

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name: **Joint distraction for ankle osteoarthritis (1276/1)**

Name of Specialist Advisor: **Andrew Bing**

Specialist Society: **British Limb Reconstruction Society (BLRS)**

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

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

Yes.

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

1.1 Does the title used above describe the procedure adequately?

Yes.

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

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

Yes.

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

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

Comments:

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

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

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

Comments:

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

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

Comments:

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

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

Comments:

3 Status of the procedure

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

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

Comments:

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

It is really a salvage procedure performed in patients not keen on fusion and too young or otherwise not suitable for joint replacement surgery. Beyond conservative treatment, injection, simple arthroscopic surgery and aggressive open debridement with soft tissue releases there is little performed that is comparative to this procedure. The next stage is fusion or joint replacement surgery.

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

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

Comments:

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

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

1. Theoretical adverse events

Infection, nerve or blood vessel injury, anaesthetic risks, blood clots, stiffness, persistent symptoms, complex regional pain syndrome, avascular necrosis of the talus

2. Anecdotal adverse events (known from experience)

None beyond those mentioned above

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

4.2 What are the key efficacy outcomes for this procedure?

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

Outcomes are variable

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

Training in application and management of frames for this type of procedure
Orthopaedic surgical training with an interest in foot and ankle surgery / limb reconstruction surgery

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, e.g. PUBMED? (This can include your own work). If yes, please list.

No

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

Not that I am aware of

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):

There are no validated scores specifically for this type of procedure but one would probably use outcome scores such as the MOX-FQ and EQ5D/QALY/SF-36
There are other scoring systems for ankle conditions such as AOFAS

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

Infection, nerve / arterial injury, blood clots, complex regional pain syndrome, stiffness, failure to improve, deterioration in arthritis, AVN of talus/collapse

6 Trajectory of the procedure

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

Slow

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

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

Comments:

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

- Major.
- Moderate.
- Minor.

Comments:

7 Other information

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

8 Data protection and conflicts of interest

8.1 Data protection statement

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

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

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

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

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

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

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

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

NO

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

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

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

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

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

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

Fellowships endowed by the healthcare industry YES
 NO

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

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

Comments:

I have a consultancy agreement with MatOrtho specifically relating to training and development work with their BOX ankle replacement. This work attracts occasional payments.

Thank you very much for your help.

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

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

February 2010

Conflicts of Interest for Specialist Advisers

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

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

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

3 **Personal family interest**

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

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

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

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

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

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

3.2 No personal family interest exists in the case of:

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

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

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

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

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

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

5 Non-personal interests

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

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

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

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

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

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name: **Joint distraction for ankle osteoarthritis (1276/1)**

Name of Specialist Advisor: **Mr Arshad Khaleel**

Specialist Society: **British Orthopaedic Foot & Ankle Society**

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

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

Yes.

1.1 Does the title used above describe the procedure adequately?

Yes.

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?

None from the people who did it. Patient selection criteria is important.

Comments:

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

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

I perform this procedure regularly.

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

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

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

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

Comments:

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

I have undertaken bibliographic research on this procedure.

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

Comments: whilst I have not undertaken formal clinical research I have observed my patients

3 Status of the procedure

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

Established practice and no longer new.

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

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

Ankle fusion

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

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

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

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

1. Theoretical adverse events

1 It does not work: symptoms of pain and stiffness persist

2 make symptoms worse

3 introduce deep infection – extremely unlikely though

4 neurovascular injury: exceedingly rare

5 add/create deformity – extremely rare

2. Anecdotal adverse events (known from experience)

1 did not work – no improvement in pain

2 minor pin site related infection – got better with antibiotics

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

As above

4.2 What are the key efficacy outcomes for this procedure?

1 improvement in symptoms

2 avoid or delay ankle fusion

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

It does not work every single time – i.e. improvement in symptoms is not guaranteed and may not be permanent

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

Regular experience with external fixators for team: surgeons, nurses, theatre staff, OPD, radiology, pain team

Would help selection if surgeon also familiar with Foot and Ankle Surgery

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

I am not aware of any trials.

BLRS is looking at outcome scores for Limb reconstruction patients

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

No

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

Limited knowledge about the procedure and results
Probably disseminated through word of mouth and personal contacts

5 Audit Criteria

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

Age
Aetiological diagnosis
Pain score
Disability grade
Ankle/Sub-talar and Foot range of movement
Ankle stability
Foot and ankle deformity
Radiological grade of arthritis

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

1 improvement in quality of life score (SF12)
2 improvement in foot and ankle functional scores (oxford)
3 avoid ankle fusion permanently or > 10 years

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

1 infection
2 failure of treatment and need for further surgery
3 iatrogenic nerve or artery injury

6 Trajectory of the procedure

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

slow

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

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

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

Minor.

Comments:

few patients qualify for this procedure and even fewer opt for this treatment option

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?

Not aware of any issue

8 Data protection and conflicts of interest

8.1 Data protection statement

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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	NO
Fee-paid work – any work commissioned by the healthcare industry – this includes income earned in the course of private practice	NO
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	NO
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	NO

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).

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

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

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

Fellowships endowed by the healthcare industry **NO**

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

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

Comments:

Thank you very much for your help.

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

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

February 2010

Conflicts of Interest for Specialist Advisers

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 - 2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
 - 2.2 No personal interest exists in the case of:
 - 2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where

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**

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

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

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name: **Joint distraction for ankle osteoarthritis (1276/1)**

Name of Specialist Advisor: **Mr Hemant K Sharma**

Specialist Society: **British Limb Reconstruction Society (BLRS)**

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

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

Yes.

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

1.1 Does the title used above describe the procedure adequately?

Yes.

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

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

Yes.

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

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

Comments:

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

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

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

Comments:

Usually in young patients with severe osteoarthritis

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

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

Comments:

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

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

Comments:

3 Status of the procedure

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

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

Comments:

This is not exactly main stream procedure (usually not provided as a standard option by most surgeons for treatment of osteoarthritis of ankle) but used regularly.

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

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

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

Comments:

Technique is usually practised by limb reconstruction surgeons.

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

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

1. Theoretical adverse events

Septic arthritis, DVT, Persistent Pain / problem (failure of procedure), worse off, tendon, nerve, artery injury. Stiffness, Pin track pain and infection, pin track related osteomyelitis, frame adjustment, CRPS

2. Anecdotal adverse events (known from experience)

Difficult to tolerate frame, broken wires,

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

Pin track problem commonest problem, Similar risks

4.2 What are the key efficacy outcomes for this procedure?

Improvement in pain
Increase in joint space

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

Regularly used in established OA but uncertainties remain in rheumatoid arthritis and arthritis with well preserved joint space.

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

Surgeon should be well versed with principles of Circular frame surgery.
Established limb reconstruction units with experienced surgeons trained in circular frame surgery.

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

None I am aware of

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

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

Whether to perform static distraction or distraction with ankle movements. Although there is a RCT performed in US.

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

Validated generic health score

Measurement of ankle joint space with standardised x rays

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

pin track infection

pin track related osteomyelitis

neurological injury

persistent pain

septic arthritis

secondary procedures

6 Trajectory of the procedure

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

I do not expect this technique to diffuse very rapidly, principally because this procedure is performed by limb reconstruction surgeons and specialised units, which are very few in the country. I suspect this may be the reason that not many foot and ankle surgeons offer this option.

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:

There would be more than 10 units in the country, theoretically all limb reconstruction units and some foot and ankle units can offer this procedure.

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:

However, if this procedure becomes main stream then resource utilization may potentially increase.

7 Other information

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

8 Data protection and conflicts of interest

8.1 Data protection statement

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Fellowships endowed by the healthcare industry YES
 NO

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

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

Comments:

I provide paid Consultancy services for Biocomposites in relation with CaSO₄ and CaPO₄ bone fillers / putty.

In next 12 months, I will be providing paid consultancy services for teaching and training for Orthofix.

Thank you very much for your help.

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

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

February 2010

Conflicts of Interest for Specialist Advisers

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

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

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

3 **Personal family interest**

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

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

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

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

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

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

3.2 No personal family interest exists in the case of:

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

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

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

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

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

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

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

5 Non-personal interests

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

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

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

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

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

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name: **Joint distraction for ankle osteoarthritis (1276/1)**

Name of Specialist Advisor: **Mr Hisham Shalaby**

Specialist Society: **British Limb Reconstruction Society (BLRS)**

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

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

Yes.

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

1.1 Does the title used above describe the procedure adequately?

Yes.

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

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

Yes.

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

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

Comments:

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

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

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

Comments:

- For a very selected group of patients

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

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

Comments:

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

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

Comments:

3 Status of the procedure

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

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

Comments:

- The technique is clearly described in the literature. But due to the paucity of cases and studies and due to selection bias it should be kept for a small group of patients and should not be advocated as standard practice.

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

- Ankle fusion or ankle replacement

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

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

Comments:

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

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

1. Theoretical adverse events
 - Infection that preclude further reconstruction with ankle fusion or ankle replacement
2. Anecdotal adverse events (known from experience)
 - Stiffness or clawing of the toes

- Pain during distraction
- Ongoing pain post frame removal

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

1. Ongoing pain due to the arthritis
2. Pin-site infection (5% risk).
3. Ankle or knee joint dislocation (1% risk).
4. Injury to nerves and vessels during frame application (1% risk).
5. Irritation of the nerves and vessels during the distraction (4% risk).
6. Complex Regional pain syndrome (1% risk).
7. Deep venous thrombosis (DVT) (3% risk of clinically significant DVT)
8. Pulmonary embolism (0.1 %risk). Can sometimes be fatal.

4.2 What are the key efficacy outcomes for this procedure?

- Improvement in the pain level
- Improvement in the joint space radiologically that continues up to 2 years post frame removal
- Improvement in the activities the patient can do and the amount of walking and exercising that they can do.

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

- There is a degree of unpredictability of the outcome and the level of improvement expected. In some patients they get an excellent improvement were as in others this improvement can take a while. In my hands patients with complex ligamentous injuries and those with clear clinical instability are unlikely to improve.

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

- Surgeons need to be experienced in Limb reconstruction techniques and the use of circular frames as well as Foot and Ankle surgery to properly evaluate the patient and to initiate adjuvant surgical techniques, which are commonly combined with the distraction like anterior ankle arthroscopic debridement.
- The hospital or facility should have available all the instruments for circular frame application and the theatre staff should have good experience with the technique to reduce the time of an already lengthy procedure. Intra operative image intensifier should be always available.

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, e.g. PUBMED? (This can include your own work). If yes, please list.

- No

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

- There is a mixed feeling among surgeons about the efficacy of this procedure. I believe the reason for that is that the procedure is undertaken by Limb Reconstruction surgeons, who have no special interest in Foot & Ankle surgery, or the other way round. Also the majority of surgeons use a TSF frame for this purpose (because it is easier to apply), which is not dynamic. It has been shown in the literature that dynamic distraction yields much better outcome.

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):

- AOFAS score
- MOXFQ
- VAS
- EQ5D
- Radiological change in joint space
- Clinical measurement of the Ankle range of movement

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

- Ultimate failure of treatment as indicated by the need for ankle fusion / replacement or below knee amputation

6 Trajectory of the procedure

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

- Very minimal due to the prerequisite of surgeon training and hospital facilities and capacity

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?

Clear selection criteria for this procedure should be set. In my practice these are:

Absolute:

- Age below 45 years
- Post traumatic arthritis (Not inflammatory)
- Limited range of dorsiflexion of the ankle
- Lack of gross ankle instability

Preferable

- Non smoker
- Other wise healthy
- BMI less than 30

Adjuvant procedures like anterior ankle arthroscopy debridement should be added to improve the outcome particularly in patients with sharp anterior ankle pain (from impingement) or with clear radiological picture of anterior osteophytes.

Dynamic distraction should be done if possible. This is done using an Ilizarov frame with constrained hinges to allow the ankle to move at the end of the distraction process.

8 Data protection and conflicts of interest

8.1 Data protection statement

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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 | <input type="checkbox"/> YES |
| | <input checked="" type="checkbox"/> NO |
| Fee-paid work – any work commissioned by the healthcare industry – this includes income earned in the course of private practice | <input type="checkbox"/> YES |
| | <input checked="" type="checkbox"/> 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 which include investments in the healthcare industry YES
 NO

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

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

Fellowships endowed by the healthcare industry YES
 NO

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

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

Comments:

I have none of the above conflicts of interests. I provide consultancy to an Orthopaedic company (Integra Lifescience) which has nothing to do with this particular procedure. Companies manufacturing the external fixators (like Smith & Nephew) make contributions (sponsorship) to annual scientific meetings in the department (just like other companies do) with no direct involvement with me personally.

Thank you very much for your help.

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

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

February 2010

Conflicts of Interest for Specialist Advisers

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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**

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

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

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

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

3.2 No personal family interest exists in the case of:

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

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

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

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

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

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

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

5 Non-personal interests

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

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

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

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

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

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name: **Joint distraction for ankle osteoarthritis (1276/1)**

Name of Specialist Advisor: **Neal Jacobs**

Specialist Society: **British Limb Reconstruction Society (BLRS)**

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

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

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

1.1 Does the title used above describe the procedure adequately?

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

Comments:

Also known as 'ankle arthrodiastasis'

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 majority of patients with Ankle OA will be presenting to and be managed by Foot & ankle specialists. However only those foot and ankle surgeons who have expertise with Ilizarov external fixation techniques or who have a close working relationship with a limb reconstruction surgeon familiar with the techniques will be positioned to offer this technique.

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

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

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

Comments:

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

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

Comments:

As part of my BOA travelling fellowship I spent 2 weeks with Drs Rozbruch and Fragomen at the Hospital of Special Surgery, New York. They have been championing this technique alongside their foot and ankle colleagues, and have published widely on it. I observed them undertake 5 cases of ankle distraction and saw many of their patients in the out-patient department, who were largely extremely satisfied. I am currently working as a new consultant specialising in trauma, complex limb reconstruction and foot & ankle surgery. I have already reviewed a few patients in my clinic that I feel would benefit from the procedure, but am yet to operate on them.

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

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

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

Comments:

3 Status of the procedure

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

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

Comments:

Ankle joint distraction has been described over 2 decades ago, however as the number of surgeons proficient with Ilizarov techniques has been relatively small, the technique has not become widespread practice.

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

Ankle fusion is the 'gold standard' for severe ankle OA – a robust reliable operation, but one that sacrifices the joint and its movement resulting in permanent stiffness. Total ankle replacement arthroplasty is the other main alternative. This aims to preserve movement but does also sacrifice the natural joint. There are concerns with long term outcomes and a few of the implants have been withdrawn from the market. Not ideal for the young patient with high functional demand.

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

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

Comments:

I would estimate at least 50% limb reconstruction surgeons proficient with Ilizarov techniques would be happy to offer this technique, but I suspect that very few

referrals for it are made from the foot and ankle community as it is not widely appreciated as an alternative option.

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

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

1. Theoretical adverse events

Pin site infections, pain, joint stiffness, lack of clinical improvement, nerve injury, fracture

2. Anecdotal adverse events (known from experience)

Superficial pin site infections are a common but very minor problem with prolonged application of circular frames, but easily managed with very low rate of deep infection.

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

Superficial pin site infections *Tellisi et al 2009, Foot & Ankle Int.*

4.2 What are the key efficacy outcomes for this procedure?

Decrease pain

Preserve/ improve range of ankle movement

Improve function

Preserve joint

Increase joint space

Does not burn any bridges for fusion or arthroplasty surgery at a later stage if required.

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

Long term efficacy of the procedure for maintaining improved function and reduced pain.

Optimal clinical indications and contraindications

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

Surgeon familiar with Ilizarov surgery techniques and ankle surgery

Circular frame external fixation equipment

Ward and out-patient support for patient with circular external-fixation frame in situ

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

Dr Rozbruch and his team at HSS, New York have been championing the technique over the recent years. They have published a lot recently regarding the technique and they are in the process of preparing a case series with for publication including 1 year follow-up MRI radiological outcome data.

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

YES:

LLRS July 2014. Short Term Results of Magnetic Resonance Imaging after Ankle Distraction Arthroplasty, Haleem AM. MD, Nwawka O. M2, Belagadi A. BS, Borst E. BS, Mintz DN. MD, Fragomen AT. MD , Rozbruch SR. MD
http://www.llrs.org/PDFs/Annual%20Meeting%20Presentations/Saturday2014Presentations/20_AnkleDistractionHaleem.pdf

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

Optimal duration of ankle distraction using external fixation? 3 months better than 6 weeks.

Hinged frame allowing ankle movement or static frame? Better results with hinged frame allowing movement.

Should the procedure be combined with debridement of the joint osteophytes and microfracture?

Use of additional biological adjuncts such as injection of concentrated bone marrow aspirate?

Any difference in efficacy when performed for primary OA or post-traumatic OA?

Role for the procedure in the presence of associated ligamentous instability or deformity?

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):

**Pre- and post-op AOFAS scores and PROMs (eg MOXFQ)
Range of movement of joint pre- and post-op
Walking distance**

Pain scores and analgesia use

Radiological measurements – such as joint space on weight-bearing views pre- and post-op

General health outcome scores- EQ5D/ SF36

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

Deep Infection

Stiffness

Nerve injury

Fracture

6 Trajectory of the procedure

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

I think uptake will be slow, as many surgeons perceive circular external fixation to be technically difficult to perform as well as difficult for the patient to live with. The majority of the UK foot and ankle surgeons are currently unaware of the potential clinical benefit this procedure could offer their patients.

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:

Difficult to predict at present, but if long term clinical benefit is proven and awareness disseminated I would envisage the procedure being performed in at least 10 UK centres.

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:

I think the biggest indication for this procedure will be younger patients (especially under 50yrs) with widespread post-traumatic ankle OA who still have reasonable range of movement of the ankle, and for whom arthrodesis is not a particularly attractive option. The aim here will be to reduce pain, improve function and delay any requirement for arthrodesis or arthroplasty surgery. Relatively speaking I think this represents a rather small, select patient group.

7 Other information

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

8 Data protection and conflicts of interest

8.1 Data protection statement

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

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

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

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

Please state any potential conflicts of interest, or any involvements in disputes or complaints, relevant to this procedure. Please use the “Conflicts of Interest for Specialist Advisers” policy (attached) as a guide when declaring any

conflicts of interest. Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

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

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

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

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

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

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

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

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

Fellowships endowed by the healthcare industry YES
 NO

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

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

Comments:

Thank you very much for your help.

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

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

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

February 2010

Conflicts of Interest for Specialist Advisers

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

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

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

3 **Personal family interest**

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

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

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

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

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

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

3.2 No personal family interest exists in the case of:

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

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

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

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

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

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

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

5 Non-personal interests

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

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

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

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

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

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name: **Joint distraction for ankle osteoarthritis (1276/1)**

Name of Specialist Advisor: **Mr Nima Heidari**

Specialist Society: **British Limb Reconstruction Society (BLRS)**

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

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

Yes.

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

1.1 Does the title used above describe the procedure adequately?

Yes.

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

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

Yes.

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

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

Comments:

This procedure spans both foot and ankle and limb reconstruction.

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

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

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

Comments:

I have performed this procedure 5 times in past 2years.

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

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

Comments:

I both select for and perform this surgery. I have had referrals from other colleagues as well.

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

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

Comments:

I have a fair knowledge of the literature on this procedure. All patients undergoing this procedure under my care will have their outcomes measured.

3 Status of the procedure

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

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

Comments:

This procedure is not new. It is not regularly performed however.

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

Ankle Arthrodesis, Ankle Arthroplasty, Ankle arthroscopy
This depends on the severity of arthritis

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

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

Comments:

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

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

1. Theoretical adverse events

All those associated with ankle arthroscopy and those associated with application of an ankle spanning frame:

Infection (ankle joint and pinsites), Thromboembolism, Non-resolution of ankle symptoms, having a frame on for 3 months restricting movements, neurovascular injury from pin placement, ankle stiffness.

Possible osteomyelitis at pintract infection site requiring prolonged antibiotics

2. Anecdotal adverse events (known from experience)

As above

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

As above

4.2 What are the key efficacy outcomes for this procedure?

Reduction in pain scores, reduction in use of analgesics, delay in performing definitive procedure such as Arthrodesis or arthroplasty

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

We don't know the cut off for when ankle arthritis is too advanced for distraction arthrolysis.

Pattern of arthritis may also be important as those with anterior wear do not do as well.

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

Surgeon needs to be able to perform ankle arthroscopy and apply fine wire circular frames.

The unit should have expertise in looking after fine wire frames both as in and out patients. This essentially requires a limb reconstruction nurse specialist.

Patients need to be counselled and assessed prior to the procedure as once the procedure is performed they are committed to 3 months of treatment with a circular frame.

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

Not to my knowledge

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

Not to my knowledge

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 has been controversy as regards whether to perform hinged or static distraction.

Patients with anterior disease seem to have worse outcomes.

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):

Manchester and Oxford F&A score

SF 36

Ankle OA Score

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

Early: Pin site infections, Hardware failure including wire breakage requiring revision surgery, neurovascular injury from pin placement, traction injury from distraction where nerves are scarred due to post traumatic scarring.

Late: Bone sequestrae from pinsites and pinsite infections. Failure to resolve ankle pain following procedure.

6 Trajectory of the procedure

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

Unsure.

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

Most or all district general hospitals.

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

Fewer than 10 specialist centres in the UK.

Cannot predict at present.

Comments:

This should probably be in a few specialist centres in the UK. The need for specialist knowledge of applying and looking after frames will restrict their use. Good data on outcome should be kept in order to assess the true value of the procedure.

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

Major.

Moderate.

Minor.

Comments:

7 Other information

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

8 Data protection and conflicts of interest

8.1 Data protection statement

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

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

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

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

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

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

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

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

Fellowships endowed by the healthcare industry YES
 NO

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

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

Comments:

Consultancy for Ideal Med a medical devices company.
Hospitality from Smith and Nephew for travel and board as faculty for an international meeting.

Thank you very much for your help.

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

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

February 2010

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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.

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

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