

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

Interventional Procedures Programme

**Specialist Adviser questionnaire**

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

**Please respond in the boxes provided.**

**Please complete and return to:** Deonee.Stanislaus@nice.org.uk

**Procedure Name:** Low intensity pulsed ultrasound to promote fracture healing

Name of Specialist Advisor: David Goodier

Specialist Society: British Limb Reconstruction Society

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

Yes.

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

**1.1 Does the title used above describe the procedure adequately?**

Yes.

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

**Comments:**

The word ‘promote’ is ambiguous. Does it mean accelerate normal healing, or treat proven delayed or non-union?

**2 Your involvement in the procedure**

**2.1 Is this procedure relevant to your specialty?**

Yes.

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

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

**Comments:**

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

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

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

**Comments:**

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

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

**Comments:**

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

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

Other (please comment)

**Comments:**

### **3 Status of the procedure**

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

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

**Comments:**

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

Waiting for union, reoperation

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

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

**Comments:**

### **4 Safety and efficacy**

#### **4.1 What is the potential harm of the procedure?**

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

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

None. No case reports or evidence of harm.

2. Anecdotal adverse events (known from experience)

none

3. Theoretical adverse events

none

**4.2 What are the key efficacy outcomes for this procedure?**

Fracture union

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

Yes. Plenty of evidence for use in established non-union. Anecdotal/ retrospective case series about treatment of fresh fractures. Meta-analyses showing not useful in fresh fractures.

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

None. Very simple. Patients need 5 minutes of teaching how to use it.

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

Unknown. Nothing sponsored by our society.

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

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

No; nothing very new I know of since BMJ 2017;356:j656

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

All the evidence suggests it does not have an effect in fresh fractures, but this is being given the message that 'it doesn't work' when it may have a role in the management of non-union.

## **5 Audit Criteria**

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

**Union as an outcome; established non-union (failure of progression over 3 months at a minimum of 9 months post fracture)**

**5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:**

**radiographic union, need for reoperation. Both are binary outcomes.**

**5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:**

**none. Non-invasive treatment**

## **6 Trajectory of the procedure**

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

**Already has.**

**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:**

Unfortunately the widespread, industry advertised, non-specialised use of the product means it is used on fractures that have good reason not to heal (avascular bone for an example). This dilutes the beneficial effect when results are looked at across the board. The same holds true of papers that mix the use in fresh fractures with non-union. If restricted to people with experience of treating non-union then it would probably be more effective and therefore more cost effective.

## **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?**

Yes. As you might have gathered by now, need to look at the use in fresh fractures separately from non-union.

## **8 Data protection and conflicts of interest**

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

#### **8.1 Data Protection**

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

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

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

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

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

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

Do you or a member of your family<sup>1</sup> have a **personal pecuniary** interest? The main examples are as follows:

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

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

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

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

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

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

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

**Fellowships** endowed by the healthcare industry  YES  
 NO

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

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

**Comments:**

Thank you very much for your help.

**Dr Tom Clutton-Brock, Interventional  
Procedures Advisory Committee Chair**

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

**Jan 2016**

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

## Conflicts of Interest for Specialist Advisers

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

- 1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.
- 1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

### 2 Personal pecuniary interests

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



### 3 **Personal family interest**

- 3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.
- 3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.
- 3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.
- 3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).
- 3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)
- 3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
- 3.2 No personal family interest exists in the case of:
- 3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)
- 3.2.2 accrued pension rights from earlier employment in the healthcare industry.

### 4 **Personal non-pecuniary interests**

These might include, but are not limited to:

- 4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review
- 4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence
- 4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration
- 4.4 other reputational risks in relation to an intervention under review.

### 5 **Non-personal interests**

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

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

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

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

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

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Interventional Procedures Programme

**Specialist Adviser questionnaire**

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**Please respond in the boxes provided.**

**Please complete and return to:** Deonee.Stanislaus@nice.org.uk

**Procedure Name:** **Low intensity pulsed ultrasound to promote fracture healing**

**Name of Specialist Advisor:** Om Lahoti

**Specialist Society:** **British Limb Reconstruction Society**

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

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

**1.1 Does the title used above describe the procedure adequately?**

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

**Comments:**

My suggested title is – Low Intensity pulsed ultrasound to enhance fracture healing. In the context of clinical practice a clinician is faced with two common situations –

1. Accelerate healing of an acute fracture i.e. enhance naturally occurring healing process so that patient can return to work/independence/free of pain earlier than the natural process.
2. More common situation is when a fracture fails to heal completely i.e. develops non-union, where the natural healing process is either incomplete or completely stalled. Does Low Intensity Pulsed Ultrasound (LIPUS) enhance i.e. kick start healing in such a situation and avoid further surgery such as bone grafting and revising the fixation? I have not used this technique for

acute fractures and I face with situation 2 on a regular basis in my clinical practice.

## **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:**

Use of LIPUS is mainly in the domain of orthopaedic surgeons and I have seen spinal surgeons use it occasionally for enhancing spinal fusion

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

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

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

#### **Comments:**

I have prescribed LIPUS on a regular basis until my own clinical experience in over 20 cases was not encouraging and recent BMJ article (BMJ2017;356:J576 doi: 10.1136/bmj.j576) reinforced my own clinical experience of very little beneficial effect of LIPUS.

### **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:**

Patients are referred to me for the management of non union and I decide whether a trial of LIPUS is indicated or not. Increasingly clinicians who have no access to LIPUS via there trust are referring cases to us for LIPUS (having decided that patient needs it).

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

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

**Comments:**

**3 Status of the procedure**

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

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

**Comments:**

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

In my view surgery (refixation of fracture with a plate or nail, autologous bone grafts or use of bone 'stimulants' such as demineralised bone matrix) is the best comparator. Institutes outside UK electromagnetic coil stimulation for non union and report similar or enhanced results.

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

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

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

**Comments:**

Across the NHS there are generally designated limb reconstruction units that have access to NHS funded LIPUS equipment. King's College Hospital is one such unit where I work. It is difficult for me to give an estimate of centres/surgeons using LIPUS but I estimate it to be around 10% of hospitals using it.

#### **4 Safety and efficacy**

##### **4.1 What is the potential harm of the procedure?**

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

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

2. Anecdotal adverse events (known from experience)

Rare - Irritation of skin from ultrasound gel – One of my patients developed severe skin rash, requiring prolonged use of corticosteroid cream.

3. Theoretical adverse events

##### **4.2 What are the key efficacy outcomes for this procedure?**

In my opinion, achieving bony union and or not requiring further surgery to heal the bone are the main outcomes. Other measures that are used in literature are return to work, ability to put full weight through the limb (i.e. ability to walk without pain in lower limb fractures).

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

In my view, uncertainties are

1. When does one start using LIPUS – after definitive non-union, or earlier than established non-union in high risk fractures such as high energy, open fractures. If latter then whether we should be providing this treatment in ALL high-risk fractures?
2. Patient factors: It is well established that smoking is detrimental to fracture healing. Should we be using LIPUS in such patients when bone biology is poor? Other examples include diabetes and alcohol abuse.

3. Human factors – compliance issues and airline restrictions on taking the equipment on board.

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

Very little training is needed to use modern LIPUS which has safeguards built in – i.e. a timer, a calendar to alert patient of non compliance.

#### **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 registry but I suspect industry keeps track of equipment (but not necessarily the outcomes). Individual hospitals keep database of patients and their outcomes but not in any agreed format.

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

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

No

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

Controversy – which fracture non union should be treated with LIPUS – Hypertrophic/Atrophic, Gap non union – what is the critical gap – circumferential or segmental defect at the fracture site.

### **5 Audit Criteria**

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

Age of the patient

Biological factors – smoker, diabetes

Trauma factors – high/low energy fractures, open/closed fractures,

Fracture treatment factors – type of implant (plate or nail). Is the fixation stable? Time since surgery and initiation of LIPUS

#### **5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:**

##### **Outcome measure**

Fracture healing –

Weight bearing through fractured limb (before full bone union), in cases that are not surgically fixed

##### **Method**

X-ray/CT scan

Patient questionnaire

**5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:**

Not relevant to this procedure

**6 Trajectory of the procedure**

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

It is already in widespread use – its use is restricted on the NHS but in private/self funded sector it is more widely used.

**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:**

If it is proven that LIPUS is effective in enhancing fracture healing (currently there is strong evidence against accelerated fracture healing or healing of non unions) then it has the potential to be widely used – it is a non invasive procedure and it is easy to master the use of equipment with very little training.

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

- Major.
- Moderate.
- Minor.

**Comments:**

The impact on the NHS will be huge if this current review concludes that LIPUS promotes faster healing in acute fracture and equipment should be provided to all acute fractures.

Impact will be moderate if its use is 'regulated' in some way i.e. limited indications such as high risk fractures, patients not fit for further surgery etc.



## 7 Other information

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

No

## 8 Data protection and conflicts of interest

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

#### 8.1 Data Protection

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

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

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Do you or a member of your family<sup>1</sup> have a **personal pecuniary** interest? The main examples are as follows:

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 NO

**Fee-paid work** – any work commissioned by the healthcare industry – **this includes income earned in the course of private practice**  YES  
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**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  
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**Investments** – any funds that include investments in the healthcare industry  YES  
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Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?  YES  
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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.

**Dr Tom Clutton-Brock, Interventional  
Procedures Advisory Committee Chair**

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

**Jan 2016**

## Conflicts of Interest for Specialist Advisers

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  - 2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
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- 2.2 No personal interest exists in the case of:
  - 2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)
  - 2.2.2 accrued pension rights from earlier employment in the healthcare industry.

### 3 **Personal family interest**

- 3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'**, or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples include the following.
- 3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.
- 3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.
- 3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).
- 3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)
- 3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
- 3.2 No personal family interest exists in the case of:
- 3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)
- 3.2.2 accrued pension rights from earlier employment in the healthcare industry.

### 4 **Personal non-pecuniary interests**

These might include, but are not limited to:

- 4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review
- 4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence
- 4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration
- 4.4 other reputational risks in relation to an intervention under review.

### 5 **Non-personal interests**

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

- 5.1.1 **Fellowships** – the holding of a fellowship endowed by the healthcare industry.
- 5.1.2 **Support by the healthcare industry or NICE** – any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:
- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
  - a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Advisor is responsible. This does not include financial assistance for students
  - the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
  - one or more contracts with, or grants from, NICE.
- 5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

Interventional Procedures Programme

**Specialist Adviser questionnaire**

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

**Please respond in the boxes provided.**

**Please complete and return to:** Deonee.Stanislaus@nice.org.uk

**Procedure Name:** Low intensity pulsed ultrasound to promote fracture healing

**Name of Specialist Advisor:** Paul Dixon

**Specialist Society:** British Orthopaedic Association (BOA)

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

Yes.

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

**1.1 Does the title used above describe the procedure adequately?**

Yes.

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

**Comments:**

**2 Your involvement in the procedure**

**2.1 Is this procedure relevant to your specialty?**

Yes.

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

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

**Comments:**

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

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

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

**Comments:**

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

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

**Comments:**

Undertaken personally only

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

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

Other (please comment)

**Comments:**

### **3 Status of the procedure**

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

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

**Comments:**

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

No intervention

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

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

**Comments:**

Hard to know as outpatient procedure

### **4 Safety and efficacy**

#### **4.1 What is the potential harm of the procedure?**

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

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

None to my knowledge



2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

**4.2 What are the key efficacy outcomes for this procedure?**

Fracture union either more quickly or because of the intervention

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

Yes, difficult to supply control group.

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

None

**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, for example PUBMED? (This can include your own work). If yes, please list.**

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

None of which I'm aware

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

Efficacy is debatable in majority of cases

**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). Please suggest the most appropriate method of measurement for each:**

**Fracture union and timescale for controlled groups of patients as measured radiographically.**

**5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:**

None

## **6 Trajectory of the procedure**

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

Established

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

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

**Comments:**

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

- Major.
- Moderate.
- Minor.

**Comments:**

## **7 Other information**

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

## 8 Data protection and conflicts of interest

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

#### 8.1 Data Protection

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

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

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

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

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

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

Do you or a member of your family<sup>1</sup> have a **personal pecuniary** interest? The main examples are as follows:

<b>Consultancies or directorships</b> attracting regular or occasional payments in cash or kind	<input type="checkbox"/> YES
	<input checked="" type="checkbox"/> NO
<b>Fee-paid work</b> – any work commissioned by the healthcare industry – <b>this includes income earned in the course of private practice</b>	<input type="checkbox"/> YES
	<input checked="" type="checkbox"/> NO

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<sup>1</sup> ‘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).

	<input type="checkbox"/>	
	<b>x</b>	
<b>Shareholdings</b> – any shareholding, or other beneficial interest, in shares of the healthcare industry	<input type="checkbox"/>	<b>YES</b>
	<input type="checkbox"/>	<b>NO</b>
	<b>x</b>	
<b>Expenses and hospitality</b> – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	<input type="checkbox"/>	<b>YES</b>
	<b>x</b>	<b>NO</b>
	<input type="checkbox"/>	
<b>Investments</b> – any funds that include investments in the healthcare industry	<input type="checkbox"/>	<b>YES</b>
	<b>x</b>	<b>NO</b>
Do you have a <b>personal non-pecuniary</b> interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	<input type="checkbox"/>	<b>YES</b>
	<b>x</b>	<b>NO</b>
	<input type="checkbox"/>	
Do you have a <b>non-personal</b> interest? The main examples are as follows:		
<b>Fellowships</b> endowed by the healthcare industry	<input type="checkbox"/>	<b>YES</b>
	<b>x</b>	<b>NO</b>
	<input type="checkbox"/>	
<b>Support by the healthcare industry or NICE</b> that benefits his/her position or department, eg grants, sponsorship of posts	<input type="checkbox"/>	<b>YES</b>
	<b>x</b>	<b>NO</b>
	<input type="checkbox"/>	

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

**Comments:**

No to all the above  
Thank you very much for your help.

**Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair**

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

**Jan 2016**

## 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**

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- 3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)
- 3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
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- 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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5.1.2 **Support by the healthcare industry or NICE** – any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:

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

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

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

Interventional Procedures Programme

**Specialist Adviser questionnaire**

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

**Please respond in the boxes provided.**

**Please complete and return to:** Deonee.Stanislaus@nice.org.uk

**Procedure Name:** **Low intensity pulsed ultrasound to promote fracture healing**

Name of Specialist Advisor: Patrick Foster

Specialist Society: British Limb Reconstruction Society

**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.

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

**Comments:**

The question depends on the exact indication to be examined. It is not meant to be used to promote “fracture healing” per se. A more accurate title could be “Low Intensity Pulsed Ultrasound to treat delayed unions and nonunions of fractures”. This may sound the same but is extremely important to differentiate.

**2 Your involvement in the procedure**

**2.1 Is this procedure relevant to your specialty?**

Yes.



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

**Comments:**

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

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

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

**Comments:**

5 per year

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

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

**Comments:**

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

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

I have had no involvement in research on this procedure.

Other (please comment)

**Comments:**

### **3 Status of the procedure**

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

Established practice and no longer new.

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

Definitely novel and of uncertain safety and efficacy.

The first in a new class of procedure.

**Comments:**

Ref NICE guidelines 2010

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

Difficult to answer this. There are no direct comparators as there are all sorts of different methods to treat delayed unions or "promote fracture healing", surgical and non-surgical. I suppose the main one is "time".

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

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

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

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

Cannot give an estimate.

**Comments:**

### **4 Safety and efficacy**

#### **4.1 What is the potential harm of the procedure?**

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

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

none

2. Anecdotal adverse events (known from experience)

none

3. Theoretical adverse events

Reaction to the gel

#### **4.2 What are the key efficacy outcomes for this procedure?**

Fracture Union rate, but more accurately treating delayed union and nonunion

Time to union

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

Yes. Prominent recent papers in the BMJ and BJJ have not shown efficacy but in my view these were flawed in that the patient selection was not reflective of the intended use. These studies compared patients with fresh fractures in terms of union rate and time to union, instead of analysing relevant patient groups: those with delayed union or non-union. Also patient compliance was not taken into account.

In my view the evidence for treatment of delayed unions and nonunions is more robust, as per 2010 NICE guidelines and relevant subsequent studies.

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

Very little. It takes about ten minutes to show the patient what to do and they do it themselves at home once a day for twenty minutes. They are supplied with the kit in clinic.

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

No registries as such

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

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

I am not aware of any obscure abstracts

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

Yes. As mentioned before because it is such a simple and risk-free procedure it is tempting for some surgeons to use it for the wrong indications, particularly if they are not experienced in treating complex fractures or delayed unions. This could mean using exogen (LIPUS) when a fracture will definitely heal anyway, and also using exogen when it is doomed to failure when it is clear that more invasive techniques are required to treat a non-union such as revision surgery. As alluded to before there is an important difference between trying to get routine fresh fractures to heal a couple of weeks sooner (not the intended use) and using exogen to promote delayed unions healing rather than becoming established nonunions.

**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). Please suggest the most appropriate method of measurement for each:**

**Success in treating delayed union and non-union in fractures**

**5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:**

**There are clearly no adverse outcomes with this procedure so it does not need auditing**

**6 Trajectory of the procedure**

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

Since it requires no skill, training, risk etc it could spread further

**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:**

Theoretically since there are millions of fractures every year, if it is used for the wrong indications (every fresh fracture) it could get quite expensive. Thus it needs to be used for the correct indications.

**7 Other information**

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

Patient compliance should be taken into account. Clearly if the patient forgets to use it every day the efficacy is limited.

**8 Data protection and conflicts of interest**

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

**8.1 Data Protection**

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

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

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

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

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

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

Do you or a member of your family<sup>1</sup> have a **personal pecuniary** interest? The main examples are as follows:

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

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

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

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

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

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

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

**Fellowships** endowed by the healthcare industry  **YES**

**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:**

---

<sup>1</sup> ‘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).

Smith and Nephew part fund the Leeds Limb Reconstruction Fellowship, not relevant to this device.

I have advised Orthofix and Smith and Nephew on product development but this is not funded and not relevant to this device.

Thank you very much for your help.

**Dr Tom Clutton-Brock, Interventional  
Procedures Advisory Committee Chair**

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

**Jan 2016**

## Conflicts of Interest for Specialist Advisers

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

- 1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.
- 1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

### 2 Personal pecuniary interests

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



### 3 **Personal family interest**

- 3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'**, or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples include the following.
- 3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.
- 3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.
- 3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).
- 3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)
- 3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
- 3.2 No personal family interest exists in the case of:
- 3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)
- 3.2.2 accrued pension rights from earlier employment in the healthcare industry.

### 4 **Personal non-pecuniary interests**

These might include, but are not limited to:

- 4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review
- 4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence
- 4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration
- 4.4 other reputational risks in relation to an intervention under review.

### 5 **Non-personal interests**

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

- 5.1.1 **Fellowships** – the holding of a fellowship endowed by the healthcare industry.
- 5.1.2 **Support by the healthcare industry or NICE** – any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:
- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
  - a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Advisor is responsible. This does not include financial assistance for students
  - the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
  - one or more contracts with, or grants from, NICE.
- 5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.