

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name: **Implantation of a graft-keratoprosthesis combination for severe corneal opacity (1160/1)**

Name of Specialist Advisor: **Professor Christopher Liu**

Specialist Society: **Royal College of Ophthalmologists (RCO)**

Please complete and return to: azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

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

Yes.

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

1.1 Does the title used above describe the procedure adequately?

Yes.

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

Comments:

Implantation of the Boston Type 1 Keratoprosthesis – corneal graft combination as an alternative to high risk keratoplasty in wet, blinking eyes

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?

Glaucoma and vitreoretinal experts need to be available.

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 two 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 which does this procedure, please indicate your experience with it:

- I have never performed this procedure.
- I have performed this procedure at least once.
- I perform 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 undertaken bibliographic research on this procedure.
- I have undertaken research on this procedure in laboratory settings (e.g. device-related research).
- I have undertaken 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 that 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?

High risk keratoplasty based on risk of rejection according to quadrants of corneal vascularisation. Repeat keratoplasty with increasing risk of graft rejection.

The indication of the Boston Type 1 KPro should only be for wet blinking eyes. The worry is surgeons using the device off label, or not having knowledge, experience, or an ever ready multidisciplinary team available when complications occur. The life-long risk for complications is high, and there is also a moderate to high risk of losing sight permanently following implantation, especially without regular and educated surveillance and speedy intervention.

3.3 Please estimate the proportion of doctors in your specialty who are performing 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 **corneal** specialists engaged in this area of work.
- Cannot give an estimate.

Comments:

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

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

1. Theoretical adverse events

2. Anecdotal adverse events (known from experience)

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

Corneal infection

Intraocular infection

Corneal melt

Device extrusion

Glaucoma

Retinal detachment

Sterile vitritis

Retroprosthetic membrane formation

4.2 What are the key efficacy outcomes for this procedure?

Improvement of visual acuity

Retention of same

Retention of device

Adequate management of glaucoma

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

Using the device off label

Errors of judgement when deciding to whom the procedure should be offered

Inadequate individual and team knowledge and organisation

4.4 What training and facilities are required to undertake this procedure safely?

Thorough knowledge of how to implant the device

The sort of patients to offer surgery to

The sort of patients to which such surgery should not be offered

Institutional specifications include a multidisciplinary team including clinical psychologist, glaucoma and vitreoretinal consultants, availability 24/7/365

The implantation is relatively easy surgery although there are details which can be taught to improve outcome

Team set up is important

Knowledge to recognise complications promptly and dealing with them promptly and adequately essential for not losing eyes

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

Already in the literature

International results not as good as USA results

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, e.g. PUBMED? (This can include your own work). If yes, please list.

Yes

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

At the moment it is free for all
I would advocate a network of a small number of units

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):

QoL
Visual acuity
Retention of same
Readmissions
Complications rate
Loss of eye
Retention of device

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

Dealt with above

6 Trajectory of the procedure

6.1 In your opinion, what is the likely speed of diffusion of this procedure?

It can be fast but numbers and danger do not justify free for all approach.

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

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

Comments:

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

- Major.
- Moderate.
- Minor.

Comments:

7 Other information

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

8 Data protection and conflicts of interest

8.1 Data protection statement

The Institute is committed to transparency. As part of this commitment your name and specialist society will be placed in the public domain, in future publications and on our website (www.nice.org.uk) and therefore viewable worldwide. This information may be passed to third parties connected with the work on interventional procedures.

A copy of the completed Specialist Adviser advice will be sent to the Specialist Society who nominated the Specialist Adviser.

Specialist Advisers should be aware that full implementation of the Freedom of Information Act 2000 may oblige us to release Specialist Advice from 2005. The Freedom of Information Act 2000 favours the disclosure of information however requests will be considered on a case by case basis. If information is made available, personal information will be removed in accordance with the Data Protection Act 1998. In light of this please ensure that you have not named or identified individuals in your comments.

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

Please state any potential conflicts of interest, or any involvements in disputes or complaints, relevant to this procedure. Please use the “Conflicts of Interest for Specialist Advisers” policy (attached) as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

Do you or a member of your family¹ have a **personal pecuniary** interest?
The main examples are as follows:

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).

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 which include investments in the healthcare industry YES
 NO

Do you have a **personal non-pecuniary** interest – eg 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.

**Professor Bruce Campbell, Chairman,
Interventional Procedures Advisory
Committee**

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

February 2010

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

Procedure Name: **Implantation of a graft-keratoprosthesis combination for severe corneal opacity (1160/1)**

Name of Specialist Advisor: **Professor Harminder Dua**

Specialist Society: **Royal College of Ophthalmologists (RCO)**

Please complete and return to: azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

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

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

1.1 Does the title used above describe the procedure adequately?

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

Comments:

The word 'graft' in the title can be ambiguous as it could refer to a 'corneal graft' specifically, or more generally to any type of graft eg. bone graft, tooth or dacron mesh graft.

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:

There is no inter-specialty controversy but the participation of a maxillo-facial surgeon or a dental surgeon is required for the osteo-odonto keratoprosthesis (bone/tooth graft keratoprosthesis).

The next two 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 which does this procedure, please indicate your experience with it:

- I have never performed this procedure.
- I have performed this procedure at least once.
- I perform this procedure regularly.

Comments:

Of the different types I have performed the one which involves use of a corneal graft only. Use of a mucosal graft is part of this procedure.

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

- I have never taken part in the selection or referral of a patient for this procedure.
- 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 referred patients for the osteo-odonto keratoprosthesis on a few occasions

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

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

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

Comments:

All types of graft keratoprosthesis are part of the spectrum of options offered to the patients with the same pathology i.e severe corneal opacity. These include stem cell transplants with or without amniotic membrane graft. Some of the principles and preparatory and ancillary procedures apply to all procedures. I have considerable clinical and basic science (published) research experience in this area.

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 that procedure's safety and efficacy.
- Definitely novel and of uncertain safety and efficacy.
- The first in a new class of procedure.

Comments:

The Osto-odonto keratoprosthesis (OOKP) and the Boston type 1, and less so the Boston type 2 keratoprosthesis (with corneal graft) have been performed for many years with a lot of experience accruing and several publications in the literature

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

The OOKP and the Boston Kpro are the standards against which any new Keratoprosthesis will be compared. Limbal stem cell transplant or ex-vivo expanded sheets of stem cells with/without corneal and or amniotic membrane graft is a procedure that is often chosen instead of a Keratoprosthesis. Usually however, the latter is performed when the former has been performed and failed.

3.3 Please estimate the proportion of doctors in your specialty who are performing 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:

This is a very specialised area and Ocular surface reconstruction for improving vision is performed in approximately less than 6 centres in the UK. OOKP is offered regularly only in one centre and the other type on an ad hoc basis in 4 or 5 centres

4 Safety and efficacy

4.1 What are the adverse effects of the procedure?

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

1. Theoretical adverse events

Resorption of the bone lamina

Extrusion

Glaucoma

Hypotony

Retinal detachment

Macular edema

Endophthalmitis

Sterile vitritis

Intraocular haemorrhage

2. Anecdotal adverse events (known from experience)

Surface infection

Necrosis of Mucosal graft

Poor visual result

Mucosal overgrowth on the optical cylinder

Retroprosthetic membrane formation

Tilt of optical cylinder

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

All of the above

Literature appended at the end.

4.2 What are the key efficacy outcomes for this procedure?

1. Visual improvement

2. Retention of prosthesis

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

It is more successful in wet eyes and where the indication is 'repeated corneal graft failure'. It is less successful in dry eyes and eyes with progressive cicatrising conditions such as Stevens Johnson syndrome and Ocular cicatricial pemphigoid, where it is needed most. At times it is difficult to ascertain the full visual potential of the eye being considered for the procedure and the outcome can be poor even after successful Kpro if the macula is affected. Glaucoma is a major problem that can affect outcome. This is difficult to monitor and control.

4.4 What training and facilities are required to undertake this procedure safely?

This procedure is essentially a team procedure with expertise required from several individuals and specialists:

Surgeon: extensive specialist post CCT training by way of Fellowship (at least one year) in a centre where the procedure is performed on a regular basis.

Nurse: Theatre nurses and out-patient nurse/ nurse councillor need special training.

Fellows: Advanced sub-specialist trainees

Electrophysiologists, radiologists, microbiologists with occasional support from Glaucoma and vitreo-retinal specialists

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

None in the UK to my knowledge

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

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?

Not really but in some parts of the world the Boston Kpro or other similar procedure may be performed when a corneal transplant is a more suitable alternative. This is partly due to the severe shortage of donor material.

In order to improve success rates of devices of interest there is a suggestion in some quarters that indications where risk of failure is high (eg Stevens Johnson syndrome, Ocular cicatricial pemphigoid, severe dry eye) are less likely to be offered the procedure though that is where the need is most. This may be true to some extent

and introduce bias but by and large the OOK P has a better success rate in the more difficult indications than the Boston Kpro.

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):

**Visual acuity, field of vision, VFQ25 and VFQ14 over time
Number of unscheduled visits to the hospital
Retention of prosthesis (anatomical success) and need for re-insertion of new graft.**

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

**Intraoperative complications: expulsive haemorrhage, retinal detachment, extensive vitreous haemorrhage.
Immediate post operative complications and late complications as listed above.**

Besides the above, the patient demographics, underlying disease condition, duration of disease, visual potential as assessed by ultrasound B scan and electrophysiological tests (ERG, VEG)

6 Trajectory of the procedure

6.1 In your opinion, what is the likely speed of diffusion of this procedure?

The procedure will not "diffuse" in the sense that it will always be restricted to a few specialised centres and the demand (patients requiring the procedure) is unlikely to surge

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:

Because of the complex nature of the procedure and the life long care required by the patients, the procedure should only be offered in specialised centres with the full team and all diagnostic, surgical and monitoring equipment and support services. Teams can link up with local consultants with training in monitoring and follow up (networks) as this will reduce the need for travelling to the specialist centre by patients coming from afar.

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

- Major.
- Moderate.
- Minor.

Comments:

The number of patients requiring this procedure per year is in the tens and will remain so for the foreseeable future

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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?

It is the only hope for sight in individuals suffering from severe corneal disease but have a functioning retina. It does and can make a huge difference to the quality of life of the individual concerned. Cosmetically the result is not often the best it can be but for the patient it is not a major concern. In some instances it is done in both eyes of the affected individual and is a controversial area as the care required and the added benefit does not justify bilateral surgery. Equally single eyed individuals with 'reasonable sight' in the seeing eye should not be offered this procedure.

8 Data protection and conflicts of interest

8.1 Data protection statement

The Institute is committed to transparency. As part of this commitment your name and specialist society will be placed in the public domain, in future publications and on our website (www.nice.org.uk) and therefore viewable worldwide. This information may be passed to third parties connected with the work on interventional procedures.

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

Please state any potential conflicts of interest, or any involvements in disputes or complaints, relevant to this procedure. Please use the "Conflicts of Interest for Specialist Advisers" policy (attached) as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

Do you or a member of your family¹ 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 which include investments in the healthcare industry **YES**
 NO

Do you have a **personal non-pecuniary** interest – eg 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. Medical Director of NuVision and Director of Dua & Dua Medical Ltd. (my private practice company together with my wife who is an anesthesiologist)
2. Shares in Glaxo SmithKline
3. Received Honoraria from Thea, Allergan, Alcon, Nicox, Bausch & Lomb for Lectures and consultancy.

Thank you very much for your help.

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).

**Professor Bruce Campbell, Chairman,
Interventional Procedures Advisory
Committee**

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

February 2010

References:

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3. Ahmad S, Akpek EK, Gehlbach PL, Dunlap K, Ramulu PY. Predictors of visual outcomes following Boston type 1 keratoprosthesis implantation. *Am J Ophthalmol*. 2015 Apr;159(4):739-747.e1.
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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.