

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

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

Please respond in the boxes provided.

Please complete and return to: Sally.Jones@nice.or.uk or Hawra.Abuqulal@nice.org.uk

Procedure Name: Extracorporeal shockwave therapy for refractory Achilles tendinopathy

Name of Specialist Advisor: Dr Anand Kirwadi

Specialist Society: British Society of Skeletal Radiologists

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

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

1.1 Does the title used above describe the procedure adequately?

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

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

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

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

Comments:

This procedure is being undertaken by radiologists, orthopaedicians, sports medicine physicians and specialist physiotherapists as well.

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

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

- I have never done this procedure.
- I have done this procedure at least once.
- I do this procedure regularly.

Comments:

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

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

Comments:

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

- I have done bibliographic research on this procedure.
- I have done research on this procedure in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure involving patients or healthy volunteers.

- I have had no involvement in research on this procedure.
- Other (please comment)

Comments:

I have read few articles recently.

3 Status of the procedure

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

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

Comments:

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

Conservative management.

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

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

Comments:

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

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

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

Transient skin reddening, mild to moderate discomfort during the procedure, calf ache

2. Anecdotal adverse events (known from experience)

Tendon rupture

3. Theoretical adverse events

Persistent or worsening of symptoms

*Reference: Extracorporeal shockwave therapy (ESWT) for refractory Achilles tendinopathy: a prospective audit with 2-year follow up
J Taylor, S Dunkerley, D Silver, A Redfern, N Talbot... - The Foot, 2015*

4.2 What are the key efficacy outcomes for this procedure?

Pain relief

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

There is still need for further research to be undertaken to quantify the efficacy of this procedure.

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

Training in using the equipment and recognising the complications.

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

There have been few studies published so far. I am not aware current trials in UK.

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

Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

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):

Improvement in the pain score (like VAS)
Improvement in the activity scores (like VISA-A)
Quality of life improvement scores

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

Early: Skin reddening, calf ache and discomfort during the procedure
Late: Tendon rupture, persistence or recurrence of symptoms.

6 Trajectory of the procedure

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

Over the next 2-3 years

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. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

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

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

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

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

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

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

Do you or a member of your 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 that include investments in the healthcare industry YES

NO

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

NO

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

Fellowships endowed by the healthcare industry YES

NO

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.**

April 2014

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.
- 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 Advisor is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

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

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

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Please respond in the boxes provided.

Please complete and return to:

nice.org.uk.
Sally.Jones@nice.org.uk or
Hawra.Abugulal@nice.org.uk

Procedure Name:

Extracorporeal shockwave therapy for refractory
 Achilles tendinopathy

Name of Specialist Adviser:

Mr Anthony Perera

Specialist Society:

British Orthopaedic Foot Surgery Society

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 speciality?

Yes.

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

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

Comments:

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

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

- I have never done this procedure.
- I have done this procedure at least once.
- I do this procedure regularly.

Comments:

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

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

Comments:

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

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

Other (please comment)

Comments:

3 Status of the procedure

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

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

Comments:

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

*Injection of corticosteroid
physiotherapy.*

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

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

Comments:

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

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

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

Bruising

*** RX REPORT ***

INCOMPLETE RECEPTION

TX/RX NO	6247
DESTINATION TEL #	
DESTINATION ID	
ST. TIME	25/01 09:56
TIME USE	03'24
PGS.	5
RESULT	NG

2. Anecdotal adverse events (known from experience)

None known.

3. Theoretical adverse events

None known though rupture is a risk there are

4.2 What are the key efficacy outcomes for this procedure?
no reports of this

Pain Relief - VISA A / VISA B.

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

I do not believe that it works for interdigital aches
tendonopathy. The literature also does not demonstrate this.

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

Company provided training - 1 session on how to use
the machine

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

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

Please note that NICE will do a literature search: we are only asking you
for any very recent or potentially obscure abstracts and papers. Please
do not feel the need to supply a comprehensive reference list (but you
may list any that you think are particularly important if you wish).

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

I do not believe that it works for interdigital aches
tendonopathy and ^{by} this condition structure is very painful.

5 Audit Criteria

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

VAS.

VISA A B.

MOXAQ.

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

VAS, Visc AIB, Max FQ.

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

Rupture
Pain

6 Trajectory of the procedure

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

Slower amongst doctors but more rapidly with physiotherapists / podiatrists.

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. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

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

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

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

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

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

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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 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

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).

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

YES

NO

Investments – any funds that include investments in the healthcare industry

YES

NO

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

YES

NO

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

Fellowships endowed by the healthcare industry

YES

NO

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.

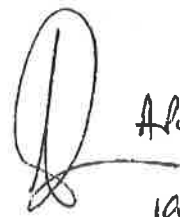
Comments:

Thank you very much for your help.

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

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

April 2014


ALONGSON
12/01/16

Conflicts of Interest for Specialist Advisers

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 - 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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 - 2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
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 - 2.2.1 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.
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- 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
- 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 Advisor 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.

*** RX REPORT ***

RECEPTION OK

TX/RX NO	6248
DESTINATION TEL #	
DESTINATION ID	
ST. TIME	25/01 10:02
TIME USE	04'59
PGS.	7
RESULT	OK

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Please respond in the boxes provided.

Please complete and return to: Sally.Jones@nice.or.uk or Hawra.Abuqulal@nice.org.uk

Procedure Name: Extracorporeal shockwave therapy for refractory Achilles tendinopathy (IP719/2)

Name of Specialist Advisor: Dr Silver

Specialist Society: BSSR

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

Yes.

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

1.1 Does the title used above describe the procedure adequately?

Yes.

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

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

Yes.

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

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

Comments:

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

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

- I have never done this procedure.
- I have done this procedure at least once.
- Y I do this procedure regularly.

Comments:

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

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

Comments:

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

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

Other (please comment)

Comments:

3 Status of the procedure

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

Established practice and no longer new.

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

Definitely novel and of uncertain safety and efficacy.

The first in a new class of procedure.

Comments:

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 doing this procedure (choose one):

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

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

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

Cannot give an estimate.

Comments:

MOSTLY FOOT AND ANKLE ORTHODS FOR THIS INDICATION?

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

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

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

LOCAL BRUISING, TENDON RUPTURE BUT VERY VERY RARE

2. Anecdotal adverse events (known from experience)

NIL SIGNIFICANT

3. Theoretical adverse events

BRUISING

4.2 What are the key efficacy outcomes for this procedure?

PAIN RELIEF IN GREATER THAN 70%

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

NOT FROM MY EXPERIENCE

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

TRAINING IN CLINICAL DIAGNOSIS, USE OF IMAGING (ULTRASOUND) AND USE OF SHOCKWAVE MACHINE

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

ASSERT 1/2

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

Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

ATTACHED

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

THERE WAS PREVIOUS CONTROVERSY BUT THIS WAS DUE TO THE PREVIOUS NICE guidance which failed to separate radial from non-radial devices

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):

pain relief and functional scores

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

6 Trajectory of the procedure

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

has significantly increased in last 5 years

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:

POPULARITY HAS BEEN DRIVEN IN LAST 5 YRS BY COMMISSIONING IN NHS AND PMI REIMBURSEMENT

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?

NOTE THAT MOST PUBLISHED SERIES SUGGEST PAIN RELIEF IS AFTER 3 MONTHS RATHER THAN 6 WKS FOR OTHER CLINICAL INDICATIONS. THE CURRENT NICE PATIENT QUESTIONNAIRE OVERLOOKS THIS

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

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

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

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

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

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

Do you or a member of your 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

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).

	N	
Fee-paid work – any work commissioned by the healthcare industry – this includes income earned in the course of private practice	Y	YES
	<input type="checkbox"/>	
	<input type="checkbox"/>	
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	<input type="checkbox"/>	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	<input type="checkbox"/>	YES
	<input type="checkbox"/>	NO
Investments – any funds that include investments in the healthcare industry	<input type="checkbox"/>	
	<input type="checkbox"/>	NO
Do you have a personal non-pecuniary interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	<input type="checkbox"/>	YES
	<input type="checkbox"/>	NO
Do you have a non-personal interest? The main examples are as follows:		
Fellowships endowed by the healthcare industry	<input type="checkbox"/>	
	<input type="checkbox"/>	NO
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	<input type="checkbox"/>	
	<input type="checkbox"/>	NO

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

Comments:

PRESIDENT ELECT OF BSSR. HAVE LECTURED FOR INDUSTRY SPONSORED EVENTS. OWN MY OWN MACHINE
Thank you very much for your help.

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

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

April 2014

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 Advisor is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

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

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

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

Please respond in the boxes provided.

Please complete and return to: Sally.Jones@nice.or.uk or Hawra.Abugulal@nice.org.uk

Procedure Name: Extracorporeal shockwave therapy for refractory Achilles tendinopathy

Name of Specialist Advisor: Mr Matthew Solan

Specialist Society: British Orthopaedic Foot Surgery Society

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:

Title should specify whether MAIN BODY of tendon or the INSERTION

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 procedure can be done by other specialists - but only after FULL ASSESSMENT and after SIMPLER FIRST LINE Therapy has failed

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

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

- I have never done this procedure.
- I have done this procedure at least once.
- I do this procedure regularly.

Comments:

The treatment is useful but reserved STRICTLY for the (minority) of patients who do not get better with proper physio stretching regimens. Many patients "fail" because they do not stretch properly or often enough

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

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

Comments:

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

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

- I have done clinical research on this procedure involving patients or healthy volunteers.
- I have had no involvement in research on this procedure.
- Other (please comment)

Comments:

I run a specialist clinic for refractory Heel Pain that includes a lot of Achilles tendon problems of the MAIN BODY and the INSERTION

3 Status of the procedure

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

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

Comments:

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

Injections (high volume or prolotherapy) or surgery

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

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

Comments:

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

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

1. Adverse events reported in the literature (if possible please cite literature)
discomfort, red skin, bruising, FAILURE TO RESPOND

2. Anecdotal adverse events (known from experience)
Failure to respond (approx 30%)

3. Theoretical adverse events
Tendon rupture

4.2 What are the key efficacy outcomes for this procedure?

Reduced pain, improved function

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

Uncertainties. Again the results depend upon which part of the TENDON (Main Body vs Insertion to heel bone) is considered. These 2 are very different conditions and I recommend that the Guidance is dealt with in 2 parts to distinguish them.

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

Training can be achieved in one day, but patient selection and decision to treat is more complex. There is a concern that shockwave will be used indiscriminantly as a "miracle" for patients who would recover with diligent use of physio stretching regimens.

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

The ASSERT protocol, which I contribute to, run by Professor Maffuli

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

Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

ASSERT is not yet reported. Good outcomes for both types of Achilles problem are anticipated from preliminary results. ASSERT 2 in progress

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

Selection. Allowing indiscriminant use of this treatment will be expensive and strict rules should be applied re completing PROPER PHYSIO exercises first.

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):

Pain score; general QUAL score eg SF-12, EQ5D; specific Foot and Ankle Score eg MOX-FQ; Specific Achilles tendon score eg VISA-A. NB need to distinguish MAIN BODY achilles problems vs INSERTIONAL type. They are very different.

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

Failure to improve; Rupture of tendon

6 Trajectory of the procedure

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

Too fast if the indications are not managed carefully. Most patients recover without this treatment

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:

see next comment

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 if used sensibly, but potentially wastefully if used for "all-comers" in a non-selective way. There is a real danger of this

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. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

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

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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 YES

NO

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

NO

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

NO

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

NO

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

NO

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

NO

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

Fellowships endowed by the healthcare industry YES

NO

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:

NHS and Private Heel Pain Clinic, treating these disorders. Industry sponsored training Fellowship for post CCT Trainee. Funds to support Training Courses for Foot and Ankle Surgery. Lectures advising on Treatments for Achilles problems
Thank you very much for your help.

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

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

April 2014

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).

Conflicts of Interest for Specialist Advisers

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 - 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)
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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.

- 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 Advisor is responsible. This does not include financial assistance for students
 - the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
 - one or more contracts with, or grants from, NICE.
- 5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

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

Please respond in the boxes provided.

Please complete and return to: Sally.Jones@nice.or.uk or Hawra.Abugulal@nice.org.uk

Procedure Name: Extracorporeal shockwave therapy for refractory Achilles tendinopathy

Name of Specialist Advisor: Dr Richard Graham

Specialist Society: British Society of Skeletal Radiologists

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

Yes.

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

1.1 Does the title used above describe the procedure adequately?

Yes.

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

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

Yes.

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

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

Comments:

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

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

- I have never done this procedure.
- I have done this procedure at least once.
- I do this procedure regularly.

Comments:

I perform an alternative technique for this condition regularly called “high volume Achilles stripping”.

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

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

Comments:

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

- I have done bibliographic research on this procedure.
- I have done research on this procedure in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure involving patients or healthy volunteers.

I have had no involvement in research on this procedure.

Other (please comment)

Comments:

3 Status of the procedure

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

Established practice and no longer new.

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

Definitely novel and of uncertain safety and efficacy.

The first in a new class of procedure.

Comments:

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

High volume Achilles Stripping

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

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

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

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

Cannot give an estimate.

Comments:

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

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

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

Skin trauma and bruising
Tendon rupture (rare)

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

4.2 What are the key efficacy outcomes for this procedure?

Reduction in pain at rest and during activity. Increase in function e.g distance can walk/run

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

It is becoming accepted practice. It is thought to work better in non-insertional than insertional Achilles tendinopathy

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

A extracorporeal shockwave therapy machine, a couch and a room.
Minimal training < 1 day

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

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

Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

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 pain score at 2 weeks both at rest and during exercise

Simple functional questions at 2 weeks:

- 1. Do your Achilles tendon symptoms limit your activity (Y/N)?**
- 2. How far can you walk/run symptom free? (measure also prior to the procedure)**
- 3. Have your symptoms improved/stayed the same/worsened?**

A more thorough assessment can be made with the VISA-A questionnaire:

http://bjsm.bmj.com/content/suppl/2001/11/09/35.5.335.DC1/01055_Fig_1_data_supplement.pdf

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

Tendon rupture, bruising, worsening of symptoms

6 Trajectory of the procedure

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

There are no great treatments for refractory Achilles tendinopathy and since this treatment has low risks and the equipment needed to perform it is relatively inexpensive I think it will become common practice soon.

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.

X Minor.

Comments:

7 Other information

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

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Fellowships endowed by the healthcare industry YES
 NO

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 undertake private practice in radiology at BMI Bath Clinic, Circle Bath and at the Royal United Hospital Bath.

I have shares in Circlehealth

My wife has a unit trust, Framlington Health, which invest in healthcare

Thank you very much for your help.

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

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

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

April 2014

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 Advisor is responsible. This does not include financial assistance for students
 - the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
 - one or more contracts with, or grants from, NICE.
- 5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

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Please respond in the boxes provided.

Please complete and return to: Sally.Jones@nice.or.uk or Hawra.Abugulal@nice.org.uk

Procedure Name: Extracorporeal shockwave therapy for refractory Achilles tendinopathy (IP719/2)

Name of Specialist Advisor: Mr Robert Clayton

Specialist Society: British Orthopaedic Foot Surgery Society

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:

It is important to differentiate between mid substance Achilles tendinopathy and insertional Achilles tendinopathy. The two are different disease entities with different treatments

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:

I am not sure what is meant by controversy. There is no particular controversy, but some physiotherapists, sports medicine physicians and musculoskeletal radiologists also perform this procedure. Similarly I have patients referred to me from specialists in these disciplines.

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

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

I have never done this procedure.

I have done this procedure at least once.

I do this procedure regularly.

Comments:

I perform this procedure on average on two patients every week

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

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

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

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

Comments:

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

I have done bibliographic research on this procedure.

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

Comments:

I had intended to sign up to the ASSERT study (a multicentre study on efficacy) but could not receive adequate reassurance about control of my data, access to my own results and whether the ethical, Caldicott and other approvals gained were valid in Scotland.

3 Status of the procedure

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

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

Comments:

This procedure has been in widespread use in Europe for over ten years

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

Physiotherapy (which is used, in my practice, in combination with this treatment). There is no good alternative. This procedure saves many patients from having to undergo surgery

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

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

Comments:

This is a proportion of specialist Orthopaedic foot and ankle surgeons, not a proportion of all orthopaedic surgeons

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

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

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

Transient pain, swelling, numbness, erythema. I am aware of two cases of Achilles rupture in the large scale trials of this treatment (Rompe et al) – considering achilles rupture is in any case occasionally observed in patients with achilles tendinopathy I am not sure that the rupture in these patients was due to the ESWT but I do advise my patients of these two cases.

2. Anecdotal adverse events (known from experience)

Temporary pain, numbness and erythema. I have not seen this to last more than 48 hours.

I have never seen, or even heard of, a patient with a tendon rupture in my own or anyone else's practice

3. Theoretical adverse events

Achilles tendon rupture as above.

4.2 What are the key efficacy outcomes for this procedure?

Relief of pain. Usually measured by Visual Analogue Pain Scores, Foot Function Index, Manchester-Oxford Foot Questionnaire.

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

There are a few studies suggesting that the procedure may not bring about significant lasting pain relief

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

One ESWT machine is needed (which involves capital outlay but minimal running costs). It takes about one hour to train a doctor or physiotherapist to perform the procedure. The procedure is performed in a clinic room or physiotherapy treatment area.

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

ASSERT trial

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

Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

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, other than a minority of clinicians who do not perform the procedure because they doubt its efficacy. The treatment is not universally available

5 Audit Criteria

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

Visual analogue Pain Score with one or both of Manchester-Oxford Foot Questionnaire and Foot Function Index measured pre-treatment and again at three months and one year

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):

As above under adverse effects.

6 Trajectory of the procedure

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

I anticipate it being available in most NHS hospitals within the next five years.

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:

At a consensus setting meeting of foot and ankle surgeons' meeting three years ago, an informal poll suggested around a third of surgeons had access to this in their NHS practice

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:

Achilles tendinopathy is a very common condition. ESWT is also used for plantar fasciitis, another common treatment. Other treatment options are not ideal, either because they lack efficacy (such as physiotherapy alone), or carry risks (such as injections). Surgery has uncertain outcomes and significant risks and recovery times for Achilles tendinopathy.

7 Other information

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

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

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

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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 YES
 NO

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

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

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

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

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

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

Fellowships endowed by the healthcare industry YES
 NO

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:

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).

I carry out ESWT as a small part of a specialist foot and ankle private practice. I receive fees for the provision of this treatment at standard commercial rates. The fees I receive for this comprise less than 5% of my private practice income.

I own a shareholding in Spire Healthcare plc worth £1000. My wife owns a shareholding of £1000 in Quintiles plc

I own a standard portfolio of investment funds, some of which will contain healthcare shares but I do not know the specific of which companies these funds invest in and I have no ability to instruct the fund managers as to where to direct their investments.

Thank you very much for your help.

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

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

April 2014

Conflicts of Interest for Specialist Advisers

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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.

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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- 3.1.2 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)
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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.

- 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 Advisor is responsible. This does not include financial assistance for students
 - the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
 - one or more contracts with, or grants from, NICE.
- 5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

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

Please respond in the boxes provided.

Please complete and return to: Sally.Jones@nice.or.uk or Hawra.Abuqulal@nice.org.uk

Procedure Name: Extracorporeal shockwave therapy for refractory Achilles tendinopathy

Name of Specialist Advisor: Mr Roland Russell

Specialist Society: British Orthopaedic Foot Surgery Society

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

Yes.

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

1.1 Does the title used above describe the procedure adequately?

Yes.

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

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

Yes.

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

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

Comments:

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

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

- I have never done this procedure.
- I have done this procedure at least once.
- I do this procedure regularly.

Comments:

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

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

Comments:

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

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

Other (please comment)

Comments:

3 Status of the procedure

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

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

Comments:

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

Physiotherapy and ultrasoundtherapy(low frequency)

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

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

Comments:

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

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

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

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

There is a theoretical risk of making pain worse and a small risk of Achilles tendon rupture

**4.2 What are the key efficacy outcomes for this procedure?
Moxfd score and VAS pain score**

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

As far as I am aware there is a lack of randomised controlled studies to show the efficacy of this procedure

**4.4 What training and facilities are needed to do this procedure safely?
Physio/clinician that is trained to do this procedure**

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.

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

Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

Eccentric loading versus Eccentric loading with shock wave for midportion Achilles tendonopathy; a randomised controlled study; Rompe. Am Journal of Medicine 2009 37, 463

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

In my view there is a lack of cocnclusive scientific evidence to advocate this procedure

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):

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

6 Trajectory of the procedure

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

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?

as above

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

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

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

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

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

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

Do you or a member of your family¹ 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

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

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

Thank you very much for your help.

Professor Bruce Campbell, Chairman, Interventional Procedures Advisory Committee

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

April 2014

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.

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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 Advisor is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

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

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

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Please respond in the boxes provided.

Please complete and return to: Sally.Jones@nice.or.uk or
Hawra.Abugulal@nice.org.uk

Procedure Name: Extracorporeal shockwave therapy for refractory Achilles tendinopathy

Name of Specialist Advisor: Mr Tim Clough

Specialist Society: British Orthopaedic Foot Surgery Society

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: Regularly assess and treat this condition

2.1 Is this procedure relevant to your specialty?

Yes.

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

Comments:

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

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

- I have never done this procedure.
- I have done this procedure at least once.
- I do this procedure regularly.

Comments:

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

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

Comments:

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

- I have done bibliographic research on this procedure.
- I have done research on this procedure in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure involving patients or healthy volunteers.

- I have had no involvement in research on this procedure.
- Other (please comment)

Comments:

3 Status of the procedure

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

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

Comments:

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 doing this procedure (choose one):

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

Comments:

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

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

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

Pain, Bruising, swelling, numbness

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

Ligament rupture and damage to the soft tissues

4.2 What are the key efficacy outcomes for this procedure?

Resolution of pain

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

Success rate of procedure

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

Training on use of the equipment.

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

ASSERT protocol (online national database)

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

Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

Translational Medicine UniSal 2014; Sep-Dec: 10: 46-51: Maffulli G, Hemmings S, Maffulli N

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.

VISA-A + MOXFQ scores (before, 3, 6, 12 months after treatment)

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

see above

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

pain, tendon rupture, failure of benefit

6 Trajectory of the procedure

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

in common 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. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

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

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

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

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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 YES

NO

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

NO

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

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

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

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

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

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

Fellowships endowed by the healthcare industry YES
 NO

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.**

April 2014

Conflicts of Interest for Specialist Advisers

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 - 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.
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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.
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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**

- 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 Advisor 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.