder neck incision or TURP

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

Bladder neck incision

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

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

Comments: iTIND is relatively new in the UK. One and three year data have been published from Porpiglia and colleagues in the BJUI. It has also undergone a multicentre study in Europe including centres in the UK and a trial in USA (data awaited)

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)

BJU Int. 2018 Jul;122(1):106-112. doi: 10.1111/bju.14141. Epub 2018 Feb 14.

3-Year follow-up of temporary implantable nitinol device implantation for the treatment of benign prostatic obstruction.
Porpiglia F1, Fiori C1, Bertolo R1, Giordano A1, Checcucci E1, Garrou D1, Cattaneo G1, De Luca S1, Amparore D1.

Abstract
OBJECTIVES:
To report 3-year follow-up results of the first implantations with a temporary implantable nitinol device (TIND® ; Medi-Tate Ltd., Or Akiva, Israel) for the treatment of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH).
PATIENTS AND METHODS:

In all, 32 patients with LUTS were enrolled in this prospective study. The study was approved by the local Ethics Committee. Inclusion criteria were: age >50 years, International Prostate Symptom Score (IPSS) ≥10, peak urinary flow (Qmax) <12 mL/s, and prostate volume <60 mL. The TIND was implanted within the bladder neck and the prostatic urethra under light sedation, and removed 5 days later in an outpatient setting. Demographics, perioperative results, complications (according to Clavien-Dindo classification), functional results, and quality of life (QoL) were evaluated. Follow-up assessments were made at 3 and 6 weeks, and 3, 6, 12, 24 and 36 months after the implantation. The Student's t-test, one-way analysis of variance and Kruskal-Wallis tests were used for statistical analyses.
RESULTS:
At baseline, the mean (standard deviation, sd) patient age was 69.4 (8.2) years, prostate volume was 29.5 (7.4) mL, and Qmax was 7.6 (2.2) mL/s. The median (interquartile range, IQR) IPSS was 19 (14-23) and the QoL score was 3 (3-4). All the implantations were successful, with a mean total operative time of 5.8 min. No intraoperative complications were recorded. The change from baseline in IPSS, QoL score and Qmax was significant at every follow-up time point. After 36 months of follow-up, a 41% rise in Qmax was achieved (mean 10.1 mL/s), the median (IQR) IPSS was 12 (6-24) and the IPSS QoL was 2 (1-4). Four early complications (12.5%) were recorded, including one case of urinary retention (3.1%), one case of transient incontinence due to device displacement (3.1%), and two cases of infection (6.2%). No further complications were recorded during the 36-month follow-up.
CONCLUSIONS:
The extended follow-up period corroborated our previous findings and suggests that TIND implantation is safe, effective and well-tolerated, for at least 36 months after treatment.

2. Anecdotal adverse events (known from experience)

   Device displacement

3. Theoretical adverse events

   Bleeding, infection, pain

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

IPSS, Flow and residue

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

Long term durability not known yet

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

Simple practice on inanimate prostate models. Easy to insert and remove.

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

European multicentre study
USA trial

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).

Minimally Invasive Incision through Temporarily Implanted Nitinol Device (ITIND): A Single-Arm, Multicenter, Prospective Study for theTreatment of Lower UrinaryTract Symptoms Secondary to Benign Prostatic Hyperplasia Investigators
• Neil Barber, Frimmley Park, Frimmley, UK
• Dr. Greogor Kadner, Canton Hospital Frauenfeld, Switzerland
• Dr. Arya Manit, University College Hospital, London, UK
• Prof. Claude Schulman, Edith Cavell, Brussels, Belgium
• Dr. Luman Nicolaas, Gent University Hospital, Belgium
• Dr. Valerio Massimo, Lausanne University Hospital, Switzerland
• Dr. Brian Ho, Hong Kong University Hospital, Hong Kong
• Prof. Francesco Propiglia, San Luigi Gonzaga University Hospital, Turin, Italy
Purpose: This report reveals the results of a multicenter, prospective study using the iTind (temporarily implanted nitinol device) to treat lower urinary tract symptoms associated with benign prostatic hyperplasia.
Materials and Methods: Men suffering from BPH with an International Prostate Symptom Score of ≥10, maximum ow rate of <12 ml per second and prostate size <75 cc underwent implantation with the iTind device. The iTind was implanted into the prostatic urethra through a rigid cystoscope and left in-situ for between 5-7 days after which it was removed through a silicon foley catheter.
The primary end point was reduction of IPSS score by at least 3 points, in at least 75 % of the subjects, at 6 months follow-up.
Treatment subjects were followed for 12 months.
Results: 81 men underwent the iTind procedure. Mean International Prostate Symptom Score was reduced from 22.47 at baseline to 8.78 points at 12 months follow-up (-13.69) and peak ow rate increased from 8.46ml/ sec at baseline to 14. 72 at 12 months follow-up (+6.26ml/sec). Quality of life improved from a mean of 4 at baseline to 1 at 12 months follow-up (-3).
No de novo erectile dysfunction or retrograde ejaculation was reported.
Adverse events were mild to moderate and resolved quickly.

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

None. The manufacturers are clear about the lack of long term data as is the case with other new devices. This data gathering continues.

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.
IPSS, Flow, residue, QoL

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:
As above

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:

Urinary retention, infection, pain, bleeding
Should settle within 1-2 weeks post procedure

6 Trajectory of the procedure

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

I can't predict this. There is a growing market for ejaculation preserving procedures in between tablets and TURP/Laser prostatectomy for BPH

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

Most or all district general hospitals - this is eventually possible

A minority of hospitals, but at least 10 in the UK - this would be my prediction

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:

Moderate.

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?
Review article 2018 by Porpiglia and colleagues.

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 agree to below. The computer does not allow me to tick the box

☐ 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 have a **personal pecuniary** interest? The main examples are as follows:

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

NO

Fee-paid work – any work commissioned by the healthcare 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

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

NO

Investments – any funds that include investments in the healthcare industry

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?

NO

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

Fellowships endowed by the healthcare industry

NO

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

NO

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

Comments:

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mark Campbell
Acting Programme Director
Devices and Diagnostics

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).

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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.

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