

**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: [Rishma.Malde@nice.org.uk](mailto:Rishma.Malde@nice.org.uk)

**Procedure Name: IP1523 Micro-invasive subconjunctival insertion of a transcleral gelatin stent for primary open-angle glaucoma**

Name of Specialist Advisor: Anthony King

Specialist Society: Royal College of Ophthalmologists

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

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

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

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

**Comments:**

**2 Your involvement in the procedure**

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

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

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

**Comments:**

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

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

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

**Comments:**

I am planning to undertake further procedures over the next few weeks

**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 undertook a systematic review of the available literature in 2016 as part of a HTA grant application to undertake an RCT of this implant against trabeculectomy (standard care) The HTA did not fund the application as they felt it required further evaluation before undertaking an RCT

**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:**

It is the only currently available subconjunctival draining minimally invasive glaucoma surgery  
It has been used for several years in the UK but limited systematic evaluation has been undertaken.  
Its mechanism is novel and of the current glaucoma surgery innovations most closely mimics that of the standard operation for glaucoma - trabeculectomy

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

MMC augmented trabeculectomy

**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:**

Has been adopted widely in 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)

Loss of vision, Hyphema, Hypotony, choiroidal effusions, hypotonous maculopathy, failure, eroin, encystment, cyclodyalisis cleft, misinsertion, extrusion from beneath conjunctival or into anterior chamber, iris damage

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

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

Intraocular pressure (IOP)

Visual Acuity

Visual Field stability

Safety

Patient experience

Cost effectiveness

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

How it compares to trabeculecomy

How many patients will be drop free or will need to continue to use glaucoma drops to control IOP

Long term IOP efficacy outcomes

What proportion of those treated will achieve an IOP of < 15mmHg or 12 mmHg

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

Company provides a dry lab with artificial eyes and a dummy inserter to practise on – these are minium requirements.

They provide trainer to oversee insertion of first 10 implants

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

There are several cohort studies ongoing but no RCTs

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

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

No

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

No it is a fairly established process now

## **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:**

**IOP with and with our drops at 12 months and 36 month**

**Safety both perioperative and postoperative**

**Rate and type of postoperative interventions**

**Number of post-operative visits required**

**Patient experience as measured by PROMS – GUI, GQL 15, CIGTS ocular discomfort index**

**Cost effectiveness evaluation**

- 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:**

**Loss of vision**

**Infection**

**Bleb leak**

**Hypotony**

**Hypotonous macuopathy**

**Need for cataract surgery**

**Need for further glaucoma surgery**

## **6 Trajectory of the procedure**

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

Already wide uptake

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

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

**Comments:**

This is a relatively straight forward intervention that will be used widely if safety and efficacy established

**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:**

It may be used as an adjunct to cataract surgery or in patients with suspected compliance problems as well as in those requiring better IOP control

**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?**

Expense of device – need to be convince of value for money

**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.

Yes – I agree

---

## 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 checked="" type="checkbox"/> YES |
|  | <input type="checkbox"/> NO             |
| <b>Shareholdings</b> – any shareholding, or other beneficial interest, in shares of the healthcare industry  | <input type="checkbox"/> YES            |
|  | <input checked="" type="checkbox"/> NO  |
| <b>Expenses and hospitality</b> – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences | <input type="checkbox"/> YES            |
|  | <input checked="" type="checkbox"/> NO  |
| <b>Investments</b> – any funds that include investments in the healthcare industry   | <input type="checkbox"/> YES            |
|  | <input checked="" type="checkbox"/> NO  |

---

<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).

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 received honoraria for speaking at meetings organised by Allergan who are the company marketing this product

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**

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: [Rishma.Malde@nice.org.uk](mailto:Rishma.Malde@nice.org.uk)

**Procedure Name:** IP1523 Micro-invasive subconjunctival insertion of a transcleral gelatin stent for primary open-angle glaucoma

**Name of Specialist Advisor:** PROFESSOR DAVID BROADWAY

**Specialist Society:** ROYAL COLLEGE OF OPHTHALMOLOGISTS

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

Yes.

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

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

Yes.

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

**Comments:**

**2 Your involvement in the procedure**

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

Yes.

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

**Comments:**

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

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

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

**Comments:**

I HAVE CARRIED OUT ROUTINE GLAUCOMA SURGERY FOR MANY YEARS (INCLUDING IMPLANTATION OF A DIFFERENT MIGS DEVICE DURING THE LAST 2-3 YEARS)

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

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

**Comments:**

I HAVE MANAGED MANY PATIENTS WHO MIGHT HAVE BEEN SUITABLE FOR THIS TYPE OF PROCEDURE AND FOR A DIFFERENT MIGS DEVICE, BUT NOT FOR THIS PARTICULAR DEVICE

**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 ATTENDED A NUMBER OF PRESENTATIONS / LECTURES RELATING TO THE DEVICE AT A NUMBER OF OPHTHALMIC MEETINGS

**3 Status of the procedure**

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

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

**Comments:**

THIS IS A NOVEL DEVICE, (AS ARE ALL MIGS DEVICES), ALTHOUGH THIS DOES HAVE A PARTICULAR FEATURE OF BEING PLACED TRANSCLERALLY BETWEEN ANTERIOR CHAMBER AND THE CONJUNCTIVAL SPACE (AKA TRABECULECTOMY), MAKING IT DIFFERENT FROM THE MAJORITY OF MIGS DEVICES. HOWEVER, THERE HAS BEEN INSUFFICIENT RESEARCH ON MEDIUM/LONG-TERM OUTCOMES AND SAFETY AT THIS STAGE

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

TRABECULECTOMY

**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:**

PROBABLY NEARER TO 2%

#### **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)

These are essentially the same as for trabeculectomy

Stalmans I. A Minimally Invasive Approach to Sub-conjunctival Outflow: 1 Year Results of an Ab-interno Gelatin Stent for the Treatment of Primary Open Angle Glaucoma.

*International Congress of Glaucoma Surgery poster 2016*

2. Anecdotal adverse events (known from experience)

I have not used the device

3. Theoretical adverse events

Stent blockage

Stent extrusion

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

Primary: Intraocular pressure (IOP)

Secondary: requirement for topical antiglaucomatous therapy, visual field preservation, visual acuity, QOL & comfort, adverse effects

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

YES; THERE HAS BEEN INSUFFICIENT RESEARCH ON MEDIUM/LONG-TERM OUTCOMES AND SAFETY AT THIS STAGE

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

I BELIEVE THAT THE COMPANY THAT MAKE THE DEVICE ARE WILLING TO OFFER TRAINING. IDEALLY TRAINING ON ARTIFICIAL / PORCINE / SIMILAR EYES WOULD BE IDEAL UNDER AN OPHTHALMIC MICROSCOPE.

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

THE APEX TRIAL

##### **4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature**

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

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

Stalmans I. A Minimally Invasive Approach to Sub-conjunctival Outflow: 1 Year Results of an Ab-interno Gelatin Stent for the Treatment of Primary Open Angle Glaucoma. *International Congress of Glaucoma Surgery poster* 2016

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

NONE OF WHICH I AM AWARE, ALTHOUGH I HAVE CONCERNS THAT THE DEVICE IS BEING USED IN NON-RESEARCH SETTINGS – IN MY OPINION IT WOULD BE MORE APPROPRIATE FOR THE DEVICES TO UNDERGO RIGOROUS ROBUST ASSESSMENT IN CLINICAL TRIALS BEFORE BEING USED OUTSIDE OF A RESEARCH SETTING

**5 Audit Criteria**

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

AS OUTLINED IN THE WORLD GLAUCOMA SOCIETY GUIDELINES:

Heuer DK, Barton K, Grehn F, Shaarawy TM, Sherwood MB (2009) Consensus on definitions of success. In: Shaarway T, Sherwood M, Grehn F, (eds). Guidelines on design and reporting of glaucoma surgical trials: World Glaucoma Association. Kugler Publications, Amsterdam, pp-15-24.

**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:**

Primary: Intraocular pressure (IOP by Goldmann Applanation Tonometry)

Secondary: requirement for topical antiglaucomatous therapy, visual field preservation (Humphrey 24-2 SITA-S visual field analyses), visual acuity (logMar), QOL & comfort, adverse effects

**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:**

As for trabeculectomy

**6 Trajectory of the procedure**

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

I hope, not until sufficient research has been carried out and published

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

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

**Comments:**

...at least in any unit with a glaucoma service

**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:**

Moderate with respect to a glaucoma service and ophthalmology department, minor with respect to the NHS as a whole

**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 have nothing else to add

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

---

## 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

---

<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).

**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 OPHTHALMIC PRACTICE, IN ADDITION TO MY MAIN NHS CONSULTANCY, BUT DO NO WORK COMMISSIONED BY THE HEALTHCARE INDUSTRY TO EARN ANY INCOME. IN MY NHS PRACTICE I RUN A RESEARCH CLINIC, IN WHICH I CARRY OUT SOME COMMERCIAL RESEARCH FOR MULTIPLE OPHTHALMIC COMPANIES (FOR NO PERSONAL INCOME).

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**

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: [Rishma.Malde@nice.org.uk](mailto:Rishma.Malde@nice.org.uk)

**Procedure Name: IP1523 Micro-invasive subconjunctival insertion of a transcleral gelatin stent for primary open-angle glaucoma**

Name of Specialist Advisor: Professor Keith Martin

Specialist Society: Royal College of Ophthalmologists

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

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

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

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

**Comments:**

**2 Your involvement in the procedure**

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

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

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

**Comments:**

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

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

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

**Comments:**

I have performed nearly 30 of these since October 2016

**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:**

Relatively new to the UK but has been performed worldwide for years and there is good evidence of efficacy in published clinical studies

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

Trabeculectomy, eyedrops or laser treatment for glaucoma

#### **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:**

10-50% of glaucoma specialists, <10% of all ophthalmic surgeons

### **4 Safety and efficacy**

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

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

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

Infection, bleeding, eye pressure too high or too low, failure due to scarring. Risks are mostly lower than for alternative surgery such as trabeculectomy.

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

Long term failure rates remain to be determined.

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

Eye pressure

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

Long term failure rates remain to be determined

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

Allergan provides excellent hands on training to glaucoma surgeons wanting to learn the procedure, including direct supervision of at least the first 10 procedures.

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

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

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

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

I would say no – there is a better evidence base than for many of the other minimally invasive glaucoma surgery techniques currently in use.

## **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:**

**Long term reduction of intraocular pressure from baseline, reduction in required number of glaucoma medications**

**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:**

**hypotony, failure to control IOP, infection**

## **6 Trajectory of the procedure**

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

I think this will spread rapidly in the UK

**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 a majority of glaucoma specialists (most district hospitals now have at least one) would eventually be likely to offer the procedure, particularly if the longer term follow up results show sustained IOP control.

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

- Major.
- Moderate.
- Minor.

### **Comments:**

## 7 Other information

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

## 8 Data protection and conflicts of interest

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

#### 8.1 Data Protection

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

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

---

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

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

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

Please use the “Conflicts of Interest for Specialist Advisers” policy 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:

---

<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

- 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 should declare that I have acted as a Global Advisory Board member for Allergan and have participated in paid Advisory Boards specifically related to the device under evaluation.

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**

---

whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

## Conflicts of Interest for Specialist Advisers

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

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

### 2 Personal pecuniary interests

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

### 3 **Personal family interest**

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

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

These might include, but are not limited to:

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

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

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

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

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

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

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

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

Interventional Procedures Programme

**Specialist Adviser questionnaire**

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: [Rishma.Malde@nice.org.uk](mailto:Rishma.Malde@nice.org.uk)

**Procedure Name:** IP1523 Micro-invasive subconjunctival insertion of a transcleral gelatin stent for primary open-angle glaucoma

Name of Specialist Advisor: Anne Fiona Spencer

Specialist Society: Royal College of Ophthalmologists

**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:**

I think should include the term “ab interno”

**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

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

**Comments:**

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

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

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

**Comments:**

I have performed a few times and am evaluating the outcomes

**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?**

Trabeculectomy

#### **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:**

I presume this relates to the comparator procedure Trabeculectomy

### **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)

Hypotony and choroidal detachment, usually transient. Blockage due to fibrosis and scarring leading to failure and requiring further surgery. Hypphaema

2. Anecdotal adverse events (known from experience)

Shallow anterior chamber one patient with possibility of aqueous misdirection. However good visual acuity, intraocular pressure control so no further intervention just observation.

3. Theoretical adverse events

Cataract earlier in phakic patient. Avascular blebs due to the anti-metabolite Mitomycin C

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

Intraocular pressure control; reduction in topical medications; maintenance visual acuity; lack of progression optic disc and visual field

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

Efficacy past first 12-24 months little evidence

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

Dry lab training on injection of implant; support of adviser during first surgical procedures

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

Previous European multicentre study undertaken (Reitsamer et al). Not aware of major on-going studies

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

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

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

Uncertainty as to whether placement subconjunctival or sub-Tenon's is better.

**5 Audit Criteria**

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

Pre-op IOP and then at 1, 3, 6, 12, 18, 24 months post-op and yearly thereafter. Number of topical glaucoma medications pre and post-op at all timepoints. Pre-op Visual acuity and post-op at all timepoints. Complications/adverse events at time of surgery and subsequently. Assessment of stability of glaucoma by optic disc and visual field assessment before and after at 6 monthly timepoints for 2 years, then yearly. Demographics : age, gender, ethnicity, previous surgery (incl cataract surgery); diagnosis i.e primary open angle glaucoma or secondary such as pigmentary/pseudexfoliation. Stage of disease i.e. mild/moderate/advanced as defined by Mean defect Visual Field and optic disc parameters.

**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:**

Intra-ocular pressure; (Goldmann applanation tonometry GAT) reduction in IOP (absolute and percentage); stability of optic disc and visual field By OCT for optic disc and assessment); visual acuity and visual rehabilitation post-operatively ( speed of return to pre-op acuity/ability to continue everyday tasks/drive) Mean defect visual field; reduction of medications required, quality of life 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:**

Hyphaema in first 1 month (usually within 1 week)  
Hypotony first 1 and 3 months  
Choroidal Detachment first 1 and 3 months  
Cataract first 1, 3, 6, 12 months  
Fibrosis and Failure first 1, 3, 6, 12, 18, 24, 36 months and long-term

**6 Trajectory of the procedure**

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

Spreading already quickly to many units and consultants

**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:**

Too soon to know if most DGH consultants in glaucoma will undertake this

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

- Major.
- Moderate.
- Minor.

**Comments:**

**7 Other information**

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

**8 Data protection and conflicts of interest**

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

**8.1 Data Protection**

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

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

---

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

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

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

Please use the “Conflicts of Interest for Specialist Advisers” policy 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

---

<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).

**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:**

Received payment for lectures on glaucoma to trainees (not related to the implant but generally in assessing optic disc and visual field in glaucoma) by Allergan £600 over last year. Allergan now market this implant

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

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: [Rishma.Malde@nice.org.uk](mailto:Rishma.Malde@nice.org.uk)

IP 1523 - Microinvasive Subconjunctival Insertion of  
a Translucal gel sheet for Primary open angle  
Glaucoma

Procedure Name:

Name of Specialist Advisor: MR MONIT GUPTA

Specialist Society: ROYAL COLLEGE OF OPHTHALMOLOGISTS

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

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

1.1 Does the title used above describe the procedure adequately?

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

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your speciality?

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

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

**Comments:**

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

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

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

**Comments:**

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

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

**Comments:**

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

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

Other (please comment)

Comments:

### 3 Status of the procedure

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

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

Comments:

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

TRABECULECTOMY

#### 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:

A small proportion of all Glaucoma specialists undertake this procedure

### 4 Safety and efficacy

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

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

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

- ① There is a cost of the Implant compared to trabeculectomy
- ② Poor drainage of Implant
- ③ Need to use mitomycin<sub>3</sub> for success contrary to recommendation
- ④ Reduction in vision

2. Anecdotal adverse events (known from experience)

- ① Loss of Implant in Eye
- ② Overcharge of Implant leading to large bleed
- ③ Failure
- ④ Hypotony

3. Theoretical adverse events

- ① Bleeding
- ② Wrong placement
- ③ Damage to Implant

4.2 What are the key efficacy outcomes for this procedure?

Reduction of intraocular pressure from Baseline  
Complications associated

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

- ① No long term efficacy data available
- ② Need for additional procedures like Needling

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

- ① Training provided by the parent company of Implant
- ② Peer training

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

- ① Not aware of any

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).

Some publications in literature which are case series

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

The surgeons use mitomycin subconjunctivally with the procedure - this is against recommendation by

5 Audit Criteria Company

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

- ① Long term efficacy of over 100 procedures including complications & need for other procedures

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:

- ① Reduction of intraocular pressure  
② Complications ③ Failure, ④ Need of further procedures

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:

- ① Bleeding ③ Drop in visual acuity  
② Failure ④ Hypotension

6 Trajectory of the procedure

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

Spreading very fast as training provided by company

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:

More expensive than trabeculectomy

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.

---

#### 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

---

<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).

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

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

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

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

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

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

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

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

**Comments:**

Thank you very much for your help.

**Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair**      **Professor Carole Longson, Director, Centre for Health Technology Evaluation.**

Jan 2016

## 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 Adviser is responsible, but that is not received by the Specialist Adviser 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.