NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name:	**Percutaneous interlaminar endoscopic lumbar discectomy for sciatica (1296/1)**
Name of Specialist Advisor:	**Mr John O'Dowd**
Specialist Society:	**British Association of Spinal Surgeons**
Please complete and return to:	azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

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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:

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:

[X] 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.

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

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

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

Comments:

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

[X] I have 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:

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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?

Open microdiscectomy

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:

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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

Dural tear
Neurological injury
Failure to complete discectomy
All less that 10%

2. Anecdotal adverse events (known from experience)

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

4.2 What are the key efficacy outcomes for this procedure?

1 Relief of leg pain
2 Improvement in disability score
3 Improvement in generic quality of life outcome measure eg EQ5D

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

Yes, no level 1 evidence establishing advantage over open procedure

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

Cadaveric course
Fellowship
mentoring

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

Not that I am aware of although in principle cases shoud be entered into tone of the spinal surgical registries

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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):

VAS leg pain
VAS back pain
Oswestry disability index
EQ5D

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

Complications-áll

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6 Trajectory of the procedure

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

Very slow, likely only to be adopted by a small number of enthusiasts

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:

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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.

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:

[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).

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Consultancies or directorships attracting regular or occasional payments in cash or kind	[x]	**YES**
	[ ]	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	[x]	**YES**
	[ ]	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	[x]	**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**
	[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?	[ ]	**YES**
	[x]	**NO**

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

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

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

Comments:

Director and shareholder of RealHealth NL

In private practice as a spinal surgeon

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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).

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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

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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.

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

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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.

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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name:	**Percutaneous interlaminar endoscopic lumbar discectomy for sciatica (1296/1)**
Name of Specialist Advisor:	**Mr Lennel Lutchman**
Specialist Society:	**British Association of Spinal Surgeons**
Please complete and return to:	azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

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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.

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? Yes.

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

Comments:
The procedure is not widely undertaken by orthopaedic surgeons in the UK. There is greater experience of this technique amongst neurosurgeons with a spinal interest. There appears to be a recognition that this is a valid technique but associated with a “steep learning curve” and some technical challenges. Conventional techniques of lumbar discectomy (microdiscectomy and open discectomy) are effective and safe. The adoption of percutaneous discectomy by orthopaedic spinal surgeons has therefore been slower than amongst neurosurgeons in the UK.

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.

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.

Comments:
The proponents of the percutaneous technique site a rapid postoperative recovery with a high proportion of same day discharge following the procedure. Many surgeons achieve same day discharge using microdiscectomy in appropriately selected patients and I have found no requirement to refer patients for percutaneous discectomy.

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.

Comments:
The published literature appears to support the use of the technique with non-inferiority compared to “conventional” lumbar discectomy techniques. Early discharge appears to be the principal benefit but with no demonstrable medium or long-term advantages.

3 Status of the procedure

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

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

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

Open or microscope-assisted lumbar discectomy

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

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

Comments:
There is likely to be an overrepresentation of spinal neurosurgeons compared to orthopaedic spinal surgeons performing this procedure. It is growing in popularity with some orthopaedic surgeons seeking training (cadaver courses and visiting neurosurgical units for fellowship purposes) in the technique. It remains to be seen whether those who learn the technique will adopt it as their preferred technique for lumbar discectomy.

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

No different to conventional discectomy. Possible higher recurrence rate or incomplete decompression associated with a "learning curve" but not supported by the published literature.

2. Anecdotal adverse events (known from experience)

Comparable to conventional discectomy.

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

No different to conventional discectomy.

4.2 What are the key efficacy outcomes for this procedure?

1. Resolution of radicular (leg) pain.
2. Recurrence rate (reoccurrence of leg pain following the procedure) following an initial resolution of the leg pain

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

Concerns about the "learning curve" are probably comparable to any new procedure being undertaken by a surgeon.

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

1. Cadaveric courses.
2. Training in a unit with an expertise in the technique.

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Special access portals are required for surgical access but are widely, commercially available.

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

No specific registries exist in the UK but practitioners should be submitting surgical data to the National Spinal Registry (BASS)

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

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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):

Visual Analogue Score (VAS) for back pain and leg pain pre and post operatively
Oswestry Disability Index (ODI) score pre and post operatively
EQ-5D score (generic patient reported outcome measure) pre and post operatively
Length of Hospital Stay
Recurrence rate of leg pain

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

Intraoperative complications including dural tear (inadvertent durotomy) rate as per conventional discectomy.
Early recurrence of leg pain requiring revision surgery (within 1 year of the index surgery)

6 Trajectory of the procedure

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

I believe the procedure will grow in popularity considerably over the next five years but it is unclear if there is any advantage to conventional discectomy and whether the increase will be sustained.

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

☐ Cannot predict at present.

Comments:
Most specialist spinal centres in the UK are likely to have at least one consultant who carries out these procedures especially as newly appointed consultants are likely to have been exposed to the technique during training.

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

☐ Moderate.

Comments:
There are a large number of eligible patients with several thousand lumbar discectomies being performed annually. The initial investment in the equipment required is likely to be offset by an increase in day-case discectomy rates. As pointed out, many conventional discectomy patients can be treated as day-cases but this is likely to be more common with percutaneous discectomy.

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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 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

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[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).

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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 Committee

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

February 2010

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Conflicts of Interest for Specialist Advisers

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

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2.1.5 **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

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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.

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.

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

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

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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

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

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

5 Non-personal interests

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

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

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

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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name:	**Percutaneous interlaminar endoscopic lumbar discectomy for sciatica (1296/1)**
Name of Specialist Advisor:	**Mr Naffis Anjarwalla**
Specialist Society:	**British Association of Spinal Surgeons**
Please complete and return to:	azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

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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:

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:

Orthopaedic and Neurosurgical trained spinal surgeons

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 am in training to perform it

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:

When patients have asked I have referred them to specialist units to seek an opinion concerning the procedure

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

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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:

On viewing the procedure there does seem to be a greater risk to the dural sac than with transforaminal, which obviously is not that easy at L5/S1 anyway

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

Standard Open Discectomy
Tubular Discectomy

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

nerve injury, dural tear, scar tissue, retained fragment, need to convert to open procedure, recurrence, haematoma

2. Anecdotal adverse events (known from experience)

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

4.2 What are the key efficacy outcomes for this procedure?

resolution of leg pain, return to activity, reduced hospital length of stay and costs

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

learning curve, any real benefit to open procedure

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

use of endoscopic equipment, percutaneous approach to the spine, learning curve in doing it, appropriate equipment and the facilities (scopes, endoscopic surgical equipment, anaesthetic, imaging and sterile environment) in which to perform the procedure and follow up the patient
Audit facility and a clinical governance oversight of new procedures

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

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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.

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

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):

VAS, EQ5D, ODI/COMI/LBOS
hospital length of stay, cost
theatre utilisation

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

complications as stated above
need to revert to open procedure
recurrence
need for further treatment

6 Trajectory of the procedure

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

Slow in the UK

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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:

My projection of how widespread it will be is looking to the future. I do not see the majority of DGH's offering this in the next 5 years.

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:

It could have a significant impact on routine treatment of one of the most common levels to be operated on.

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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 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

☐ **NO**

☐ **YES**

Fee-paid work – any work commissioned by the healthcare

[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).

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industry **– this includes income earned in the course of private practice**

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? ☐ **YES**

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:

It is a procedure that I am hoping to become trained in and eventually be able to offer to my patients

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

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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

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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.

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

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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.

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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name: **Percutaneous interlaminar endoscopic lumbar discectomy for sciatica (1296/1)**

Name of Specialist Advisor: **Nihal gurusinghe**

Specialist Society: **Society of British Neurological Surgeons**

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

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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:

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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?

① Percutaneous endoscopic transforaminal Laser discectomy
② Open Lumbar Microdiscectomy

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:

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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

Dural Injury - CSF Leak
Nerve Injury - new neurological symptoms
Infection
Bleeding
Recurrence.

2. Anecdotal adverse events (known from experience)

none

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

Dural injury with CSF leak + Dysaesthesiae (Choi - Neurosurgery Feb 2006. Vol 58 no 1. Suppl. p. ONS59)

Also, ① Choi - Pain Physician Nov 2013 vol 16 no. 6 p 547-556.
② Singh - Pain Physician 2013: 16: SE229

4.2 What are the key efficacy outcomes for this procedure?

Relief of Sciatica.
Length of stay
Time to return to work
Operating Time

Mainly suitable for L5/S1 discs.

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

Is it suitable for Recurrent disc prolapse?
Scar tissue from previous operation may make it more difficult and risky.

Is it more suitable for <u>contained</u> or <u>extruded</u> discs

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

- Courses with hands on experience
- Workshops with hands on Cadaver work
- Training in Specialist Unit
- Fellowship

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

Dont know

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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?

Dont Know

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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):

VAScore for Leg Pain
Oswestry Disability score
Time to return to work

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

- No benefit
- Recurrence
- Nerve injury
- CSF leak
- Infection
- Epidural haematoma

6 Trajectory of the procedure

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

Slow

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

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

Comments:

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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.
- [x] 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?

Discectomy can be done by physical methods other than Laser.

8 Data protection and conflicts of interest

8.1 Data protection statement

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

☐ YES
☑ NO

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:

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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

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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.

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

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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.

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