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.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name: Artificial iris implant insertion for aniridia IP1738

Name of Specialist Advisor: Bruce Allan

Job title: Consultant Ophthalmic Surgeon

Professional Regulatory Body: GMC ☒

Other (specify) ☐

Registration number:

Specialist Society: The Royal College of Ophthalmologists

Nominated by (if applicable):

1 About you and your speciality's involvement with the procedure

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

☒ Yes.

☐ No – please answer no more questions and return the form

Comments: I have been performing anterior segment surgery since the 1980s and have a strong background in anterior segment reconstruction including iridoplasty and the implantation if iris prostheses. Non traumatic aniridia is less common, and I have limited experience of iris prosthesis implantation for congenital aniridia.

1.2 Is this procedure relevant to your specialty?

☒ Yes.

☐ No - please answer no more questions. Please give any information you can about who is likely to be doing the procedure and return the form.

Comments:

1.3 Is this procedure performed by clinicians in specialities other than your own?

☐ Yes – please comment

☒ No

Comments:

1.4 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 assuming the brief here relates to the Customflex Silicone Iris Prostheses from Human Optics AG rather than the range of PMMA (non flexible) black occlusive segments and optic surrounds from Morcher AG which are well established.

1.5 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 regularly see and repair iris defects, or implant occlusive ring segments. The Customflex iris prostheses are CE marked and FDA approved, but they are very expensive. So none of us in the UK has a wide experience of implantation.

1.6 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 no current or past direct involvement with iris prosthesis research, but I do have a strong background in biomaterials, procedure development and evaluation in anterior segment surgery. I have done the company training for the Customflex device.

1.7 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: Most iris reconstruction and prosthesis implantation is performed by surgeons with a subspecialist interest in cornea and anterior segment surgery.

2 About the procedure

2.1 Does the title used above describe the procedure adequately?

☐ Yes

☒ No - If no, please suggest alternative titles.

Comments: 'Flexible silicone iris prostheses for aniridia and traumatic iris defects' would be more appropriate. Traumatic iris defects make up the bulk of the work. It is unclear here whether the brief relates just to new silicone iris prostheses or PMMA iris segments which are much longer established.

2.2 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: PMMA iris prostheses are well established, silicone iris implants have a shorter track record but the FDA data at one year looks good. Implantation within the lens capsular bag at the time of cataract surgery (not in contact with uveal tissue or the cornea) may have less longer term risk than implantation in the ciliary sulcus and fixation of the fibre reinforced embodiment with sutures.

2.3 What is/are the best comparator(s) (standard practice) for this procedure?

See above - PMMA iris segments and intraocular lenses with an occlusive optic surround are well established. Silicone prostheses are more expensive, and have a shorter track record.

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

Multicentre safety and efficacy data available at https://www.fda.gov/medical-devices/recently-approved-devices/customflextm-artificial-iris-p170039

2.5 Please list any abstracts or conference proceedings that you are aware of that have been *recently* presented / published on this procedure (this can include your own work). Please note that NICE will do a comprehensive literature search on this procedure and we are only asking you for any very recent or abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

There is some longer term data indicating better safety for the non-fibre reinforced prostheses Rickmann A et al Graefe's Arch Clin Exp Ophthalmol 2016 Jul;254(7):1419-24

3 Safety and efficacy of the procedure

3.1 What are the potential harms of the procedure?

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

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

See FDA safety study and 2016 longer term data above. Problems can include glaucoma, uveitis, cystoid macular oedema, and corneal endothelial failure

Anecdotal adverse events (known from experience)

Difficult - many of the eyes implanted have had serious trauma or extensive previous surgery, so may have complications unrelated to the implanted prosthesis

Theoretical adverse events

3.2 Please list the key efficacy outcomes for this procedure?

See FDA study.
CDVA
Glare symptoms (QoV or similar PROM)
Comfort
Satisfaction with cosmesis (emotional well-being)
Intraocular pressure
Corneal endothelial cell count
CMO

3.3 Please list any uncertainties or concerns about the *efficacy* of this procedure?

The main concern is cost

3.4 What clinician training is required to do this procedure safely?

Implantation requires some technical adaptations. CST in ophthalmology with expertise in cataract surgery and iridoplasty plus the training program offered by Human Optics would be minimum requirements.

3.5 What clinical facilities are needed to do this procedure safely?

An ophthalmic operating theatre equipped for cataract surgery with appropriate intraocular instrumentation. Note that the block to NHS use would be the cost of the prostheses rather than the instrumentation required.

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

Primarily cost. The FDA clinical trial data looks solid. There are three important outcomes in eye surgery: Vision, comfort, and cosmesis. These implants aim to cover an important area of unmet clinical need particularly for patients with light irides in which conventional black PMMA prostheses can be unsightly.

4 Audit Criteria

Please suggest potential audit criteria for this procedure.

4.1 Beneficial outcome measures. This should include short and long term clinical outcomes, quality-of-life measures and patient related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured:

CDVA (LogMAR letter counting)
Glare symptoms, comfort, emotional well-being (none of the existing PROMs are great but we are working on it) - both at one year after surgery

4.2 Adverse outcome measures. This should include early and late complications. Please state the post procedure timescales over which these should be measured.

Patients losing 2 lines of logMAR CDVA at 1 year after surgery
Secondary surgical intervention and medication - at 1 and 5 years after surgery (ideally)

5 Uptake of the procedure in the NHS

5.1 If it is safe and efficacious, in your opinion, how quickly do you think use of this procedure will be adopted by the NHS (choose one)?

☒ Rapidly (within a year or two).

☐ Slowly (over decades)

☐ I do not think the NHS will adopt this procedure

Comments:

All depends on cost - significant pressure should be exerted to reduce the prosthesis cost for NHS and private use in the UK

5.2 If it is safe and efficacious, in your opinion, will this procedure 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: The technical skill set required for cataract surgery only requires relatively minor adaptation to accommodate safe implantation of the silicone only prostheses in the lens capsular bag of the ciliary sulcus. The fibre reinforced devices require more a subspecialist anterior segment reconstruction background

5.3 If it is safe and efficacious, in your opinion, the potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources:

☐ Major.

☒ Moderate.

☐ Minor.

Comments:

6 Other information

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

Comments:

Look at the existing FDA data as a starting point.

7 Data protection and conflicts of interest

7.1 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. For more information about how we process your personal data please see our privacy notice

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7.2 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. Conflicts of Interest for Specialist Advisers

Declarations of interest form			
Type of interest	**Description of interest**	**Relevant dates**	
		Interest arose	**Interest ceased**
I have performed iris reconstruction surgery including CustomFlex iris prosthesis implantation at Moorfields Eye Hospital			

* Guidance notes for completion of the Declarations of interest form

Name and role	Insert your name and your position in relation to your role within NICE
Description of interest	Provide a description of the interest that is being declared. This should contain enough information to be meaningful to enable a reasonable person with no prior knowledge to be able to read this and understand the nature of the interest. Types of interest: **Direct interests** **Financial interests** - Where an individual gets direct financial benefits from the consequences of a decision they are involved in making. *For examples of financial interests please refer to the policy on declaring and managing interests.* **Non-financial professional and personal interests -** Where an individual obtains a non-financial professional or personal benefit, such as increasing or maintaining their professional reputation, from the consequences of a decision they are involved in making. *For examples of non-financial interests please refer to the policy on declaring and managing interests.* **Indirect interests -** Where there is, or could be perceived to be, an opportunity for a third party associated with the individual in question to benefit. A benefit may arise from both a gain or avoidance of a loss.
Relevant dates	Detail here when the interest arose and, if applicable, when it ceased.
Comments	This field should be populated by the guidance developer and outline the action taken in response to the declared interest. It should include the rationale for this action, and the name and role of the person who reviewed the declaration.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mirella Marlow Programme Director

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.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name:	**Artificial iris implant insertion for aniridia**
Name of Specialist Advisor:	Professor Harminder Dua
Job title:	Chair and Professor of Ophthalmology, University of Nottingham
Professional Regulatory Body:	GMC ☒
	Other (specify) ☐
Registration number: 3369326	
Specialist Society:	Royal College of Ophthalmologists
Nominated by (if applicable):	

1 About you and your speciality's involvement with the procedure

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

☒ Yes.

☐ No – please answer no more questions and return the form

Comments: I perform this procedure as part of my regular practice

Is this procedure relevant to your specialty?
1.2

☒ Yes.

☐ No - please answer no more questions. Please give any information you can about who is likely to be doing the procedure and return the form.

Comments:

1.3 Is this procedure performed by clinicians in specialities other than your own?

☐ Yes – please comment

☒ No

Comments:

1.4 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:

There are different designs and makes of this artificial implant. I have implanted a few of these but not all of them, some are more expensive than others and were not funded through IFR

1.5 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 not referred patients to another centre as I perform the procedure myself

1.6 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:

1.7 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:

2 About the procedure

2.1 Does the title used above describe the procedure adequately?

☒ Yes

☐ No - If no, please suggest alternative titles.

Comments:

2.2 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:

2.3 What is/are the best comparator(s) (standard practice) for this procedure?

In cases where there is partial loss of iris, pupilloplasty is possible and undertaken. Where there is complete aniridia, there are not comparators other than different makes or designs of the same item.

Painted colour contact lenses are effectively used in some cases who can tolerate the lens. As power correction (aphakia) is also needed, the lenses are relatively thick and cannot be worn for long periods. There are definite risks associated with long term use of contact lenses, especially if worn for several hours daily.

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

None to my knowledge

2.5 Please list any abstracts or conference proceedings that you are aware of that have been *recently* presented / published on this procedure (this can include your own work). Please note that NICE will do a comprehensive literature search on this procedure and we are only asking you for any very recent or abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

Not much recently. Mostly case reports

3 Safety and efficacy of the procedure

3.1 What are the potential harms of the procedure?

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

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

Glaucoma, corneal decompensation. Xiaodi Qiu, Yinghong Ji, Tianyu Zheng, Yi Lu. The efficacy and complications of black diaphragm intra-ocular lens implantation in patients with congenital aniridia. 2016; 94(5):e340-e344

Anecdotal adverse events (known from experience)

Dislocation of implant with capsular bag

Theoretical adverse events

Colour mismatch, patient not liking the colour and wanting the implant explanted, decentration, tilted implant.

3.2 Please list the key efficacy outcomes for this procedure?

Patient satisfaction (cosmetic and visual function), improvement in symptoms of glare and photophobia, visual improvement.

3.3 Please list any uncertainties or concerns about the *efficacy* of this procedure?

Nothing specific. Obtaining exact match with other eye in unilateral cases is a concern as it requires standard photographs of the normal eye and expert photography is required.

3.4 What clinician training is required to do this procedure safely?

Workshops, wetlab and supervised training

3.5 What clinical facilities are needed to do this procedure safely?

Nothing specific

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

No

4 Audit Criteria

Please suggest potential audit criteria for this procedure.

4.1 Beneficial outcome measures. This should include short and long term clinical outcomes, quality-of-life measures and patient related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured:

Vision including glare and contrast sensitivity, Patient satisfaction and quality of life

4.2 Adverse outcome measures. This should include early and late complications. Please state the post procedure timescales over which these should be measured.

Vision loss, intraoperative and post operative complications (within 1st month hyphena and vitreous bleeding, lens tilt, pressue rise; and over 5 years post transplantation for glaucoma and corneal decompensation)

5 Uptake of the procedure in the NHS

5.1 If it is safe and efficacious, in your opinion, how quickly do you think use of this procedure will be adopted by the NHS (choose one)?

☒ Rapidly (within a year or two).

☐ Slowly (over decades)

☐ I do not think the NHS will adopt this procedure

Comments:

Some types of aniridia lens implanta are already in use in the NHS

5.2 If it is safe and efficacious, in your opinion, will this procedure 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:

Most patients with congenital aniridia have other problems such as (paediatric) cataract, glaucoma, nystagmus and limbal stem cell deficiency, which need expert co-management provided by specialists in these areas. Centres which have the comprehensive expertise should be undertaking thse implants for such patients.

Acquired aniridia, mostly traumatic or surgical, are usually adult patients and need the implant when associated truama related complications are managed. These too require specialist expertise. Hence though immediate management of trauma has to be undertaken locally, late management of sequelae such as aniridia, should be undertaken in specialist centres.

5.3 If it is safe and efficacious, in your opinion, the potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources:

☐ Major.

☐ Moderate.

☒ Minor.

Comments:

Total number of patients requiring this procedure will be relatively low. As stated, some types on aniridia implants are already offered on the NHS. The comparatively cheaper lenses are used in congenital aniridia becuause the though the choice of colour is limited, the same colour can be chosen for both eyes.

For unilateral cases, where a perfect colour match with the other eye is required, the more modern (and expensive) lenses are likely to be required. The total number will increase only by these relatively few individuals.

6 Other information

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

Comments:

Unilateral traumatic aniridia mostly affects young individuals and cosmesis is very important for them from a psychological standpoint, for selfconfidence and performance at the workplace.

7 Data protection and conflicts of interest

7.1 Data Protection

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

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

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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. Conflicts of Interest for Specialist Advisers

Declarations of interest form			
Harminder S Dua, Specialist adviser to NICE **No financial interest is directly or indirectly related to the product being considered.**			
Type of interest	**Description of interest**	**Relevant dates**	
		Interest arose	**Interest ceased**
Financial Dompe	*Travel, accommodation and honorarium*	*Current*	
Financial	*Travel, accommodation*	*Current*	

Thea	*and honorarium and research support*		
Financial Santen	*Travel, accommodation and honorarium and research support*	*Current*	
Financial Visufarma	*Travel, accommodation and honorarium*	*Current*	
Financial Chiesi	*Travel, accommodation and honorarium*	*Current*	

* Guidance notes for completion of the Declarations of interest form

Name and role	Insert your name and your position in relation to your role within NICE
Description of interest	Provide a description of the interest that is being declared. This should contain enough information to be meaningful to enable a reasonable person with no prior knowledge to be able to read this and understand the nature of the interest. Types of interest: **Direct interests** **Financial interests** - Where an individual gets direct financial benefits from the consequences of a decision they are involved in making. *For examples of financial interests please refer to the policy on declaring and managing interests.* **Non-financial professional and personal interests -** Where an individual obtains a non-financial professional or personal benefit, such as increasing or maintaining their professional reputation, from the consequences of a decision they are involved in making. *For examples of non-financial interests please refer to the policy on declaring and managing interests.* **Indirect interests -** Where there is, or could be perceived to be, an opportunity for a third party associated with the individual in question to benefit. A benefit may arise from both a gain or avoidance of a loss.
Relevant dates	Detail here when the interest arose and, if applicable, when it ceased.
Comments	This field should be populated by the guidance developer and outline the action taken in response to the declared interest. It should include the rationale for this action, and the name and role

	of the person who reviewed the declaration.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mirella Marlow Programme Director

Signed: Harminder S Dua. 25.09.19

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.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name: Artificial iris implant insertion for aniridia IP1738

Name of Specialist Advisor: Stephen Tuft

Job title: Consultant Ophthalmologist

Professional Regulatory Body: GMC ☒

Other (specify) ☐

Registration number: 2385844

Specialist Society: The Royal College of Ophthalmologists

Nominated by (if applicable): The Royal College of Ophthalmologists

1 About you and your speciality's involvement with the procedure

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

☒ Yes.

☐ No – please answer no more questions and return the form

Comments:

1.2 Is this procedure relevant to your specialty?

☒ Yes.

☐ No - please answer no more questions. Please give any information you can about who is likely to be doing the procedure and return the form.

Comments:

1.3 Is this procedure performed by clinicians in specialities other than your own?

☒ Yes – please comment

☐ No

Comments:

This may be performed by other specialities within ophthalmology (surgical retina, glaucoma, but not by non-ophthalmologists

1.4 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 not performed surgery using all the different implant types available, but I have seen patients who have had most of the procedure types

1.5 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 now refer patients for this surgery

1.6 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:

1.7 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:

This related to aniridia of all types (congenital and traumatic). A minority will perform this surgery for congenital aniridia.

2 About the procedure

2.1 Does the title used above describe the procedure adequately?

☐ Yes

☒ No - If no, please suggest alternative titles.

Comments:

I think that there will be major difficulties if traumatic loss of the whole or part of the iris (traumatic aniridia) is grouped with congenital aniridia. The associated pathologies are completely different, as well as the long-term risks. For example, the visual potential in congenital aniridia if significantly reduced and there is a natural history for corneal opacity and secondary glaucoma. In addition, bilateral surgery is usually required for congenital aniridia, whilst unilateral surgery is normally the situation with trauma (rare exceptions may occur). In my view the analysis should be done separately for each indication, or 2 reviews performed.

2.2 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:

The concept is well established, but new designs have been introduced recently

2.3 What is/are the best comparator(s) (standard practice) for this procedure?

1. No treatment (tinted glasses), or cataract surgery without an inserted implant
2. A tinted contact lens

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

None to my knowledge

2.5 Please list any abstracts or conference proceedings that you are aware of that have been *recently* presented / published on this procedure (this can include your own work). Please note that NICE will do a comprehensive literature search on this procedure and we are only asking you for any very recent or abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

None that would not be identified by recent search

3 Safety and efficacy of the procedure

3.1 What are the potential harms of the procedure?

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

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

Long term risk of secondary glaucoma

Long term risk of implant dislocation

Long term risk of corneal endothelial damage

Reduced view of the posterior segment of the eye that may make certain subsequent interventions more difficult

Anecdotal adverse events (known from experience)

Theoretical adverse events

3.2 Please list the key efficacy outcomes for this procedure?

1. Reduction in glare with bright light
2. Cosmetic improvement

3.3 Please list any uncertainties or concerns about the *efficacy* of this procedure?

The long-term stability of the implants (congenital aniridia especially)

3.4 What clinician training is required to do this procedure safely?

Watching an instructional video is probably sufficient
Specific training/supervision may be recommended by the manufacturer

3.5 What clinical facilities are needed to do this procedure safely?

Ophthalmic operating theatre. Some specialist equipment.

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

None known

4 Audit Criteria

Please suggest potential audit criteria for this procedure.

4.1 Beneficial outcome measures. This should include short and long term clinical outcomes, quality-of-life measures and patient related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured:

Reduction in glare (short term)

Quality of life (cosmetic improvement will be a key component)

4.2 Adverse outcome measures. This should include early and late complications. Please state the post procedure timescales over which these should be measured.

All measured over 5 to 10 years

1. **Secondary glaucoma**
2. **Implant dislocation**
3. **Corneal decompensation (corneal oedema and opacity)**
4. **Inadequate effect**

5 Uptake of the procedure in the NHS

5.1 If it is safe and efficacious, in your opinion, how quickly do you think use of this procedure will be adopted by the NHS (choose one)?

☒ Rapidly (within a year or two).

☐ Slowly (over decades)

☐ I do not think the NHS will adopt this procedure

Comments:

5.2 If it is safe and efficacious, in your opinion, will this procedure 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:

Most = traumatic aniridia, minority = congenital aniridia. Although the surgery is not technically challenging, the patients with congenital aniridia tend to be referred to specialist centres

5.3 If it is safe and efficacious, in your opinion, the potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources:

☐ Major.

☐ Moderate.

☒ Minor.

Comments:

6 Other information

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

Comments:

None known

7 Data protection and conflicts of interest

7.1 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. For more information about how we process your personal data please see our privacy notice

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7.2 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. Conflicts of Interest for Specialist Advisers

Declarations of interest form			
Type of interest	**Description of interest**	**Relevant dates**	
		Interest arose	**Interest ceased**
None declared			

* Guidance notes for completion of the Declarations of interest form

Name and role	Insert your name and your position in relation to your role within NICE
Description of interest	Provide a description of the interest that is being declared. This should contain enough information to be meaningful to enable a reasonable person with no prior knowledge to be able to read this and understand the nature of the interest. Types of interest: **Direct interests** **Financial interests** - Where an individual gets direct financial benefits from the consequences of a decision they are involved in making. *For examples of financial interests please refer to the policy on declaring and managing interests.* **Non-financial professional and personal interests -** Where an individual obtains a non-financial professional or personal benefit, such as increasing or maintaining their professional reputation, from the consequences of a decision they are involved in making. *For examples of non-financial interests please refer to the policy on declaring and managing interests.* **Indirect interests -** Where there is, or could be perceived to be, an opportunity for a third party associated with the individual in question to benefit. A benefit may arise from both a gain or avoidance of a loss.
Relevant dates	Detail here when the interest arose and, if applicable, when it ceased.
Comments	This field should be populated by the guidance developer and outline the action taken in response to the declared interest. It should include the rationale for this action, and the name and role of the person who reviewed the declaration.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mirella Marlow Programme Director