

# 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: [tristan.mckenna@nice.org.uk](mailto:tristan.mckenna@nice.org.uk)

**Procedure Name:** IP1520 High Intensity Focused Ultrasound (HIFU) for symptomatic breast fibroadenoma

Name of Specialist Advisor: Ashu Gandhi

Specialist Society: Association of Breast Surgery.

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

I have a general awareness of this procedure but not specialist detailed knowledge as it is a procedure not in common usage in breast surgery in the UK

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

I would consider

High Intensity Focused Ultrasound (HIFU) for treatment of symptomatic breast fibroadenoma

an improvement

**Comments:**

### 2 Your involvement in the procedure

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

I feel that this is a procedure in search of an indication. There are some preliminary publications on HIFU/fibroadenomas in the literature. They are generally proof of concept papers with largely unimpressive findings.

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

No, as I am not aware of any common uses of this 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.

**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.

**Comments:**

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

I have done bibliographic research on this procedure.

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

I have done clinical research on this procedure involving patients or healthy volunteers.

I have had no involvement in research on this procedure.

Other (please comment)

**Comments:**

I have looked at recent publications on this topic relating to use of HIFU in benign breast disease

**3 Status of the procedure**

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

Definitely novel and of uncertain safety and efficacy.

**Comments:**

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

Vacuum assisted biopsy of fibroadenomas (established practice) or surgical excision biopsy (for the larger fibroadenomas)

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

**Comments:**

I would guess that <1% would be undertaking this procedure in regular clinical practice.

**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)  
superficial skin burns with blister-like aspect, hyperpigmentation over the treated area, subcutaneous induration at site of procedure
2. Anecdotal adverse events (known from experience)
3. Theoretical adverse events  
Chronic pain, cosmetic impairment, incomplete treatment of the fibroadenoma

4.

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

cost effectiveness, recurrence of symptoms in short and long term, time taken to perform the procedure

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

So far, the literature shows that the FA are reduced in size rather than completely removed. Reduction in pain from the FA is claimed. I am sceptical of the latter claim due to poor quality pain assessment. Reduction in size of lesion is poor in comparison with vacuum assisted biopsy which eliminates the FA completely when below a certain size.

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

training - probably comfortably within the grasp of most consultant breast radiologists  
facilities - cannot comment

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

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

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

N/K

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

Uncertainty as to the benefits of this technology compared to current standard of care

**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):**

cost effectiveness, recurrence of symptoms in short and long term, time taken to perform the procedure, patient related outcome measures eg pain,

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

as per 5.1

**6 Trajectory of the procedure**

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

I would be surprised if it spread at all

**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?**

N/A

## 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 |
| <b>Shareholdings</b> – any shareholding, or other beneficial interest, in shares   | <input type="checkbox"/> YES           |

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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).

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  **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:**

In our breast surgery department we have a research fellow who is funded by Acclivity, the company that makes a type of Acellular Dermal Matrix. I am not personally involved with the appointment or mentoring of this research fellow.

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.

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

## Specialist Adviser questionnaire

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**Please respond in the boxes provided.**

Please complete and return to: [tristan.mckenna@nice.org.uk](mailto:tristan.mckenna@nice.org.uk)

**Procedure Name:** IP1520 High Intensity Focused Ultrasound (HIFU) for symptomatic breast fibroadenoma

Name of Specialist Advisor: Siobhan Laws

Specialist Society: Association of Breast Surgery.

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

I have knowledge of many options to remove fibromata from the breast and of radiofrequency ablation as a technique I general but no specific knowledge of the technique in this context.

#### 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?

This is not a technique commonly used in routine practice.

- 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. **BUT I regularly treat patients with fibroadenoma of the breast.**
- 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) – I have not had sufficient time to run a literature search.

**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:**

Radiofrequency ablation is used in the breast in experimental settings only. In malignant or uncertain lesions, excision needs to allow for histological examination of the lesion intact in its entirety or to assess margins. This is not possible with HIFU. Its use would be limited to *confirmed* benign fibromata (not possible phyllodes lesions). In the majority of cases surgeons and breast radiologists recommend no treatment (no excision and no extra surveillance) unless significant symptoms.

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

Surgical excision under local or general anaesthetic. Vacuum excision of lesion (piecemeal) under image guidance and local anaesthetic.

#### **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:**

None of our team perform this procedure. We are short staff regarding interventional breast radiology staff and would not see them developing this technique as a unit priority. Surgeons do not have the support set up to easily adopt this approach even if trained in ultrasound.

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

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

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

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

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

Damage to the overlying skin with poor cosmetic outcome. Chronic pain/sensitivity.

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

Symptom relief. Cost effectiveness.

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

Cosmetic and symptom control.

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

Ability to perform ultrasound guided techniques. To be trained in HIFU. To have access to appropriate clinical setting (trained staff, equipment)

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

N/A

##### **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).**

N/K

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

N/K

## **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):**

Cosmetic outcome – photographic assessment. Symptoms assessment. Breast Q score.

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

Cosmetic (including contour changes), skin changes, chronic pain

## **6 Trajectory of the procedure**

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

I do not think we have the staff to adopt this for benign disease.

**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:**

I think this would be an appropriate technique to offer for audit in centre that are research HIFU for other indications.

**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?**

I would not consider this priority technology in this instance as the alternatives are acceptable, safe with minimum morbidity and there are established support systems in place.

## **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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- 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:

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

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

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

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

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

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

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

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

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

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

**Comments:**

I occasionally speak at educational events organised by industry and have set on a data monitoring committee for a commercial study. Neither involved in this technology. I provide specialist advice to the NHS Ombudsman and have a small private practice outside the NHS. I am an oncoplastic surgeon and clinical lead for the breast unit. I am actively involved in breast research and audit.

Thank you very much for your help.

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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).

**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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  - 2.2.2 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.
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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: [tristan.mckenna@nice.org.uk](mailto:tristan.mckenna@nice.org.uk)

**Procedure Name:** IP1520 High Intensity Focused Ultrasound (HIFU) for symptomatic breast fibroadenoma

Name of Specialist Advisor: Professor Michael Douek

Specialist Society: Association of Breast Surgery.

**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:**

High intensity focussed ultrasound for the treatment of symptomatic breast fibroadenomata

**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:**

I completed a prospective trial of this procedure on 51 patients, largest series in the world, and was the first clinician in the UK to use a specific HIFU device CE marked for the treatment of breast fibroadenomata

**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:**

None of these: established practice means there is a randomised controlled trial favoring this procedure over standard practice - but there is no randomised controlled trial data. It is a novel non-invasive technique, novel in the UK, for the treatment of breast fibroadenomata and has cohort trial data supporting its use. The technology is CE marked for HIFU of breast fibroadenomata.

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

Surgical excision of fibroadenomata. Also vacuum assisted mammotomy (VAM) – but the later is CE marked for diagnosis and not for therapy (excision of known fibroadenoma). So individuals can use VAM but not sure if it can be recommended given it is not licensed.

**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)

Hyperpigmentation of the skin, skin burn

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

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

Reduction in lesion size; resolution of symptoms (eg: pain)

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

Limited long-term data on outcome.

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

Treatment room with facilities to monitor local anaesthesia, training in breast ultrasound and in HIFU.

##### **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 major trails in progress.

##### **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).**

Yes – HIFU F trial on 51 patients is written up and we will be submitting for publication.

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

No

**5 Audit Criteria**

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

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

**Reduction in lesion size (%) and resolution of symptoms**

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

**Hyperpigmentation of skin, skin burns**

**6 Trajectory of the procedure**

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

Once available – it is a very attractive alternative to surgery

**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:**

On condition that general hospitals have a breast unit with experienced surgeons and radiologists.

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

- Major.
- Moderate.

x  Minor.

**Comments:**

Or moderate depending on definition – since breast surgery is a large specialty within surgery.

**7 Other information**

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

No

**8 Data protection and conflicts of interest**

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

**8.1 Data Protection**

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

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:**

King's College London has received an unrestricted grant supporting HIFU research and also the device on loan (Echopulse, Theraclion). KCL or myself receive no funding at present from Theraclion and the device has been returned to the company over a year ago.

Thank you very much for your help.

**Dr Tom Clutton-Brock, Interventional      Professor Carole Longson, Director,**

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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).

**Procedures Advisory Committee Chair    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.

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  - 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.
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# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

## Specialist Adviser questionnaire

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**Please respond in the boxes provided.**

Please complete and return to: [tristan.mckenna@nice.org.uk](mailto:tristan.mckenna@nice.org.uk)

**Procedure Name:** IP1520 High Intensity Focused Ultrasound (HIFU) for symptomatic breast fibroadenoma

Name of Specialist Advisor: Fiona MacNeill

Specialist Society: Association of Breast Surgery.

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

Yes. To a point as this is not a mainstream procedure. My understanding is that HIFU targeted on the lesion using US guidance 'destroys' the lesion.

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

**NO: it would better read  
IP1520 The use of High Intensity Focused Ultrasound (HIFU) for destruction of symptomatic breast fibroadenoma**

### 2 Your involvement in the procedure

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

Potentially Yes. But not for the destruction of fibro-adenoma's (F/A)

Is there any kind of inter-specialty controversy over the procedure?  
Probably as its utility in the management of breast tumours/lesions is not proven.

**Possibly with surgery:** F/A can be removed using surgery ( with GA and or LA) However surgeons very rarely need to remove F/A nowadays. ‘Symptomatic’ F/A are rare presumably the symptoms will be pain or very large (usually >3-4cm) that are visible to the patient. This means the postulated indications for HIFU are rare. Research would need to be directed to assess if HIFU can relieve the pain of F/A and for the large F/A’s to ensure the cosmetic result is as good as surgery. ....however not aware of what evidence there is out there.

**Radiology:** F/A can be easily removed under US guidance using a vacuum device. This is simple and relatively cheap and avoids the need for GA and gives fragments of tissue for analysis ( if required)

**Pathology:**  
If large F/A are recommended for removal is often because of concern over the possibility they may be phyllodes tumours which have malignant potential. The distinction between F/A and phyllodes can only be made when the pathologist sees the whole lesion not fragments. For this reason large F/A that need removal are recommended surgery for complete excision for pathological analysis

**The procedure could be done by radiologists and/or surgeons with interventional radiology skills**

**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.

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

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

**Comments: I would only consider this procedure if it was part of a research trial but even then it is difficult to think in whom it would have utility.**

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

Other (please comment). I have discussed with colleagues the utility of HIFU in breast disease management

**3 Status of the procedure**

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

Definitely novel and of uncertain safety and efficacy.

**Comments:**

HIFU may have some useful future applications in destroying small cancers/lesions of uncertain malignant potential and may help to reduce the need for surgery in the future so the technology is interesting but not sure of the relevance of the current application

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

Vacuum assisted excision of breast lesions under LA and US guidance. Usually done by radiologists

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

Fewer than 1% of specialists engaged in this area of work.

**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)

I do not know the literature

2. Theoretical adverse events ( in my opinion)

Pain, infection, severe fibrosis and poor aesthetic outcomes

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

That is the real question!

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

Do not know- not familiar with the literature

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

Learn the new technology and machinery but otherwise probably not much more than the skills already possessed by interventional breast radiologists

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

Not that I am aware of

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

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

Not that I am aware of

**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 sure of the utility of the technology for symptomatic F/A's

## **5 Audit Criteria**

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

**Pain reduction, breast cosmesis, patient acceptability, speed and painlessness of intervention, does it 'remove' the lesion targeted**

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

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

## **6 Trajectory of the procedure**

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

Not for F/A

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

Technology is interesting but not the current application

**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:**

**Comments:** Technology is interesting especially for small cancers/other lesions but not the current application

## **7 Other information**

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

No

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

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

#### **8.1 Data Protection**

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

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:

**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  **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.**

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

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