

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name: **Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache, migraine and medication overuse headaches (1116/1)**

Name of Specialist Advisor: **Dr Alok Tyagi**

Specialist Society: **British Association for the Study of Headache**

Please complete and return to: azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

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

Yes.

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

1.1 Does the title used above describe the procedure adequately?

Yes.

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

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

Yes.

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

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

Comments:

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

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

- I have never performed this procedure.
- I have performed this procedure at least once.
- I perform this procedure regularly.

Comments:

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

- I have never taken part in the selection or referral of a patient for this procedure.
- I have taken part in patient selection or referred a patient for this procedure at least once.
- I take part in patient selection or refer patients for this procedure regularly

Comments:

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

- I have undertaken bibliographic research on this procedure.
- I have undertaken research on this procedure in laboratory settings (e.g. device-related research).
- I have undertaken clinical research on this procedure involving patients or healthy volunteers.
- I have had no involvement in research on this procedure.

Other (please comment)

Comments:

3 Status of the procedure

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

Established practice and no longer new.

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

[Definitely novel and of uncertain safety and efficacy.](#)

The first in a new class of procedure.

Comments:

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

[Oral or injectable treatments](#)

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

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

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

[Fewer than 10% of specialists engaged in this area of work.](#)

Cannot give an estimate.

Comments:

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

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

1. Theoretical adverse events

[Cardiac arrhythmias](#)

2. Anecdotal adverse events (known from experience)

[Muscle pulling / irritation](#)

[Irritation of skin due to gel](#)

[Palpitations, dizziness, blood pressure or pulse rate changes](#)

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

4.2 What are the key efficacy outcomes for this procedure?

[Reduction in headache days](#)

[Reduction in headache frequency](#)

[Reduction in headache severity](#)

[Reduction in headache duration](#)

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

Efficacy unclear. No published data to support its use in headache disorders
Double blind trial conducted in cluster headaches and presented at meetings
suggests good efficacy in prevention and acute treatment of cluster headaches

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

Minimal. Training can be done in 10 minutes by clinical staff or online modules

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

Trial on use of this device in migraine due to commence in the UK this year

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.

[gammaCore® Use for Prevention and Acute Treatment of Chronic Cluster Headache: Findings From the Randomized Phase of the PREVA Study](#)

[Non-invasive Vagus Nerve Stimulation With gammaCore® for Prevention and Acute Treatment of Chronic Cluster Headache: A Report From the Extension Phase of the PREVA Study](#)

[Health-Related Quality of Life in Subjects Treated by Non-Invasive Vagus Nerve Stimulation Using gammaCore® for the Prevention and Acute Treatment of Chronic Cluster Headache: Report From the Extension Phase of the PREVA Study](#)

Each of these studies were presented at the EHMTIC (Migraine trust meeting) in Copenhagen in Sep 2014.

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):

Reduction in the number of headache days by more than 30 % from baseline
Reduction in the severity of headaches
Reduction in the use of acute headache medications
Reduction in headache disability scores (MIDAS / HIT6)

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

Any cardiac side effects

6 Trajectory of the procedure

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

I think this treatment will be used after standard treatments have failed

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

- Most or all district general hospitals.
- A minority of hospitals, but at least 10 in the UK.
- Fewer than 10 specialist centres in the UK.
- Cannot predict at present.

Comments:

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

Major.

Moderate.

Minor.

Comments:

7 Other information

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

8 Data protection and conflicts of interest

8.1 Data protection statement

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

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

Specialist Advisers should be aware that full implementation of the Freedom of Information Act 2000 may oblige us to release Specialist Advice from 2005. The Freedom of Information Act 2000 favours the disclosure of information however requests will be considered on a case by case basis. If information is made available, personal information will be removed in accordance with the Data Protection Act 1998. In light of this please ensure that you have not named or identified individuals in your comments.

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

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

Do you or a member of your family¹ have a **personal pecuniary** interest?
The main examples are as follows:

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

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

[NO](#)

Fee-paid work – any work commissioned by the healthcare industry – **this includes income earned in the course of private practice** YES

NO

Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry YES

[NO](#)

Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences YES

NO

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

[NO](#)

Do you have a **personal non-pecuniary** interest – eg have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic? YES

NO

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

Fellowships endowed by the healthcare industry YES

[NO](#)

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

[NO](#)

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

Comments:

Thank you very much for your help.

**Professor Bruce Campbell, Chairman,
Interventional Procedures Advisory
Committee**

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

February 2010

Conflicts of Interest for Specialist Advisers

- 1 **Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee**
 - 1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.
 - 1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.
- 2 **Personal pecuniary interests**
 - 2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as ‘**specific**’ or to the industry or sector from which the product or service comes, in which case it is regarded as ‘**non-specific**’. The main examples are as follows.
 - 2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
 - 2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
 - 2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.
 - 2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
 - 2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
 - 2.2 No personal interest exists in the case of:
 - 2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where

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

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

3 **Personal family interest**

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

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

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

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

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

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

3.2 No personal family interest exists in the case of:

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

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

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

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

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

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

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

5 Non-personal interests

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

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

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

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

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

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name: **Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache, migraine and medication overuse headaches (1116/1)**

Name of Specialist Advisor: **Dr Nicholas C Silver**

Specialist Society: **Association of British Neurologists**

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**

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:

I run a clinic in the NHS for severe and refractory headache disorders and also see patients privately. I have been involved as a Principal Investigator for 2 studies of Gammacore VNS device in treatment of Cluster Headache (Electrocore). The procedure is certainly relevant to my specialty, but also of potential interest to other specialisms including general, respiratory and GI medicine.

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

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

- I have never performed this procedure.
- I have performed this procedure at least once.
- I perform this procedure regularly.

Comments:

I have used handheld vagal nerve stimulation in clinical practice for more than 2 years on a regular basis, primarily for treatment of migraine, medication overuse and cluster headache. I have seen variable benefits, sometimes excellent, often in highly refractory patients with disabling headache syndromes. I have not come across any side effects or deleterious effects of using the device. In general, the device is well tolerated by a majority of patients.

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

- I have never taken part in the selection or referral of a patient for this procedure.
- I have taken part in patient selection or referred a patient for this procedure at least once.
- I take part in patient selection or refer patients for this procedure regularly.

Comments:

I commonly consider this procedure in patients requiring acute attack treatment where we have stopped painkillers and other acute attack treatments such as triptans (because of issues related to medication overuse / rebound headache), and this procedure may be useful as we are not aware of any rebound occurring with this device from initial experience. In addition, I have initiated use of this device as a preventative for migraine and cluster headache, as well as in syndromes of central sensitization presenting with predominant non-headache symptoms.

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

- I have undertaken bibliographic research on this procedure.
- I have undertaken research on this procedure in laboratory settings (e.g. device-related research).
- I have undertaken clinical research on this procedure involving patients or healthy volunteers.
- I have had no involvement in research on this procedure.
- Other (please comment)

Comments:

I have been Principal Investigator at the Walton Centre for two studies of Gammacore VNS (Electrocore) in cluster headache, both multicentre studies performed through Europe (GC02 and GC03). I am an author on abstracts related to these studies and on a paper submitted for publication related to the GC02 (PREVA) study.

At the Walton Centre, we had the largest recruitment numbers for patients in the UK for both of the above studies. We experienced no problems related to the device. We saw a number of patients who had excellent results, including some with severe refractory Cluster Headache. The device was generally popular and very well tolerated amongst patients. Patients with positive experience were keen to continue using the device as opposed to considering medical drug regimes with potential toxicity.

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 is a new technique, albeit not significantly different from existing procedures used in other areas of medicine. For example, whilst the nature of the electrical signal differs greatly from TENS and whilst this directly stimulates subcutaneous nerves as opposed to sending electrical signals into painful tissues, this device in essence (at least to patients and in terms of safety) shares many similar properties in

terms of general use. There is considered to be no concern related to efferent nerve stimulation and effects on the heart or gut as the voltage of the VNS device is much lower than required to stimulate such organs. It is considered that the device sends signals along the vagus nerve centrally in an afferent manner to effect the abnormal nerve functioning within the nervous system related to the above headache disorders. It is generally considered as very safe and there has been good safety data from preclinical and clinical studies to date.

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

For cluster headache acute treatment – high flow 100% oxygen, nasal triptans or subcutaneous triptan injectors (all potentially complicated by rebound headache or limited in frequency of use)

For cluster headache prevention – Verapamil (high dose to 960mg or more), Lithium, Topiramate, Occipital nerve stimulation (implantable device)

For migraine acute attacks – paracetamol, NSAIDS, triptans

For migraine prevention – Beta blockers, topiramate, candesartan, tricyclic antidepressants, valproate, flunarizine, cranial botox, riboflavin, magnesium, etc

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:

Most people using this device in clinical practice are neurologists with specialist interest in headache and many have participated and continue to participate in UK research trials for this device. Some use this in their private practice and a few of us have tried to initiate within the NHS, but this is difficult in the absence of NICE guidance and commissioning agreement (requirement of IPFR). A few doctors in other specialisms have also been interested in the device (eg gastroenterology, respiratory medicine, psychiatry) but I am not aware of whether any of these practitioners are using the device in their clinical as opposed to research practices.

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

Interaction with pacemaker devices

2. Anecdotal adverse events (known from experience)

Discomfort in neck (during stimulation only)

Hoarse voice (during stimulation only)

Shortness of breath (during stimulation only)

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

Not aware of any

4.2 What are the key efficacy outcomes for this procedure?

Reduction in headache frequency

Reduction in headache duration

Reduction in headache severity

Improved quality of life

Reduced disability

**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 required to undertake this procedure safely?

It takes approximately 5 minutes to teach patients to use this device successfully. No facilities are required.

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

There have been 2 large RCTs in cluster headache in the UK and there have been studies in migraine in the US. We are due to embark on phase 3 studies in migraine in the UK. I am not aware of a registry for this procedure.

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.

Non-Invasive Vagus Nerve Stimulation Using gammaCore for Prevention and Acute Treatment of Chronic Cluster Headache: Report from the Randomized Phase of the PREVA Study.

Presented at the Annual Meeting of the German Migraine and Headache Society (DMKG); October 22-25, 2014; Hamburg, Germany, and at the 4th European Headache and Migraine Trust International Congress; September 18-21, 2014; Copenhagen, Denmark.

Non-Invasive Vagus Nerve Stimulation Using gammaCore for Prevention and Acute Treatment of Chronic Cluster Headache: Report from the Open-label Phase of the PREVA Study.

Presented at the Annual Meeting of the German Migraine and Headache Society (DMKG); October 22-25, 2014; Hamburg, Germany, and at the 4th European Headache and Migraine Trust International Congress; September 18-21, 2014; Copenhagen, Denmark.

Quality of Life in Subjects Treated With Non-Invasive Vagus Nerve Stimulation Using gammaCore for the Prevention and Acute Treatment of Chronic Cluster Headache.

Presented at the Annual Meeting of the German Migraine and Headache Society (DMKG); October 22-25, 2014; Hamburg, Germany, and at the 4th European Headache and Migraine Trust International Congress; September 18-21, 2014; Copenhagen, Denmark.

Non-Invasive Vagus Nerve Stimulation for Chronic Migraine Prevention in a Prospective, Randomized, Sham–Controlled Pilot Study (the EVENT Study): Report from the Double blind Phase.

Presented at the American Headache Society (AHS), June 2014

Chronic Migraine Prevention With Non-Invasive Vagus Nerve Stimulation in a Prospective Pilot Study (the EVENT Study): Report from the Open-label Phase.

Presented at the American Headache Society (AHS), June 2014

Update On Non-Invasive Vagus Nerve Stimulation (nVNS) For The Treatment Of Primary Headache.

Satellite Symposium 4th European Headache and Migraine Trust International Congress, September 20, 2014

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):

Headache diary

HIT6

MIDAS

SF36

Weekly visual analogue scores (of headache condition severity)

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

Nil

6 Trajectory of the procedure

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

Fast

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 is likely to have widespread application if the device is appropriately costed and shows significant cost-effectiveness in the field of cluster headache, whereby it would be used in a majority of UK specialist neuroscience centres. If forthcoming studies in migraine show positive benefit, I would expect wider application in primary and secondary care. I am also aware of trials in UK primary care for multisymptomatic individuals where central sensitisation states are suspected and if these studies are positive, this may have impact for wider application in primary as well as secondary care. The ease of use, lack of side effects, and probable lack of rebound worsening all point to a useful, easy to use and safe modality of treatment.

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:

As above. However, the impact on the NHS will depend largely on cost of the device and more cost-effective payment options which allow unlimited use to allow best efficacy. It will be important that patients are allowed to use the device enough times to derive benefit and, as such, one would anticipate that cost effectiveness will rely on a low cost of the device as well as possible low and high use subscription models. If this proves effective in migraine for acute attacks or for prevention, the potential number of eligible and suitable patients in the UK will be very high, especially when taking into account the likely safety of the device and lack of drug-related side effects.

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 family¹ have a **personal pecuniary** interest?
The main examples are as follows: I have received reimbursement for

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).

educational stipend, I have received expenses and hospitality, and I have been provided research equipment by Electrocore. I have also participated as a paid Principal Investigator in clinical studies (all monies for the PI role have been given to the Walton Centre and I have derived no pecuniary interest from that particular role).

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

Fee-paid work – any work commissioned by the healthcare industry – **this includes income earned in the course of private practice** YES NO

Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry YES NO

Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences YES NO

Investments – any funds which include investments in the healthcare industry YES NO

Do you have a **personal non-pecuniary** interest – eg have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic? YES NO

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

Fellowships endowed by the healthcare industry YES NO

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

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

Comments:

I have received expenses to attend conferences and meetings
 I have participated in reimbursed working groups and provided consultancy advise as a scientific advisor to Electrocore
 I have received research equipment from Electrocore (approximate value £1000)
 I have received hospitality from Electrocore
 I have acted as a Principal Investigator for research studies funded by Electrocore and my employer has taken fees on my behalf for my involvement (paid to the research unit) – I have not and shall not receive money or income for participating in such studies.

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.
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- 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: **Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache, migraine and medication overuse headaches (1116/1)**

Name of Specialist Advisor: **Dr Giles Elrington**

Specialist Society: **Association of British Neurologists**

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.

1.1 Does the title used above describe the procedure adequately?

Yes.

Comments:

It's Medication overuse Headache – not Headaches

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?

Comments:

I don't share the enthusiasm of some of my colleagues for this procedure

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 performed this procedure at least once.

Comments:

I used to offer this to my patients but no longer as I was not impressed with efficacy; plus it is painful to use.

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

Comments:

Used to use it quite a lot when it was new but no longer

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

I have had no involvement in research on this procedure.

Other (please comment) When I was at the National Migraine Centre we tried to set up research on this device but never succeeded

Comments:

3 Status of the procedure

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

Definitely novel and of uncertain safety and efficacy.

Comments:

Problem is in blinding for clinical trials

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

None

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

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

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

It is painful to use. Could potentially slow the heart though I doubt it does so.

2. Anecdotal adverse events (known from experience)

Painful to use

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

None that I am aware of other than pain

4.2 What are the key efficacy outcomes for this procedure?

Improved QOL; diminished headache impact & frequency

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

Yes. I suspect the positive “blinded” trials reflect poor blinding

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

Very little it is quite simple to use

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

None that I am aware of

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

I am aware but do not have data to hand

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

Yes I think there is a big issue with placebo control and blinding – probably impossible with a device that delivers an electric shock

5 Audit Criteria

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

**QOL scores
MIDAS
HIT-6**

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

As above

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

Nopt a lot other than pain

6 Trajectory of the procedure

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

Rapid early adoption then rapid loss of enthusiasm in light of experience

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

Most or all district general hospitals.

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:

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?

Effective use requires maximum tolerable stimulation, achieving ipsilateral periorbital paraesthesia. This cannot be achieved with a placebo device. Therefore I suspect trial subjects can distinguish verum from placebo and this accounts for positive trial data.

8 Data protection and conflicts of interest

8.1 Data protection statement

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

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

Specialist Advisers should be aware that full implementation of the Freedom of Information Act 2000 may oblige us to release Specialist Advice from 2005. The Freedom of Information Act 2000 favours the disclosure of information however requests will be considered on a case by case basis. If information is made available, personal information will be removed in accordance with the Data Protection Act 1998. In light of this please ensure that you have not named or identified individuals in your comments.

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

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

Do you or a member of your family¹ have a **personal pecuniary** interest?
The main examples are as follows:

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 which include investments in the healthcare industry **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? **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.

**Professor Bruce Campbell, Chairman,
Interventional Procedures Advisory**

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

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).

Committee
February 2010

Conflicts of Interest for Specialist Advisers

- 1 **Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee**
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2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 **Personal family interest**

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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.

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

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

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

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

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

- 4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration
- 4.4 other reputational risks in relation to an intervention under review.

5 Non-personal interests

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- 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: **Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache, migraine and medication overuse headaches (1116/1)**

Name of Specialist Advisor: **Sarah Love-Jones**

Specialist Society: **Neuromodulation society of UK 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?

Yes.

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

1.1 Does the title used above describe the procedure adequately?

Yes.

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

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

Yes.

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

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

Comments:

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

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

- I have never performed this procedure.
- I have performed this procedure at least once.
- I perform this procedure regularly.

Comments:

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

- I have never taken part in the selection or referral of a patient for this procedure.
- I have taken part in patient selection or referred a patient for this procedure at least once.
- I take part in patient selection or refer patients for this procedure regularly.

Comments:

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

- I have undertaken bibliographic research on this procedure.
- I have undertaken research on this procedure in laboratory settings (e.g. device-related research).
- I have undertaken clinical research on this procedure involving patients or healthy volunteers.
- I have had no involvement in research on this procedure.
- Other (please comment)

Comments:

I have read papers and seen a poster presentation on this procedure

3 Status of the procedure

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

- Established practice and no longer new.
- A minor variation on an existing procedure, which is unlikely to alter that procedure's safety and efficacy.
- Definitely novel and of uncertain safety and efficacy.
- The first in a new class of procedure.

Comments:

Less invasive than Implanted vagal nerve stimulator

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

Implanted vagal nerve stimulator

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

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

Comments:

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

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

1. Theoretical adverse events

Cardiac arrhythmia

2. Anecdotal adverse events (known from experience)

Patient dislike of sensation

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

Skin irritation to conducting gel

Mild discomfort during use

Side- shifting attacks (pain changes side)

Worsening headache symptoms

Initial use of novel non-invasive vagus nerve stimulator for cluster headache. Nesbitt AD, Marin JCA, Tompkins E, Rutledge MH, Goadsby PJ. *Neurology* 10, Feb 20 2015.

4.2 What are the key efficacy outcomes for this procedure?

Reduction in medication

Cessation of headache

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

No. Initial pilot data suggest efficacy in acute migraine and cluster headache.

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

Operator training – fairly simple

Patient training

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

Acute Migraine US study: Goadsby P. Noninvasive Vagus nerve stimulation (nVNS) for acute treatment of migraine: an open-label pilot study, American Academy of Neurology's 65th AAN Annual Meeting, San Diego, California, USA

Cluster Headache EU Study: Nesbitt et al. Non-invasive Vagus Nerve Stimulation for the treatment of Cluster Headache: a case series. *The Journal of Headache and Pain* 2013, 1 (sup-p11):p231

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.

Yes

Initial use of novel non-invasive vagus nerve stimulator for cluster headache. Nesbitt AD, Marin JCA, Tompkins E, Ruttlegde MH, Goadsby PJ. Neurology 10, Feb 20 2015.

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):

reduction in frequency of headaches
reduction in length of headache episode
reduction in medication
patient satisfaction
ease of use

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

skin irritation
discomfort during use
worsening headache
cardiac arrhythmias

6 Trajectory of the procedure

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

A simple procedure to undertake. If efficacious and depending on cost, could gain widespread use

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

- Most or all district general hospitals.
- A minority of hospitals, but at least 10 in the UK.
- Fewer than 10 specialist centres in the UK.
- Cannot predict at present.

Comments:

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

- Major.
- Moderate.
- Minor.

Comments:

7 Other information

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

8 Data protection and conflicts of interest

8.1 Data protection statement

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

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Do you or a member of your family¹ have a **personal pecuniary** interest?
The main examples are as follows:

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

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

√
 NO

Fee-paid work – any work commissioned by the healthcare industry – **this includes income earned in the course of private practice** YES

√
 NO

Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry YES

√
 NO

Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences YES

√
 NO

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

√
 NO

Do you have a **personal non-pecuniary** interest – eg have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic? YES

√
 NO

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

Fellowships endowed by the healthcare industry YES

√
 NO

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

√
 NO

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

Comments:

Thank you very much for your help.

**Professor Bruce Campbell, Chairman,
Interventional Procedures Advisory**

**Professor Carole Longson, Director,
Centre for Health Technology**

Committee

Evaluation.

February 2010

Conflicts of Interest for Specialist Advisers

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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.

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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.

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- 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: **Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache, migraine and medication overuse headaches (1116/1)**

Name of Specialist Advisor: **Dr Shazia Afridi**

Specialist Society: **British Association for the Study of Headache**

Please complete and return to: azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

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

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

1.1 Does the title used above describe the procedure adequately?

- Yes.
- No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

- Yes.
- Is there any kind of inter-specialty controversy over the procedure?
- No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

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

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

- I have never performed this procedure.
- I have performed this procedure at least once.
- I perform this procedure regularly.

Comments:

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

- I have never taken part in the selection or referral of a patient for this procedure.
- I have taken part in patient selection or referred a patient for this procedure at least once.
- I take part in patient selection or refer patients for this procedure regularly.

Comments:

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

- I have undertaken bibliographic research on this procedure.
- I have undertaken research on this procedure in laboratory settings (e.g. device-related research).
- I have undertaken clinical research on this procedure involving patients or healthy volunteers.
- I have had no involvement in research on this procedure.
- Other (please comment)

Comments:

3 Status of the procedure

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

- Established practice and no longer new.
- A minor variation on an existing procedure, which is unlikely to alter that procedure's safety and efficacy.
- Definitely novel and of uncertain safety and efficacy.
- The first in a new class of procedure.

Comments:

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

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

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

Comments:

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

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

1. Theoretical adverse events

Cardiac,

2. Anecdotal adverse events (known from experience)

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

Hoarse voice, tingling

4.2 What are the key efficacy outcomes for this procedure?

Reduction in frequency/severity of headache episodes

Reduction in rescue medication

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

It appears to be more effective in cluster headache rather than migraine.
Need to have placebo/sham controlled studies

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

minimal

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

unaware

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

no

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

no

5 Audit Criteria

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

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

**Reduction in headache episode frequency/duration
MIDAS/HIT-6**

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

List any side effects-e.g sensory disturbance, voice change,

6 Trajectory of the procedure

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

6 months

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

- Most or all district general hospitals.
- A minority of hospitals, but at least 10 in the UK.
- Fewer than 10 specialist centres in the UK.
- Cannot predict at present.

Comments:

Depends on cost as well as efficacy

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:

Minor in migraine but maybe more significant proportion of cluster headache patients

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?

How does it compare to sham/placebo

How does it compare to other stimulator devices e.g TMS

8 Data protection and conflicts of interest

8.1 Data protection statement

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

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

Specialist Advisers should be aware that full implementation of the Freedom of Information Act 2000 may oblige us to release Specialist Advice from 2005. The Freedom of Information Act 2000 favours the disclosure of information however requests will be considered on a case by case basis. If information is made available, personal information will be removed in accordance with the Data Protection Act 1998. In light of this please ensure that you have not named or identified individuals in your comments.

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

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

Do you or a member of your family¹ have a **personal pecuniary** interest?
The main examples are as follows:

¹ ‘Family members’ refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for

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:

No conflicts of interest

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

whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

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.
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