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: Sally.Jones@nice.org.uk or Hawra.Abugulal@nice.org.uk

Procedure Name:	Implantation of miniature lens systems for advanced age-related macular degeneration IP375/2
Name of Specialist Advisor:	Professor Ngai (Victor) Chong
Specialist Society:	The 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 was involved in the design of the UK-IMT study but due to moving job, I did not take part in the study. I had performed the IOL-VIP implant in 10 patients.

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

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

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

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

Comments:

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

☒ I have 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:

There are more than one type of implant, one have FDA approval, so we have long term safety and efficacy data. Others have CE mark only, so it is relatively safe, but poor efficacy data

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

Standard cataract surgery

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

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

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

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

☐ Cannot give an estimate.

Comments:

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

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

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

Boyer et al., Clin Ophthalmol. 2015 Jun 17;9:1099-107.

2. Anecdotal adverse events (known from experience)

The IMT implant has more complication but more efficacy, surgeon skill is important, so learning curve issue

The IOL-VIP and iolAMD implants are safer and easier to do but the efficacy is rather limited.

The main adverse event is corneal decompression, and higher surgical complication with posterior capsule rupture and iris damage.

3. Theoretical adverse events

4.2 What are the key efficacy outcomes for this procedure?

Visual acuity gain

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

See above, IMT is higher risk and higher gain, iolAMD is lower risk and lower gain, iolAMD has mostly replaced IOL-VIP system

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

Same as cataract surgery for the surgical part
From the selection part, retinal specialist and visual rehab specialist to select patients.

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

I think there is a database / registries on IMT by the company Visioncare

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?

In the UK, this procedure is carried out in private hospitals. There is a component of overpromising by some centres.

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):

Distance visual acuity, and reading acuity

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

Corneal cell count

6 Trajectory of the procedure

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

If it is available in the NHS, it would be picked up quickly

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:

To make this cost – effective, patient selection is very important, so I don't think all hospital should do this, but should be provided as regional services with significant expertise.

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

☐ Major.

☒ Moderate.

☐ Minor.

Comments:

7 Other information

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

I think NICE should consider and provide different cost-effective assessment for the IMT and iolAMD.

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

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

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[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional payments in cash or kind	☒	**YES**
	☐	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☐	**YES**
	☒	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	☒	**NO**
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☒	**YES**
	☐	**NO**
Investments – any funds that include investments in the healthcare industry	☐	**YES**
	☒	**NO**
Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	☐	**YES**
	☒	**NO**

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

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

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

Comments:
I am a consultant for Allergan, Bayer, Novartis, Boehringher Ingelheim, and Quantel Medical, and I was given travel support by Bayer to attend medical conferences, and received speaker fee from Allergan, Bayer, Heidelberg, and Quantel Medical. My department has received funding from Allergan, Bayer, Novartis for research. However, none of these companies is in direct conflict of this technology.

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

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

Conflicts of Interest for Specialist Advisers

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

1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.

1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

2 Personal pecuniary interests

2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'** or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples are as follows.

2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.

2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place.

2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

2.2 No personal interest exists in the case of:

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

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

3 **Personal family interest**

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

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

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

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

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

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

3.2 No personal family interest exists in the case of:

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

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

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

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

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

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

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

5 Non-personal interests

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

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

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

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

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

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

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: Sally.Jones@nice.org.uk or Hawra.Abugulal@nice.org.uk

Procedure Name:	**Implantation of miniature lens systems for advanced age-related macular degeneration IP375/2**
Name of Specialist Advisor:	Miss Giuliana Silvestri
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:

Yes good title which is all encompassing. Important as there are a number of different devices available.

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 procedure can be done by any experienced cataract surgeon however patients are likely to be selected by a team which includes a Ophthalmologists with an interest in age-related macular degeneration and an optometrist wioth an interest in visual rehabilitation.

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 experience of implanting one device type. I have implanted 8 IMT (VisionCare Technology devices). 1 for an NHS patient and 8 though the UK-IMT Research Study .

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 selected patients and implanted one type of device (IMT) as above. I have not referred any patients to anyone else.

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 experience of implanting one device type. I have implanted 8 IMT (VisionCare) devices) for the UK IMT Study ClinicalTrials.gov Identifier: NCT00555165. I was the Principal Investigator for this study which sought to evaluate pre and post−implantation management of patients with end−stage age−related **macular degeneration** (**AMD**) who have been implanted with the implantable **telescope** (IMT) under CE Mark indicated use. The study was multicentre and enrolled 18 patients (Target 75). The visual results were good but as recruitment fell very short of target, the results were not published.

I also have recently been successful in acquiring an EME NIHR grant for an RCT on the Lipshitz (LMI) Mirror Implant (OriLens) (2015-2009). This trial seeks to evaluate the efficacy and safety of the new OriLens device as compared with conventional low vision aids and visual rehabilitation.

I have no experience with the IOL-VIP and AMD IOL devices.

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:

I have difficulty choosing between options 3 and 4. The procedure is novel, safety data do exist for the IMT (large patient dataset with long follow-up) and the IOL VIP with a smaller dataset for the Lipshitz LMI implants and more recently for the AMD IOL device. The devices are safe but patient selection is crucial for efficacy.

Data from 2010 for the United Kingdom, show that over 600,000 persons are estimated to have age-related macular degeneration (AMD) with over 220,000 suffering sight loss. AMD can be either wet (neovascular) or atrophic (geographic atrophy), both of which cause loss of vision. Over the past five years anti-VEGF therapies have made a significant impact on reduction of visual loss in wet AMD, however no therapy exists for the atrophic form of the disease. In addition a

substantial proportion of patients with wet AMD still lose vision either because of late diagnosis or lack of effect of current treatments. The only treatment option for these individuals is the enhancement of remaining vision through the use of external low vision aids. These devices are variably accepted but use can be tedious as the field of vision is small and tracking can be difficult. A novel concept is the use of implantable intraocular magnifying telescopes. A number of new intraocular technologies have been developed with the aim of improving residual vision in those who are in the advanced stage of the disease. These technologies aim to allow improved visual acuity by implanting a magnifying system within the eye either at the time of cataract surgery or at a subsequent time, thereby improving visual acuity and reducing the requirement for high powered external low visual aids. If successful these devices could improve the quality of life and reduce dependency thereby potentially reducing the costs associated with caring for visually impaired individuals, hence there is a definite place for such devices.

Four devices are known to me, although there may be others. The technologies currently available for intraocular use are: the "Centrasight" (IMT) implantable miniature telescope (VisionCare Ophthalmics) the IOL-VIP (Veni-Vedi), the OriLens (Optolight Vision Technologies) and the AMD IOL through the London Clinic. Data from a small number of non-randomised studies are available but none have been studied in randomised controlled trials. The most extensive information available is on the IMT device with some small case series published on the IOL-VIP. Data on the LMI is limited to a case series and little is available on the newer OriLens device. There is one recent publication on the AMD IOL.

Although the Centrasight device produces excellent magnification (x 2.5 - 3), there is significant reduction in contrast and peripheral field in the implanted eye. In addition the implant is large, requiring a larger surgical incision, a lengthy recovery time and potentially increases risk of damage to the corneal endothelium. I understand that a new foldable version of this device is now under trial which will reduce the incision size. I have not had experience of this. The IOL-VIP is a 2-lens system that is easier to implant however again concerns exist regarding long-term safety in terms of corneal damage. Also as the magnification potential is low (x1.3) the visual outcomes appear to be more modest. I understand that the AMD IOL also has a magnification potential of (x 1.3). The OriLens offers x 2.5 magnification and is based on mirror or "Cassegrain" (mirror) telescopic principles. This principle has facilitated the design of a telescope with several advantages such as 2.5 x magnification, a small wound size and shorter recovery time.

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

Visual rehabilitation with conventional low vision aids

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:

Very few (handful) and only in the private sector

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)

The adverse events are mostly the same as those for standard cataract surgery. The most serious being infectious endophthalmitis, suprachoroidal haemorrhage and posterior capsular rupture. All of the devices can cause increase endothelial cell loss, those with an anterior component or those large in size in theory more than the others but the data to date show that the rate of corneal decompensation is low.

More specific to the devices are:

- Difficulties with tolerating the difference in magnification in each eye for the devices that give the larger magnification
- Failure to sufficiently improve vision in those that have lower magnification.
- Reduction of contrast sensitivity in the implanted eye
- Reduction of peripheral visual field

2. Anecdotal adverse events (known from experience)

A number of patients are disappointed by outcomes – management of patient expectations is key and time consuming both before and after the procedure. It is important that patients understand that this procedure will not return vision to normal, the scotoma (black spot from AMD) will still be there but will be smaller. They will still likely still need external low vision aids for finer detail. However vision for facial recognition (very important to people), TV etc should be improved.

3. Theoretical adverse events

Increase in fall rate due to different magnification in each eye in those with the larger magnification power.

4.2 What are the key efficacy outcomes for this procedure?

- Best corrected distance visual acuity
- Quality of life improvement
- Best corrected near acuity/reading speed

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

Patient selection is key and is difficult due to the poor understanding of why some patients tolerate and use these devices well whilst other patients, despite good improvement in visual function, find them difficult to manage. Other questions that remain unanswered is whether it is better to implant the better seeing eye or the dominant eye. There is concern that some of the devices with lower magnification potential ie x 1.3 cannot provide sufficient improvement in patients with advanced disease. These may be more suited to those with a lesser degree of vision loss.

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

Experienced cataract surgeons will be able to insert with relative little training.

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

- **Post-Approval Study of the Implantable Miniature Telescope (PAS-01)**
  Sponsor: VisionCare Ophthalmic Technologies, Inc. **ClinicalTrials.gov Identifier:** NCT01757132
- **Efficacy of the Telescopic Mirror Implant for Age-related Macular Degeneration:** The MIRROR Trial (acronym MIRROR). A Multicentre Randomised Controlled Clinical Trial. EME NIHR funded Start date November 2015. First patient enrolment in May 2016 (Silvestri et al)

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

None

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

There is some concern about patient selection and how patients are being advised about the potential outcomes with some of the devices in the private sector. Patient follow-up and training with these devices after implantation is also key. From speaking to patients it has been difficult to quantify how this is being provided in the private sector.

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

- Pre–op best corrected distance visual acuity with refraction both eyes
- Pre–op best corrected distance visual acuity with refraction and telescopic simulator both eyes

- Pre–op best corrected near visual acuity with refraction both eyes
- Pre–op best corrected distance visual acuity with refraction and telescopic simulator both eyes
- Post –operative best corrected distance visual acuity with refraction at 12 months in both eyes
- Post –operative best corrected near visual acuity with refraction at 12 months
- In both eyes
- Patient reported outcomes such as activities of Daily Living and Quality of Life pre and post intervention.
- Corneal clarity/endothelial cell count
- Surgical complications

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

Best corrected visual acuity for distance and near and Quality of life improvement.

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

Corneal decompensation**.**

6 Trajectory of the procedure

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

Once good evidence is available for efficacy for a device that is affordable, easy to implant/surgeon friendly and is efficacious and safe with good guidance for patient selection – the procedure is likely to spread quickly. Patient interest is high.

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

☐ Most or all district general hospitals.

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

☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

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

☒ Major.

☐ Moderate.

☐ Minor.

Comments:

7 Other information

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

Although at present more good quality evidence is required on most of the devices (only the IMT device has robust Level 2 data), this type of procedure would fill a great unmet need for this population.

The benefits of cataract surgery in the general population are well established with 91% (37,096) of eyes achieving a best corrected visual acuity of 6/12 or better. The presence of AMD as a co-morbidity has been highlighted as a risk factor for poor visual outcome following cataract surgery. Individuals with “no AMD” gained a mean of 8.36 letters, those with “mild AMD” 6.13 letters, those with “intermediate AMD” 3.92 letters and those with advanced AMD” 1.94 letters. (95% CI: 0.05-3.82) Despite the small improvement in vision in these patients with AMD, most studies demonstrate that the majority of individuals found that cataract surgery improved quality of life. The addition of an intraocular magnifying device in appropriately selected patients could substantially augment the improvement in vision following cataract surgery in patients with advanced AMD and therefore further reduce the burden of blindness and its consequences in this population and their carers.

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

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

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[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐	**YES**
	☒	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☒	**YES**
	☐	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	☒	**NO**
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☐	**YES**
	☒	**NO**
Investments – any funds that include investments in the healthcare industry	☐	**YES**
	☒	**NO**
Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	☒	**YES**
	☐	**NO**

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

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

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

Comments:

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

Fee-paid work: I have been paid for Advisory Board work by Bayer and Allergan but not related to this topic.

Personal non-pecuniary interest: I am the Chief Investigator for the current EME NIHR grant as mentioned above. As yet patient enrolment has not started. I have also lectured on the topic of intraocular magnifying devices but have been objective and neutral on the subject.

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

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