NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name:	**Sacral nerve stimulation for chronic non-obstructive urinary retention (1238/1)**
Name of Specialist Advisor:	**Mr Chris Harding**
Specialist Society:	**British Association of Urological Surgeons**
Please complete and return to:	azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

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

√ Yes.

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

1.1 Does the title used above describe the procedure adequately?

√ Yes.

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

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

√ Yes.

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

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

Comments:

This procedure may be carried out by urologists or urogynaecologists.

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

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

☐ I have never performed this procedure.

☐ I have performed this procedure at least once.

√ I perform this procedure regularly.

Comments:

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

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

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

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

Comments:

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

☐ I have undertaken bibliographic research on this procedure.

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

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

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

√ Other (please comment)

Comments:

Clinical audit of personal data only.

3 Status of the procedure

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

√ Established practice and no longer new.

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

☐ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

This procedure is offered in most large Urology units in the UK. It is currently the only alternative to long term catheterisation (either indwelling or intermittent)

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

Long term catheterisation or intermittent self-catheterisation

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

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

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

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

☐ Cannot give an estimate.

Comments:

This procedure is usually performed by Urologists / Urogynaecologists with a sub-specialist interest in Lower Urinary Tract Dysfunction.

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

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

1. Theoretical adverse events

   Infection / Device Migration / Leg or buttock pain or paraesthesia / Device failure / Change in bowel function

2. Anecdotal adverse events (known from experience)

As Above

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

As Above

Herbison GP, Arnold EP. Sacral neuromodulation with implanted devices for urinary storage and voiding dysfunction in adults. Cochrane Database of Systematic Reviews 2009, Issue 2. Art. No.: CD004202. DOI: 0.1002/14651858.CD004202.pub2

4.2 What are the key efficacy outcomes for this procedure?

Subjective measures
• Patient perception of cure or improvement
• Perception of Flow rate
• Frequency of urination or nocturia
• Sensation of Incomplete emptying
• Pain relief

Objective measures
• Urodynamic measurements eg voiding pressure, flow rate, residual volume
• Frequency volume chart
• ISC volumes / ISC frequency
• Pad tests or number of leaks per day (if overflow incontinence)

Health status measures
• Quality of life (QOL)
• General health status (e.g. SF-36)
• Psycho-social measures
• Impact of self-catheterisation or incontinence

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

Uncertainty mainly surrounds which patients are likely to benefit. There is no high quality research that has identified predictors of a successful outcome from this procedure (or indeed those who will fail treatment) therefore a trial of sacral neuromodulation is considered suitable for all patients.

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

Evidence of training i.e. an accredited course, Adequate mentorship and a suitable caseload e.g. 30 cases per year. The procedure itself carries only moderate technical difficulty but dealing with the complications requires sufficient experience of the technique.

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

Sacral Neuromodulation for Neurogenic LUT Dysfunction ClinicalTrials.gov Identifier: NCT02165774

Time of Effect Onset in Treating Overactive Bladder or Non Obstructive Urinary Retention by Sacral Neuromodulation ClinicalTrials.gov Identifier: NCT02040519

Sacral Neuromodulation Test With Bilateral First Stage Tined Lead Procedure in Patients With Non-obstructive Urinary Retention: A Pilot Study ClinicalTrials.gov Identifier: NCT00878176

Ambulatory Urodynamic Evaluation of Sacral Neuromodulation for Non-Obstructive Urinary Retention ClinicalTrials.gov Identifier: NCT00970242

Sacral Neuromodulation With InterStim® Therapy for Intractable Urinary Voiding Dysfunctions (SOUNDS): an Observational Study ClinicalTrials.gov Identifier: NCT02186041

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

No

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

The test phase of this procedure can be carried out using a temporary implantable electrode which is unipolar or a permanent electrode which is quadripolar. The published literature would suggest a higher success rate with the latter and most units would therefore implant the quadripolar electrode for the test phase but some variation still exists.
Secondly the preliminary test phase can be carried out under local or general anaesthesia dependant on patient and surgeons preference.

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):

Subjective measures

• Patient perception of cure or improvement
• Perception of Flow rate
• Frequency of urination or nocturia
• Sensation of Incomplete emptying
• Pain relief

Objective measures
• Urodynamic measurements eg voiding pressure, flow rate, residual volume
• Frequency volume chart
• ISC volumes / ISC frequency
• Pad tests or number of leaks per day (if overflow incontinence)

Health status measures
• Quality of life (QOL)
• General health status (e.g. SF-36)
• Psycho-social measures
• Impact of self-catheterisation or incontinence

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

Adverse events
• Removal of device
• Device malfunction
• Pain
• Need to re-position electrodes
• Problems specifically linked to the device or stimulation

6 Trajectory of the procedure

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

The diffusion of this procedure is potentially rapid due to the lack of alternative treatments.

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:

This procedure should be restricted to regional units with sufficient experience and expertise in the field of Lower Urinary Tract dysfunction.

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

☐ Major.

√ Moderate.

☐ Minor.

Comments:

7 Other information

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

Patient forums such as Embarrassing Bodies, Bladder and Bowel Foundation etc. reveal significant testimonies regarding the potentially life-changing impact of this treatment. It can transform patients' quality of life and render them catheter-free.

The effect of indwelling and intermittent catheters on QoL is highlighted in the following publications:

Shaw C, Logan K, Webber I, Broome L, Samuel S. Effect of clean intermittent self-catheterization on quality of life: a qualitative study. J Adv Nurs. 2008 Mar;61(6):641-50.

Woodward S, Rew M. Patients' quality of life and clean intermittent self-catheterization. Br J Nurs. 2003 Oct 9-22;12(18):1066-74

Kralik D, Seymour L, Eastwood S, et al. Managing the self: Living with an indwelling urinary catheter. J Clin Nurs 2007;16:177-85.

De Jaeger M. Exploring urinary catheters: The perspectives of patients and nurses. Br J Nurs 2011;20:400-8.

Wilde MH. Life with an indwelling urinary catheter: The dialectic of stigma and acceptance. Qual Health Res 2003;13:1189-204.

O'Donohue D, Winsor G, Gallagher R, et al. Issues for people living with longterm urinary catheters in the community. Br J Community Nurs 2010;15: 65-70.

8 Data protection and conflicts of interest

8.1 Data protection statement

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

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

Specialist Advisers should be aware that full implementation of the Freedom of Information Act 2000 may oblige us to release Specialist Advice from 2005.

The Freedom of Information Act 2000 favours the disclosure of information however requests will be considered on a case by case basis. If information is made available, personal information will be removed in accordance with the Data Protection Act 1998. In light of this please ensure that you have not named or identified individuals in your comments.

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

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

Do you or a member of your 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 which include investments in the healthcare industry	☐	**YES**
	√	**NO**
Do you have a **personal non-pecuniary** interest – eg have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	√	**YES**
	☐	**NO**

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

Fellowships endowed by the healthcare industry	☐	**YES**
	√	**NO**
Support by the healthcare industry or NICE that benefits his/her	☐	**YES**

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

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:

Advisory Board for Pierre Fabre Pharmaceuticals
Speaker for Astellas, Pfizer, Ferring, GSK and Lilly
Member of British Association of Urological Surgeons subsection of Female, Neurological and Urodynamic Urology executive committee.

Thank you very much for your help.

Professor Bruce Campbell, Chairman, Interventional Procedures Advisory Committee

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

February 2010

Conflicts of Interest for Specialist Advisers

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

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

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

2 Personal pecuniary interests

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

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

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

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

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

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

2.2 No personal interest exists in the case of:

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

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

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

3 Personal family interest

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

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

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

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

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

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

3.2 No personal family interest exists in the case of:

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

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

4 Personal non-pecuniary interests

These might include, but are not limited to:

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

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

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

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

5 Non-personal interests

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

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

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

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

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

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name:	**Sacral nerve stimulation for chronic non-obstructive urinary retention (1238/1)**
Name of Specialist Advisor:	**Mr Nikesh Thiruchelvam**
Specialist Society:	**British Association of Urological Surgeons**
Please complete and return to:	azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

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

X Yes.

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

1.1 Does the title used above describe the procedure adequately?

X Yes.

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

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

X Yes.

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

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

Comments:

Generally SNS is performed by urologists in the UK and the rest of the world. There are some gynaecologists who also undertake the procedure in the UK. SNS is commonly used by colorectal surgeons in the UK (for bowel symptoms)

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

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

☐ I have never performed this procedure.

☐ I have performed this procedure at least once.

X I perform this procedure regularly.

Comments:

The minority of patients undergo SNS for retention (the majority undergo SNS for overactive bladder symptoms)

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.

X 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 undertaken bibliographic research on this procedure.

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

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

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

☐ Other (please comment)

Comments:

3 Status of the procedure

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

X Established practice and no longer new.

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

☐ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

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

Catherisation (urethral, suprapubic, clean intermittent self catheterisation [CISC]), mitrofanoff catheterisation, ileal conduit urinary diversion

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

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

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

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

☐ Cannot give an estimate.

Comments:

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

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

1. Theoretical adverse events

Lead migration (and so loss of efficacy), lead pain, implantable pulse generator (IPG) pain, IPG mobility, equipment failure, device infection

2. Anecdotal adverse events (known from experience)

Nil else

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

Overall reoperation rate is between 1 in 10 and 1 in 20

Van Kerrebroeck PE, Marcelissen TA. Sacral neuromodulation for lower urinary tract dysfunction. World J Urol. 2012 Aug;30(4):445-50

4.2 What are the key efficacy outcomes for this procedure?

Ability to spontaneously void
Lowered residual volume
Reduced rates of CISC

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

Multiple studies showing efficacy of SNS for overactive bladder and bowel symptoms. Only few studies examining outcome of SNS for urinary retention, all single centre series, inadequate long-term outcome data

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

Training course and mentored cases. Low invasive procedure. Reprogramming of device requires training, improvement with experience

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

Swiss registry and French registry. Both published and ongoing.
Not aware of current trials or RCTs.

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

No

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

Ongoing National Commissioning Board, now NHS England, discussions of the availability of SNS throughout UK. There is obvious inequality of access to treatment.

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):

Ability to spontaneously void
Lowered residual volume
Reduced rates of CISC
UTI rates
PROMS: ICIQ UI SF, EQ5D5L

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

Failure, lead migration leading to lead pain or loss of efficacy, device infection, IPG mobility and pain

6 Trajectory of the procedure

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

This depends on NHSE and commissioning. I don't think there will be widespread uptake, the technique should remain within specialist tertiary centres for appropriate patient selection if commissioned.

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:

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:

Although used for a small number of patients, it is expensive (the device itself costs around £7000). Hence the requirement for NHSE for commissioning.

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?

The device is of low risk but careful patient selection is key. Units currently undertake the test period by peripheral nerve evaluation, placement of a tined lead or placement of bilateral tined leads. It remains unclear which implantation technique during testing gives the best results.

8 Data protection and conflicts of interest

8.1 Data protection statement

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

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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 – Speaker fee from Astellas**	**y**	**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 which include investments in the healthcare industry	☐	**YES**
	x	**NO**
Do you have a **personal non-pecuniary** interest – eg have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	**x**	**YES**
I sit on the executive committee of the Female and Functional urology Section of the British Association of Urological Surgeons	☐	**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:

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).

Professor Bruce Campbell, Chairman, Interventional Procedures Advisory Committee

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

February 2010

Conflicts of Interest for Specialist Advisers

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2.1.1 **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.

NICE National Institute for Health and Care Excellence

10 Spring Gardens
London
SW1A 2BU

azeem.madari@nice.org.uk
www.nice.org.uk

DATA PROTECTION

In order to comply with the Data Protection Act 1998 we ask you to read the following statement and to sign it if you are willing for your data to be used in the way described.

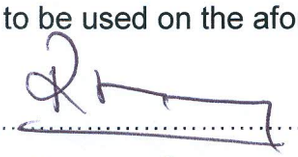
Any personal data such as your name, job title, mailing address, email, telephone, specialist societies and specialist interests will be used by the National Institute for Health and Clinical Excellence (NICE) to carry out its work on interventional procedures and will be kept on a NICE database for future reference.

Your name and specialist society will be placed in the public domain, in future publications and on our website (www.nice.org.uk) and is therefore viewable worldwide. This information may be passed to third parties connected with the work on interventional procedures.

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

Specialist Advisors should be aware that full implementation of the Freedom of Information Act 2000 may oblige us to release Specialist Advice on request from 2005. The Freedom of Information Act 2000 favours the disclosure of information however requests will be considered on a case by case basis against the exemptions in the Act. If information is made available, personal information will be removed if its disclosure would contravene the Data Protection Act 1998.

I agree for the above information to be used on the aforementioned website and in any relevant publications.

Signed: 

Print name: ROLAND MORLEY

Date: 30/3/15

Please return this form via email to: *azeem.madari@nice.org.uk alternatively you can return this via post to: Interventional Procedures, 10 Spring Gardens, London SW1A 2BU.*
Please note forms returned by email must be from an email address associated with your name

NICE National Institute for Health and Care Excellence

PERSONAL DATA – SPECIALIST ADVISORS

NAME	ROLAND MORLEY.
Main Job Title	CONSULTANT UROLOGIST
Mail Address	EFFINGHAM HOUSE 39 B. LOWER ROAD FETHAM SURREY KT22 9EL
Email :	roland.morley@gmail.com
Telephone:	07973 332273
Name of relevant Specialist Society/ies or Association(s)	BRITISH ASSOCIATION OF UROLOGICAL SURGEONS
Specialist Interests	INCONTINENCE AND RECONSTRUCTIVE UROLOGY

Please return this form via email to: azeem.madari@nice.org.uk alternatively you can return this via post to: Interventional Procedures, 10 Spring Gardens, London SW1A 2BU. *Please note forms returned by email must be from an email address associated with your name*

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name:	**Sacral nerve stimulation for chronic non-obstructive urinary retention (1238/1)**
Name of Specialist Advisor:	**Mr Roland Morley**
Specialist Society:	**British Association of Urological Surgeons**
Please complete and return to:	azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

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

☑ Yes.

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

1.1 Does the title used above describe the procedure adequately?

☐ Yes.

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

Comments:

NIL

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:

NIL SOME GYNAECOLOGISTS DO THIS

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

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

☐ I have never performed this procedure.

☑ I have performed this procedure at least once.

☐ I perform this procedure regularly.

Comments:

PATIENTS REFERED DUE TO COMMISIONING PATHWAYS

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: NIL

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

☐ I have undertaken bibliographic research on this procedure.

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

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

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

☐ Other (please comment)

Comments:

NIL

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 that procedure's safety and efficacy.
- [ ] Definitely novel and of uncertain safety and efficacy.
- [ ] The first in a new class of procedure.

Comments:

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

CATHETERISATION . MITROFANOFF PROCEDURE OR ILEAL CONDUIT DIVERSION

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

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

Comments:

MANY UROLOGIST SEE THESE PATIENTS BUT ONLY A FEW PERFORM THE PROCEDURE

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

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

1. Theoretical adverse events

PAIN
INFETION
LEAD MIGRATION
LEAD REVISION.
DEVICE REMOVAL

2. Anecdotal adverse events (known from experience)

SEE (1)

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

ALL OF (1)

4.2 What are the key efficacy outcomes for this procedure?

ABILITY TO VOID NORMALLY.
REDUCE ISR.
LOWER RESIDUAL VOLUME

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

LIMITED RCT FOR THE PROCEDURE
ALL SINGLE CENTRE SERIES

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

TRAINING COURSE
MENTORING

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

FRENCH & SWISS REGISTRIES
NO RCTS

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

No

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

No BUT COMMISSIONING ISSUES WITH NHS AT PRESENT

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):

1) ~~PROMS~~ WITH ICIQ VI SF EQ5D5L
2) LOWER RESIDUAL VOLUME
3) UTI RATES 4) ABILITY TO VOID

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

FAILURE
LEAD MIGRATION
PAIN
INFECTION

6 Trajectory of the procedure

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

ALREADY ESTABLISHED SO QUICK DIFFUSION BUT LIMITED BY NHS COMMISSIONING

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:

NONE BUT LIKELY TO BE 10-30 HOSPITALS

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:

MORE PTS BECOME ELIGIBLE BUT RESOURCES GENERALLY IN PLACE. A FEW COMMISIONED UNITS WOULD REQUIRE EQUIPMENT

7 Other information

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

No

8 Data protection and conflicts of interest

8.1 Data protection statement

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

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

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

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

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

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

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

Comments:

Nil

Thank you very much for your help.

Professor Bruce Campbell, Chairman, Interventional Procedures Advisory Committee

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

February 2010

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name:	**Sacral nerve stimulation for chronic non-obstructive urinary retention (1238/1)**
Name of Specialist Advisor:	**Simon Thomson**
Specialist Society:	**Neuromodulation Society of the United Kingdom and Ireland**
Please complete and return to:	azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

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

X☐ Yes.

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

1.1 Does the title used above describe the procedure adequately?

X☐ Yes.

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

Comments:

Although the testing procedure and requirement for general anaesthesia for implant will need to be changed. Implant procedure can be satisfactorily done under local anaesthesia with some supervised sedation (if required) as a day case.
Leads should be placed under image intensifier rather than by probing based upon surface landmarks. Better to use the definitive leads with temporary extension for test procedure and then either remove or completion implant after testing period.
If selection is good, technique good then high rates of testing period success may obviate the need for a testing period.

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

X☐ Yes.

X☐ 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:

Chronic urinary retention is diagnosed by specialist urological services. By the nature of the problem a purely biomedical assessment is not sufficient to select and follow up suitable candidates. Patients will need a biopsychosocial assessment sometimes drawing upon the expertise of a multidisciplinary team (nurse, psychologist, NM implanter). Those with the expertise and institutional capacity are best to carry out SNS implantation. This does not necessarily mean that this will be the diagnosing urologist but another associated member with expertise in neuromodulation implants and management

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

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

☐ I have never performed this procedure.

☐ I have performed this procedure at least once.

X☐ I perform this procedure regularly.

Comments:

The skills required for SNS are similar to other implantable neuromodulation devices that I perform regularly. I regularly perform SNS for other conditions such as pudendal neuropathic pain and incontinence

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.

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

Comments:

See above

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

X☐ I have undertaken bibliographic research on this procedure.

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

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

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

☐ Other (please comment)

Comments:

In order to prepare a business case to try to get SNS service commissioned. It failed thus far due to the current commissioning service framework.

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 that procedure's safety and efficacy.

☐ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

SNS is well established and not new. The indication (Chronic non-obstructive urinary retention) is not new, but to date there is no NICE IPG

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

Chronic intermittent self catheterisation

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

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

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

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

☐ Cannot give an estimate.

Comments:

More would do this procedure if it was properly commissioned.

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

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

1. Theoretical adverse events

2. Anecdotal adverse events (known from experience)

Discomfort of stimulation

Discomfort of implant materials

Decubitus ulceration

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

Implant infection requiring extended antibiotic administration or device removal

Damage to pre-sacral visceral structures, associated with poor technique

Lead migration or internal corruption requiring lead replacement procedure

Premature implantable pulse generator exhaustion or failure

4.2 What are the key efficacy outcomes for this procedure?

Specific and generic outcomes
Specific outcomes – Reduction in requirement of intermittent catheterisation and a 50% reduction of catheter volume per catheterisation
Generic outcomes – Global Impression of change, Health related quality of life

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

No there are no concerns about the efficacy of SNS in chronic non-obstructive urinary retention

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

Access to operating theatre with image intensifier
All members of team and theatre team should be familiar with their role

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

Currently there is only ONE device manufacturer for SNS, Medtronic. There is another manufacturer, Axonics, who are seeking CE mark and FDA regulatory approval. This is a rechargeable, smaller device

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

No

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

The main controversy is that currently NHS funding and capacity is unable to provide adequate access to this therapy

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):

Requirement for intermittent urinary catheterisation
Health related quality of life measures – SF36, (Not sure if EQ5D-5L used in this indication)

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

Lead migration and revision rates
IPG replacement rates

6 Trajectory of the procedure

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

There is a requirement for the systematic growth in access for patients for SNS both for urinary retention and incontinence.
The establishment of a suitable network needs NHS leadership in coalition with the already willing providers.

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:

There is an unmet need. Current provision of service is poorly organised and haphazard.
Commissioning of such services is chaotic.
However it is likely that one hospital network per SHA will be required

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:

For SNS in chronic urinary non-obstructive retention only.
Many more will benefit from SNS (OAB) for urinary and faecal incontinence

7 Other information

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

No

8 Data protection and conflicts of interest

8.1 Data protection statement

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

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

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

Do you or a member of your 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**

[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).

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

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

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

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

Comments:

I serve as President of International Neuromodulation Society (until June 2015), a professional education society. The INS advocates for improved access for patients to all types of neuromodulation. It encourages appropriate use and research.

I act as a consultant to Boston Scientific (Not a manufacturer of SNS, but other neuromodulation devices) and as a consultant to Axonics (pre-commercial company). Income is received based upon a fee for service and reasonable expenses

Thank you very much for your help.

Professor Bruce Campbell, Chairman, Interventional Procedures Advisory Committee

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

February 2010

Conflicts of Interest for Specialist Advisers

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

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

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

2 Personal pecuniary interests

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

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

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

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

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

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

2.2 No personal interest exists in the case of:

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

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

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

3 Personal family interest

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

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

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

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

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

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

3.2 No personal family interest exists in the case of:

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

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

4 Personal non-pecuniary interests

These might include, but are not limited to:

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

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

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

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

5 Non-personal interests

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

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

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

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

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