

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name: **Endoscopic CO2 laser cricopharyngeal myotomy for relief of dysphgia (1291/1)**

Name of Specialist Advisor: **Mr Chris Hartley**

Specialist Society: **Royal College of Speech and Language Therapists**

Please complete and return to: [azeem.madari@nice.org.uk](mailto:azeem.madari@nice.org.uk) OR [sally.compton@nice.org.uk](mailto: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:**

Spelling of dysphagia incorrect!

**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:**

Have performed this procedure a number of times over the last 5-10 years

**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.

**X I perform this procedure regularly.**

**Comments:**

I perform the surgery usually where a patient has had treatment for head and neck cancers. In non cancer patients a colleague usually undertakes this.

**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.

**X 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):**

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

**Comments: I have audited and published my results**

### 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 place of the procedure is not widely accepted nor practiced.

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

Open Myotomy or Non Oral Feeding as alternatives

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:**

It is a very small minority I imagine

### 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

Perforation (under 5%)

Voice problems/recurrent nerve injury (1%)

Bleeding (under 5%)

2. Anecdotal adverse events (known from experience)

Scarring and stenosis at same site

V dependent upon the preoperative tissue status. More likely with radiotherapy patients.

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

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

Reduced Aspiration

Reduced Chest infections

Reduced non oral feeding

Improved normalcy of diet

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

Yes – the identification of specific patient groups who may benefit has not really become common place. Patients with neuromuscular conditions for example.

When should it be used instead of non oral or modified oral feeding?

In patients with post radiotherapy strictures for example, if very fibrosed my work has suggested it is not effective whereas with less fibrosis it may be.

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

Experienced CO2 laser unit with experienced operator. Adequate Speech and Language therapist input before and after. Videofluoroscopy. Flexible endoscopic assessment. FEES Ideally a multidisciplinary approach to patient selection Adequate video recording equipment to demonstrate.

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

Unsure

**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.**

My colleague Mr Arul has recently presented HIS data in Sunderland. My data is in Clinical Otolaryngology hence via PUBMED etc....

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

Its largely word of mouth and maybe a little ad hoc.

## **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):**

**Pre and Post:**

**Normalcy of Diet**  
**100ml water swallow test**  
**Chest infections**  
**Tube feeding**  
**Hospitalisation related to the dysphagia**  
**MDADI**

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

**Death**  
**Perforation/Neck space infection**  
**Chest infection**  
**Non Oral Feeding**  
**Length of Stay for procedure**

**6 Trajectory of the procedure**

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

**Slow**

**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.
- X** **Cannot predict at present.**

**Comments:**

Depends how widely it is taken up. Initially in specialist centres I would suggest.

**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:**

With the ageing population, there may be many patients who could benefit from this intervention.

## 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](http://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.

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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 family<sup>1</sup> have a **personal pecuniary** interest?  
The main examples are as follows:

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

- 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

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  - 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: **Endoscopic CO2 laser cricopharyngeal myotomy for relief of dysphgia (1291/1)**

Name of Specialist Advisor: **Guri Sandhu**

Specialist Society: **ENT UK**

Please complete and return to: [azeem.madari@nice.org.uk](mailto:azeem.madari@nice.org.uk) OR [sally.compton@nice.org.uk](mailto: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:**

### **2 Your involvement in the procedure**

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

Yes.

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

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

**Comments:**

**The next 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?**

Open surgical cricopharyngeal myotomy

### **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:**

## **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)

Pharyngeal perforation and infection, possible mediastinitis

3. Adverse events reported in the literature (if possible please cite literature)  
Pharyngeal perforation and infection, possible mediastinitis

3.

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

Traditionally 10-14 days in hospital with nasogastric feeding. With this technique overnight stay and return to oral intake next day.

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

In the wrong hands risk of perforation and infection, possibly fatal

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

Endoscopic laser techniques and surgical observation

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

NO

**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.**

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

None I know of.

**5 Audit Criteria**

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

**History and demographic data**

**Indications (pure dysphagia or part of pharyngeal pouch)  
(EAT-10 dysphagia score and videofluoroscopy)**

**SF-36**

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

**EAT-10**

**Videofluoroscopy**

**SF-36**

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

**Time in hospital**

**Infection bleeding**

**Conversion to open approach**

**Return to normal diet**

## 6 Trajectory of the procedure

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

1-3 years

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](http://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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**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**

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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.

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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.

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- 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.

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# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Interventional Procedures Programme

Procedure Name: **Endoscopic CO2 laser cricopharyngeal myotomy for relief of dysphagia (1291/1)**

Name of Specialist Advisor: **Kate Young**

Specialist Society: **Royal College of Speech and Language Therapists**

Please complete and return to: [azeem.madari@nice.org.uk](mailto:azeem.madari@nice.org.uk) OR [sally.compton@nice.org.uk](mailto: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:**

### **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:**

As a referring clinician, my experience is in Head & Neck cancer, ENT and laryngectomy dysphagia.

**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:**

I am experienced in referring for procedures that are an alternative to endoscopic laser cricopharyngeal myotomy.

**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:**

I speak regularly with my surgical colleagues regarding procedures and progress in treatment modalities. This approach has been covered in professional discussions I have been part of. I have attended national ENT meetings (e.g., BACO) and listened to a limited number of peer presentations on this procedure.

### **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?**

External approach cricopharyngeal myotomy, botox to the cricopharyngeal muscle, cricopharyngeal dilation, do nothing and conservative management by SLT input.

**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:**

### **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

Oesophageal perforation, scarring, stricture of upper oesophagus, no change in dysphagia symptoms, worsening of dysphagia symptoms due to scarring, unsuitable post radiotherapy due to fibrosis.

2. Anecdotal adverse events (known from experience)

n/a

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

Oesophageal perforation, no change in dysphagia symptoms, worsening of dysphagia symptoms,

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

As a speech & swallowing therapist I would propose the following:

Office / bedside swallow assessment

Videofluoroscopy / modified barium swallow

Patient rated swallowing quality of life questionnaires (eg., FOSS, EOR-QoL)

Manometry

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

Unsuitable for post radiotherapy tissue changes, progressive neurological (e.g., bulbar symptoms) dysphagia, concern that as the oesophagus is a collapsing structure that the area could potentially heal and result in limited or no benefit.

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

Not known regarding surgery.

Speech & Swallowing therapy- requires an experienced dysphagia therapist who is skilled in assessment and management of dysphagia, access to videofluoroscopy for pre and post treatment assessment, patient rated dysphagia symptom scales and access to manometry. Understanding and experience in managing GORD (Gastroesophageal reflux disease) and LPR (Laryngopharyngeal Reflux disease)

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

Unknown

**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.**

3 suggested papers:

J Laryngol Otol. 2014 Dec;128(12):1105-10. Epub 2014 Nov 11.

Targeted use of endoscopic CO2 laser cricopharyngeal myotomy for improving swallowing function following head and neck cancer treatment.

Dawe N, Patterson J, Hamilton D, Hartley C.

Laryngoscope 2014 April;124(4): 950-954

Indications and Outcomes of Endoscopic CO2 Laser Cricopharyngeal Myotomy.

Bergeron JL, Chhetri DK.

Operative Techniques in Otolaryngology (2011) 22, 135-141

Endoscopic Cricopharyngeal Myotomy

Pittman, M.J., Weissbrod, P.

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

This is a technique that has been used for several years by a limited number of surgeons. I am unaware of specific controversy at this time other than the potential significant risks involved with this procedure.

## **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):**

Speech & swallowing therapy:

- Videofluoroscopy / modified barium swallow
- Office / bedside swallow assessment
- Water swallow test
- Patient rated swallowing quality of life questionnaires (eg., FOSS, EOR-QoL, MDADI)
- Manometry

Surgery:

- Perforation rate
- Infection rate
- Duration of symptom improvement
- Incidence of other complications (literature states other authors' complication rates as 1.8-3%)

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

Mediastinitis  
Oesophageal perforation  
Infection  
Worsening of symptoms

**6 Trajectory of the procedure**

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

I cannot comment on this.

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

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

**Comments:**

I do not feel I can comment in my current role.

**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:**

This procedure would potentially replace current procedures of choice for patients in appropriately selected cases.

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?**

Do not know any further information at this time

## **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](http://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.

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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 family<sup>1</sup> have a **personal pecuniary** interest?  
The main examples are as follows:

**Consultancies or directorships** attracting regular or occasional  **YES**

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

- payments in cash or kind  **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: **Endoscopic CO2 laser cricopharyngeal myotomy for relief of dysphgia (1291/1)**

Name of Specialist Advisor: **Nimesh Patel**

Specialist Society: **ENT UK**

Please complete and return to: [azeem.madari@nice.org.uk](mailto:azeem.madari@nice.org.uk) OR [sally.compton@nice.org.uk](mailto: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:**

(Misspelling)  
Endoscopic CO<sub>2</sub> LASER cricopharyngeal myotomy for relief of dysphagia

**2 Your involvement in the procedure**

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

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

**Comments:**

**The next 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:**

Procedure normally performed by ENT surgeons

**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?

Open cricopharyngeal myotomy

#### 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:**

### 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

Damage to recurrent laryngeal nerves

Airway fire related to LASER use

2. Anecdotal adverse events (known from experience)

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

Failure/Recurrence (<10% approximately from case series)

Perforation or Leakage (<3% estimated from case series)

Mediastinitis (<3% estimated from case series)

Scarring or stenosis (uncertain %)

Dental damage (<1%)

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

Improved swallowing

Reduced choking

Reduced cough and throat irritation

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

Some uncertainty about efficacy exists, ie. Proportion of patients who have a durable improvement in symptoms

Case series suggest >80% have an improvement

Non randomised trials suggest at least equivalence with balloon dilation and open cricopharyngeal myotomy

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

Essential equipment and facilities:

Carbon Dioxide LASER

Operating microscope with micromanipulator

LASER safety framework in place

Appropriate laryngology equipment

Monopolar diathermy for endoscopic surgery

Ability to admit patients overnight  
Framework to manage perforation/tear/mediastinal infection including access to thoracic services

Essential Training:

ENT training with laryngology and/or head and neck subspecialty training  
Training in use of Carbon Dioxide LASER  
Training in open cricopharyngeal myotomy and pharyngeal pouch stapling  
Training in transoral LASER surgery (usually this is training for upper aerodigestive tract cancers, but the skills are transferable)

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

No

**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?**

Yes, there is currently little evidence as to where this procedure sits within the management paradigm for cricopharyngeal disorders  
Although it is an attractive approach for a difficult clinical problem

## **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):**

**essential:**

**post op follow up and clinical assessment**

**desirable:**

**Swallowing related quality of life (eg. EAT-10) OR  
Functional Outcome Swallowing Scale (FOSS)**

**Consideration may be given to: (but these are expensive and probably not necessary unless patient has post op problems or poor response to treatment)  
post treatment contrast swallow (preferably videoflouroscopy)  
post treatment oesophageal manometry**

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

**Failure**

**Perforation or tear**

**Mediastinitis/death ensuing from this serious complication**

**Dental damage**

**Scarring and stenosis**

## **6 Trajectory of the procedure**

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

**It is already a procedure that is established amongst most specialists in dealing with cricopharyngeal dysphagia**

**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:**

Equipment already widespread (for other related procedures)  
Skills relatively widely disseminated

## 7 Other information

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

No

## 8 Data protection and conflicts of interest

### 8.1 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](http://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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Do you or a member of your family<sup>1</sup> have a **personal pecuniary** interest?  
The main examples are as follows:

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

**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

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    - 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).
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  - 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.

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- 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: **Endoscopic CO2 laser cricopharyngeal myotomy for relief of dysphgia (1291/1)**

Name of Specialist Advisor: **Puveendran Arullendran**

Specialist Society: **Royal College of Speech and Language Therapists**

Please complete and return to: [azeem.madari@nice.org.uk](mailto:azeem.madari@nice.org.uk) OR [sally.compton@nice.org.uk](mailto:sally.compton@nice.org.uk)

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

**X** Yes.

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

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

**X** Yes.

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

**Comments:**

### **2 Your involvement in the procedure**

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

**X** Yes.

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

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

**Comments:**

**The next 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?

#### 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:**

### 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)

Oesophageal Perforation, teeth damage

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

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

Improvement in swallow and subsequent nutritional state

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

Optimal management to reduce the risk of perforation

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

Proficient in use of CO2 laser, and guidance from those who regularly perform the procedure

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

not aware

**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?**

No

## **5 Audit Criteria**

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

Using a recognised swallow assessment tool. I use the EAT 10 score (Belafsky)

Duration of inpatient hospital stay.

Complications ( Perforation and teeth damage)

Ensure at least a one year follow up.

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

EAT 10

Swal Quol

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

perforation , teeth damage, oesophageal bleeding ( early)

Re stenosis of oesophagus (late)

## 6 Trajectory of the procedure

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

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?

ROGAN CORBRIDGE in Oxford has published a large case series.

<http://www.ncbi.nlm.nih.gov/pubmed/24337898>

## 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](http://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.

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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 family<sup>1</sup> have a **personal pecuniary** interest?  
The main examples are as follows:

**Consultancies or directorships** attracting regular or occasional  **YES**

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

- payments in cash or kind  **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:**

I did present my first 8 cases as a Case series at a national ENT conference in July 2015 and will present an update review at another meeting in November this year.

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.
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