

**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:** [azad.hussain@nice.org.uk](mailto:azad.hussain@nice.org.uk) and [IPSA@nice.org.uk](mailto:IPSA@nice.org.uk)

**Procedure Name:** **Balloon dilation of a eustachian tube for eustachian tube dysfunction**

Name of Specialist Advisor: Ian Bottrill

Specialist Society: British Association of Otorhinolaryngologists, Head and Neck Surgeons (ENT UK)

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

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

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

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

**Comments:**

**2 Your involvement in the procedure**

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

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

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

**Comments:**

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

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

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

**Comments:**

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

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

**Comments:**

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

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

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

**Comments:**

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

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

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

**Comments:**

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

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

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

**Comments:**

### **4 Safety and efficacy**

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

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

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

Research not required as part of your instruction

2. Anecdotal adverse events (known from experience)

As a specialist in the management of patulous Eustachian tube syndrome, I have seen this as a complication of over vigorous balloon treatment

3. Theoretical adverse events

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

Resolution of ear fullness due to ETD. Reversal of tympanometry abnormality.  
Possible clearance of OME and resolution of retraction pockets

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

Yes, exactly which patients are the best to offer this treatment. Seems a good option for barotrauma but the rest is still under investigation

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

Company and expert practical hands on instruction

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

No done full review but I understand James Tysome in Cambridge is investigating

**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).**

You need to do the search

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

Seems the company are pushing but the indications are still not clear. Some patients having the treatment who have not had the correct diagnosis

## **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:**

**Resolution of symptoms, hearing change, ear drum appearance, middle ear effusion, tympanometry change. Need short and longterm results**

**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:**

**Bleeding, pain, ear fullness within 1 week – 4 weeks.  
Patulous symptoms – 1 week – 1 year**

## **6 Trajectory of the procedure**

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

Slowly rolling out as part of company push. I have had an email this week to get me to use it.

**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:**

Easy procedure, suspect all major teaching hospitals or DGH could be performing when indications decided. Common disease.

**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.

Y 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. For more information about how we process your personal data please see our [privacy notice](#)

#### **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**      **Mark Campbell**  
**Acting Programme 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).

June 2018



## 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:** [azad.hussain@nice.org.uk](mailto:azad.hussain@nice.org.uk) and [IPSA@nice.org.uk](mailto:IPSA@nice.org.uk)

**Procedure Name:** **Balloon dilation of a eustachian tube for eustachian tube dysfunction**

Name of Specialist Advisor: Simon Lloyd

Specialist Society: British Association of Otorhinolaryngologists, Head and Neck Surgeons (ENT UK)

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

Yes.

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

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

Yes.

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

**Comments:**

**2 Your involvement in the procedure**

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

Yes.

**No** 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.

x Other (please comment)

**Comments:**

I am currently collecting prospective outcome data regarding the efficacy of this treatment

**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.

x Definitely novel and of uncertain safety and efficacy.

The first in a new class of procedure.

**Comments:**

The treatment has been used widely in many countries since its introduction approximately 5 years ago. In the UK it is increasingly frequently being offered.

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

Placement of ventilation tubes in the tympanic membrane

**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.

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

Cannot give an estimate.

**Comments:**

I do not have exact figures so the above is an estimate and relates only to the UK

**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

Epistaxis

Patulous Eustachian tube

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

This depends on the condition being treated. There are 4 main groups:

- 1) Symptoms but no signs of Eustachian tube dysfunction other than negative middle ear pressure on tympanometry. The outcome measure is improvement/resolution in symptoms.
- 2) Otitis media with effusion. The outcome measure is resolution of middle ear effusion and improvement/resolution of conductive hearing loss
- 3) Tympanic membrane retraction. The outcome measure is improvement or absence of progression of tympanic membrane retraction on otoscopy
- 4) Patients that get pain with rapid changes in atmospheric pressure eg. Flying or scuba diving

There are other ways to potentially assess outcome including tubomanometry. These objective ways of measuring Eustachian tube function have not become routine clinical practice because of difficulties in obtaining consistent results

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

There are concerns regarding its efficacy. The literature would suggest that it is more successful in treating groups 2 and 4 above than groups 1 and 3 but the quality of the literature is poor with no good quality prospective clinical trials.

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

The procedure is simple to perform and could be undertaken by any ENT surgeon on the specialist register. The ideal training would consist of:

- 1) Observation of the procedure being undertaken
- 2) Training on surgical technique on cadaveric material
- 3) Medically supervised undertaking of the procedure in patients
- 4) Independent undertaking of the procedure in patients with company support
- 5) Unsupported undertaking of the procedure

The procedure can be undertaken in any operating theatre, including day case facilities. The equipment required include:

- 1) Rigid nasendoscope
- 2) Camera system and stack
- 3) Balloon Eustachian tuboplasty insertion tool
- 4) Balloon for dilatation
- 5) Pump to inflate balloon

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

Not as far as I am aware. There are a number of publications in the literature as well as on going studies within individual units but no formal clinical trials or registries.

**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).**

There is an excellent PhD thesis (which I examined) undertaken in Cambridge on the subject of balloon dilation of the Eustachian tube. This was completed last year by Matthew Smith and would make up a useful part of the assessment of this intervention.

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

There is no controversy around the surgical technique but there is controversy around the efficacy of the procedure.

## **5 Audit Criteria**

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

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

**There are several ways in which outcomes can be measured. This includes:**

- 1) Patient reported outcome measures (PROMS). There a number of different measures. The most commonly used is the Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7). This is a questionnaire that is specifically designed to assess current Eustachian tube dysfunction symptoms
- 2) Clinical assessment. For retractions and otitis media with effusion there are clinical signs of middle ear dysfunction and response to treatment can be assessed by identifying improvement in the clinical appearance of the



tympanic membrane. The ability to carry out a valsalva manoeuvre can also be used to assess patency of the Eustachian tube

- 3) Audiological tests. Some forms of ETD result in conductive hearing loss and this can be measured using a pure tone audiogram. The pressure behind the ear drum can also be measured using tympanometry.
- 4) Objective measures of ET function. Tests such as tubomanometry are available to objectively test ET function but they are not consistent and have not been used widely in clinical practice although there a number of publications that have used these techniques as outcome measures.

**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 no reported complications following this procedure. There is however a theoretical risk of causing a nose bleed during the procedure as it is necessary to pass the balloon and its introducer as well as an endoscope in to the nose whilst undertaking the treatment. There was initially concern that the internal carotid artery could potentially be damaged during the procedure as it lies in the wall of the Eustachian tube. As a result most clinicians used to carry out a CT scan of the skull base prior to carrying out the procedure. There has never been a report of damage to the artery, however, and most clinicians now do not carry out a CT scan before the procedure.

**6 Trajectory of the procedure**

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

Currently there is uncertainty about its efficacy and its up take is likely to be slowed because of this. If further research suggests that it is effective as a treatment for one or more of the above indications then its up take is likely to become much faster.

**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:**

ETD is very common and if BET was an effective way of treating it it would become common place very quickly. It is unlikely that it will be used for all forms of ETD in the long run given that it may not be effective in all cases but if its efficacy is proven for certain indications then it is likely to become widespread.

**7 Other information**

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

**8 Data protection and conflicts of interest**

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

**8.1 Data Protection**

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

X I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above. For more information about how we process your personal data please see our [privacy notice](#)

**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).

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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 have a private practice and treat patients with BET both privately and in the NHS. I am a partner in 52 Alderley Road LLP. This is a LLP involved in providing healthcare at Wilmslow Hospital in Wilmslow, Cheshire. I run two surgical courses that are sponsored by a range of healthcare organisations including Minim Healthcare, the company that supplies the Spieggle and Theis BET system in the UK.

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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).

Thank you very much for your help.

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

**Mark Campbell  
Acting Programme Director  
Devices and Diagnostics**

**June 2018**

## Conflicts of Interest for Specialist Advisers

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  - 2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.
  - 2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
  - 2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
- 2.2 No personal interest exists in the case of:
  - 2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where 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.