NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Professional Expert 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:	Repetitive short pulse transscleral cyclophotocoagulation for glaucoma	
Name of Professional Expert:	HARI JAYARAM	
Job title:	CONSULTANT OPHTHALMIC SURGEON HONORARY UCL ASSOCIATE PROFESSOR	
Professional Regulatory Body:	GMC	☒
	Other (specify)	☐
Registration number:	4645854	
Specialist Society:	ROYAL COLLEGE OF OPHTHALMOLOGISTS	
Nominated by (if applicable):	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:

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:

This is a new procedure that we are very familiar with, as our conventional treatment is the continuous wave laser which although useful, does have its drawbacks. We are currently in the process of evaluating different micropulsed diode laser machines with a view to developing a clinical study to look for patient centred outcomes for micropulsed diode vs conventional diode laser. The treatment itself is not technically challenging and is essentially very similar to the laser we currently perform in terms of technique.

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: As we are in the process of trialling this equipment at our hospital, I have recommended this treatment to several patients under my care.

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 coordinated international peer-review on 2 recent manuscripts on this emerging technology in my role as editorial board member for the journal Translational Vision Science and Technology. We are currently developing an investigator led trial protocol to study clinical and patient related outcomes with this treatment compared to conventional cyclodiode laser treatment.

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 is relatively new technology and most units will be reluctant to invest in the laser machines required for this process until NICE guidance is issued and initial experience with the laser has been obtained.

2 About the procedure

2.1 Does the title used above describe the procedure adequately?

☒ Yes

☐ No - If no, please suggest alternative titles.

Comments:

However in the field, it is referred to as “Micropulsed Cyclophotocoagulation for Glaucoma” by the majority of glaucoma specialists.

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:

It will likely be associated with an increased safety profile, but may have a slight reduction in efficacy (reduced overall cumulative laser power). It is a minor but very novel variation on the current technique used.

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

Standard Laser - ie. continuous wave cyclophotocoagulation of the ciliary body

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

NCT00349414
NCT02627352
NCT03187418
Cochrane Review for Class of Treatments in Refractory Glaucoma (PMID: 30852841)

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.

These are interesting relevant presentations from recent meetings that I have attended.

American Glaucoma Society, Washington DC, Feb 2020

Poster Abstracts

- PO001: Outcomes of Iridex MicroPulse P3 (MP3) with Higher-Than-Usual Settings for the Management of Elevated Eye Pressure
- PO007: Comparison of Clinical Outcomes After Micropulse and Continuous Wave Transscleral Cyclophotocoagulation
- PO010: The Effect of Iris Color on Outcomes of Micropulse Cyclophotocoagulation (mTSCPC) in Adult Glaucoma Patients at One Year
- PO019: Efficacy and Safety of Micropulse Transscleral Cyclophotocoagulation (M-TSCPC) in Uncontrolled Mild to Severe Glaucoma: A Single Center Canadian Study.

American Academy of Ophthalmology Meeting, San Francisco, November 2019

Poster Abstract

- PO208 Three-Year Outcomes of Micropulse Trans-scleral Cyclophotocoagulation in Medically Uncontrolled Glaucoma

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)

Reduction in vision, inflammation eg. PMID 29979339 and https://doi.org/10.1016/j.ogla.2019.02.002

Anecdotal adverse events (known from experience)

Reduced efficacy

Theoretical adverse events

Inflammation, cystoid macular oedema, phthisis, loss of vision, scleral perforation (associated with continuous wave laser)

3.2 Please list the key efficacy outcomes for this procedure?

Reduced IOP
Reduced Dependence on IOP lowering drops
Reduced Ocular Surface Disease (Drop induced) and therefore increase QoL parameters

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

Does the reduction in laser energy delivered impact efficacy of the treatment

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

Fellowship trained glaucoma specialist, or doctor under supervision of such an individual.

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

Sterile procedure room with ability to seal windows for laser safety purposes.

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

Most published studies examine the role of this treatment in refractory glaucoma although this may have a role in less advanced glaucomas where patients do not wish to have invasive surgery.

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:

IOP (short, medium, long term ie. 1-2 years post laser)
Number of Glaucoma Medications Used
Ocular Surface Assessment (OSDI)
Glaucoma Symptom Score (GSS)

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

Non response rate (IOP, medications)
Need for re-treatment and/or treatment escalation
Complications: short-medium term: prolonged inflammation, cystoid macular oedema; medium-long term: loss of vision, phthisis

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:

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:

Use in refractory glaucoma, and pending appropriate research into use in les advanced cases as an alternative to invasive surgery then it maybe classed as moderate.

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:

Ensure no monopoly of companies who provide machines for this purpose

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 professional expert 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**
Consultancy	Consultancy to Allergan	March 2018	

* 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

Professional Expert 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: Repetitive short pulse transscleral cyclophotocoagulation for glaucoma

Name of Professional Expert: Philip Bloom

Job title: Consultant Ophthalmologist

Professional Regulatory Body: GMC ☒

Other (specify) ☐

Registration number: 2930804

Specialist Society: RCOphth / UKEGS

Nominated by (if applicable): RCOphth

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:

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:

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:

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?

Trans-scleral cyclophotocoagulation

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

Not that I am aware

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.

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)

Anecdotal adverse events (known from experience)

Pupil irregularity

Theoretical adverse events

3.2 Please list the key efficacy outcomes for this procedure?

Intra-ocular pressure reduction

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

Longevity of effect

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

Routine training

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

Laser safety

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

Uncertainty if it is any better than the existing treatment

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:

Percentage IOP reduction

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

Complications, side effects

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:

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:

7 Data protection and conflicts of interest

7.1 Data Protection

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Declarations of interest form			
Type of interest	**Description of interest**	**Relevant dates**	
		Interest arose	**Interest ceased**
Speaker fees	*2 one-off payments (Carleton)*	*2018*	*2019*
Friendship	*I know the owner of Daybreak Medical*	*2017*	

* 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