NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

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

Procedure Name:	**Transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia**
Name of Specialist Advisor:	Mr Chadwan Al Yaghchi
Specialist Society:	British Association of Otorhinolaryngologists, Head and Neck Surgeons (ENT 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 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

☒ I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

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

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

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

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

Comments:

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

☐ I have done bibliographic research on this procedure.

☐ I have done research on this procedure in laboratory settings (e.g. device-related research).

☐ I have done clinical research on this procedure involving patients or healthy volunteers.

☒ I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

☐ Established practice and no longer new.

☐ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

☒ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

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

Standard swallowing therapy

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

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

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

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

☐ Cannot give an estimate.

Comments:

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

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

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

Minor side effects including neck pain, and burning sensation has been reported.

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

Skin burns and irritation, muscle spasm, muscle pain and laryngeal spasm.

4.2 What are the key efficacy outcomes for this procedure?

Oral intake and dietary modification (i.e thickeners)
Recurrent chest infections
Patient reported outcomes i.e MDADI, EAT-10, SSQ
Videofluoroscopy studies including penetration-aspiration scale
Endoscopic evaluation of swallowing (FEES)

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

Variable results reported in literature. Difficult to make conclusions due to different reported outcome and different methodology. Some studies compared neurostimulation vs therapy alone or combination while others compared NMES vs sham simulation.

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

Practitioners should be trained on the use of NMES Procedure should be conducted in clinical area with access to emergency equipment especially O2 and suction in the unlikely event of laryngeal spasm.

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, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

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.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

Penetration-aspiration scale on videofluroscopy
Dietary modification and gastrostomy dependence
Quality of life: EAT-10

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

Mostly short term: pain, skin burns, skin irritation

6 Trajectory of the procedure

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

Slow implementation to select groups of patients, mainly neurological conditions.

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. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

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

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

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

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

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

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

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

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

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

Comments:

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

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

Jan 2016

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

Conflicts of Interest for Specialist Advisers

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

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

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

2 Personal pecuniary interests

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

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

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

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

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

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

2.2 No personal interest exists in the case of:

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

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

3 **Personal family interest**

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

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

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

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

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

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

3.2 No personal family interest exists in the case of:

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

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

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

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

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

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

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

5 Non-personal interests

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

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

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

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

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

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Interventional Procedures Programme

Specialist Adviser questionnaire

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Please respond in the boxes provided.

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

Procedure Name:	**Transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia**
Name of Specialist Advisor:	Dr Jonathan M Fishman
Specialist Society:	British Association of Otorhinolaryngologists, Head and Neck Surgeons (ENT UK)/ British Laryngological Association (BLA)

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:

Consider extending the title to include transcutaneous neuromuscular electrical stimulation (TNMES), pharyngeal intraluminal electrical stimulation and palatal electrical stimulation. Suggest broaden title to:
'Neuromuscular electrical stimulation for oropharyngeal 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 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

☒ I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

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

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

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

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

Comments:

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

☒ I have done bibliographic research on this procedure.

☐ I have done research on this procedure in laboratory settings (e.g. device-related research).

☐ I have done clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

☐ Established practice and no longer new.

☐ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

☒ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

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

Speech-therapy guided swallowing exercises/ therapy/ training. NG tubes and percutaneous gastrostomy tubes may be required in severe cases to provide adequate nutrition.

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

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

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

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

☐ Cannot give an estimate.

Comments:

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

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

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

Carnaby-Mann GD, Crary MA (2008) Adjunctive neuromuscular electrical stimulation for treatment-refractory dysphagia. Annals of Otology, Rhinology, and Laryngology 117 (4): 279-287

- 1 patient was withdrawn due to unrelated seizure activity.
- A burning sensation was reported in 50% (3/6) of patients during sessions.
- Skin irritation was reported in 33% of patients at the site of electrodes.
- The sensation of gastric fullness was reported in 33% of patients.
- Neck soreness at the electrodes sites was reported in 17% (1/6) of patients.
- Coughing and expectoration were reported during 22% of NMES sessions.

Chaudhuri G, Brady S, Caldwell R (2006) Electric stimulation for dysphagia following stroke: pilot data. Archives of physical medicine and rehabilitation 87 (11): e51

'Headache as well as neck and jaw pain were the most commonly reported side effects following stimulation; however, they were reported as mild'.

Geegenage C et al (2012). Interventions for dysphagia and nutritional support in acute and subacute stroke. Cochrane Database Syst Rev 2012;10:CD000323.

Chen YW et al (2016). The effects of surface neuromuscular electrical stimulation on post-stroke dysphagia: a systematic review and meta-analysis. Clin Rehabil; 30(1): 24-35.

Frost J, Robinson HF, Hibberd J. A comparison of neuromuscular electrical stimulation and traditional therapy, versus traditional therapy in patients with longstanding dysphagia. Curr Opin Otolaryngol Head Neck Surg. 2018 Jun;26(3):167-173.

- Low incidence of adverse effects with only minor adverse events occurring in 1.3% (4/300 electrode pair placements, in 4/10 subjects).
- One subject had both skin irritation/soreness and a burning sensation beneath the electrodes; two subjects had skin irritation or soreness beneath the electrodes; and one subject had neck or jaw pain.
- In each case, the problem was resolved by repositioning the electrodes.

2. Anecdotal adverse events (known from experience)

N/A

3. Theoretical adverse events

Theoretical adverse events include:

- Chemical burns due to electrode application
- Electrical/heat burn due to current intensity
- Electrical shock
- Muscle soreness/aches
- Haematoma/bleeding
- Laryngospasm
- Arrhythmia, hypotension
- Initial worsening of dysphagia.

4.2 What are the key efficacy outcomes for this procedure?

- Physiological changes that objectively quantify changes in swallowing biomechanics (e.g. extent of hyolaryngeal elevation, airway closure timing following electrical stimulation intervention, pharyngeal transit time, timed water swallow test).
- Improvements in swallowing outcomes by outcome scales, both clinician-rated and patient-reported (e.g. subjective questionnaires such as MD Anderson Dysphagia Inventory, EAT-10, Swallowing-related Quality of Life Scale, Swallow Function Scoring System, Functional Oral Intake Scale, Dysphagia Outcome and Severity Scale, Clinical Dysphagia Scale), or objective measures of improvements in swallowing on videofluoroscopy, or functional endoscopic evaluation of swallowing (FEES) assessment (e.g. Penetration-aspiration scale, piriform stasis time etc).
- Improved quality of life, as demonstrated on disease-specific and generic QoL questionnaires (e.g. University of Washington QoL questionnaire, Performance Status Scale-Head and Neck, SF36 etc).
- Nutritional status (e.g. weight change)/ route of feeding and feeding tube dependence – whether patient dependent on nasogastric tube, or percutaneous gastrostomy tube to maintain adequate nutrition.

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

Conflicting findings in the literature due to heterogeneity of treatments across different studies, e.g. electrical stimulation alone vs. electrical stimulation as an adjunct to traditional therapy. Also different electrode types, application sites, and treatment parameters. Reported studies in the literature often have small sample sizes, lack of randomised controls and lack of blinding. Large-scale research trials are required which incorporate control groups, randomisation processes and clear outcome measures on homogenous samples of patients.

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

Resuscitation facilities required in case of an adverse reaction.

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

- NCT01971320 Evaluation of Transcutaneous Electrical Stimulation in Post Stroke Dysphagia (TENSDEG)
- NCT01363973 Effect of Transcutaneous Electrical Stimulation on Post-stroke Dysphagic Patients (EETI-01)
- NCT02170506 Effect of Sub-mental Sensitive Transcutaneous Electrical Stimulation on Pharyngeal Muscles Control : TENSVIRT Study (TENSVIRT)
- NCT01202968 Effect of Pre-emptive Transcutaneous Neuro-muscular Electrical Stimulation for Dysphagia in Long Term Intubated Patients
- NCT01237704 Dysphagia Rehabilitation for Nasopharyngeal Carcinoma Patients Post Radiotherapy: a Randomised-controlled Trial
- NCT02379182 Effect Of Vitalstim In Patients With Chronic Post-stroke Oropharyngeal Dysphagia VITAL
- NCT01777672 Effect of Afferent Oropharyngeal Pharmacological and Electrical Stimulation on Swallow Response and on Activation of Human Cortex in Stroke Patients With Oropharyngeal Dysphagia
- NCT01723358 Neuromuscular Electrical Stimulation (NMES) Treatment Technique Therapy in the Management of Young Infants With Severe Dysphagia

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

Frost J, Robinson HF, Hibberd J. A comparison of neuromuscular electrical stimulation and traditional therapy, versus traditional therapy in patients with longstanding dysphagia. Curr Opin Otolaryngol Head Neck Surg. 2018 Jun;26(3):167-173.

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.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

Improvement in any of the following scales (where appropriate):

Qualitative scales:
- Swallowing-related quality of life (SWAL-QOL)
- MD Anderson dysphagia inventory (MDADI)
- Swallow function scoring system (SFSS)

Clinical qualitative and quantitative scales:
- Dysphagia outcome and severity scale (DOSS)
- Functional oral intake scale (FOIS)

Quantitative scales:
- Penetration aspiration scale (PAS)
- Epiglottic dysfunction scale
- Normalised residue ratio scale

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

The percentage of patients undergoing transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia who have had any of the following adverse events:
- burning sensation
- skin irritation
- soreness
- coughing/expectoration
- neck or jaw pain
- headaches
- increasing severity of dysphagia whilst receiving neuromuscular electrical stimulation
- bleeding
- other.

6 Trajectory of the procedure

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

Within 10 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?

N/A

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

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

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

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

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

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

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

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

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

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

Comments:

- Research funding provided by the Academy of Medical Sciences to JMF to study injectable materials into the larynx for regeneration (unrelated to current NICE topic).
- Also Editor of an ENT journal (Journal of Laryngology & Otology).

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

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

Jan 2016

Conflicts of Interest for Specialist Advisers

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

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

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

2 Personal pecuniary interests

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

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

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

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

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

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

2.2 No personal interest exists in the case of:

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

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

3 **Personal family interest**

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

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

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

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

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

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

3.2 No personal family interest exists in the case of:

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

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

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

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

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

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

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

5 Non-personal interests

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

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

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

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

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

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

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

Procedure Name:	**Transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia**
Name of Specialist Advisor:	Dr Justin Roe
Specialist Society:	British Association of Otorhinolaryngologists, Head and Neck Surgeons (ENT 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:

There are mixed opinions on NMES. E-stim is often used in the world of physiotherapy and devices have been approved by the FDA since 2002 for specific use to treat dysphagia. However, the evidence base is limited and swallowing problems are often multifactorial and the e-stimulation itself lack specificity.

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

☒ I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

At present, I do not offer the intervention based on the limited evidence base for my cohort of patients (head and neck cancer/ complex ENT disorders) and resource implications.

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

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

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

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

Comments:

I have had patients who have travelled overseas to have the treatment. Swallowing biomechanics were altered, changing the nature of the swallowing impairment but not yielding any improvements in swallowing safety or efficiency.

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

☒ I have done bibliographic research on this procedure.

☐ I have done research on this procedure in laboratory settings (e.g. device-related research).

☐ I have done clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

☐ Established practice and no longer new.

☐ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

☒ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

The evidence base is limited and there are conflicting findings with studies being conducted for example by firms who manufacture the equipment. Systematic reviews have also highlighted methodological flaws.

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

Standard isometri and isotonic exercises to optimise the swallowing musculature

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

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

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

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

☐ Cannot give an estimate.

Comments:

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

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

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

A systematic review has highlighted that e-stim should be used with caution in thoise with pacemakers and cardioverter defibrillators (Badger et al 2017). Known that e-stim can cause discomfort to patients.

2. Anecdotal adverse events (known from experience)

In the heads and neck population and cases I have managed has compounded rather than improved swallowing difficulties

3. Theoretical adverse events

It has been argued that concurrent stimulation of the supra and infra hyoid muscles may impact negatively on hyolaryngeal excursion (Humbert et al 2006)

4.2 What are the key efficacy outcomes for this procedure?

To improve swallowing biomechanics through an improvement in muscle strength and recruitment

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

The specificity of the technique and the fact that those utilising the technique may not have sufficient understanding of swallow biomechanics and may not be utilising instrumental evaluations to accurately understand improvements in biomechanics. There are also differences between manufacturers. There is also the feeling that the technique may be better suited to certain client groups.

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

Currently manufacturers provide a single day course to learn how to carry out the procedure using the e-stim device

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

No to my knowledge/ recent review of clinicaltrials.gov

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature

search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

Not that I am aware of

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

While use is limited in the UK, patients of mine who have sought the treatment in the US have not had critical measures completed to understand how the treatment has impacted on swallowing biomechanics. Again, the limited evidence base and concerns re methodological quality have led to the procedure being deemed as controversial.

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). Please suggest the most appropriate method of measurement for each:

NEED TO AGREE ON SPECIFIC CLIENT GROUP(S) FOR EVALUATION – THE FOLLOWING REPRESENT BROAD ASESSMENT BUT COULD BE MORE REFINED, FOR EXAMPLE IF ASSESSED IN HEAD AND NECK CANCER

Clinician rated – Functional Oral Intake Scale/ 100mL Water Swallow Test
Patient Reported – Sydney Swallow Questionnaire,
Instrumental – Penetration Aspiration Scale/ Residue Rating/ MBSImp under videofluoroscopy using contrast materials currently developed for use in large oncology trials in the UK (DARS/ PATHOS)

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

Largest RCT to date in Head and neck cancer assessed at baseline and following 12 weeks of treatment.

6 Trajectory of the procedure

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

In light of the current evidence, financial/ human resource implications, adoption is likely to be slow in the UK

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:
Even if recommended for implementation, there are significant costs in relation to the equipment required which would have to be considered in line with departmental financial plans.

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. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

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

be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

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

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

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

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

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

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

---

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

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.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

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

Jan 2016

Conflicts of Interest for Specialist Advisers

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

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

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

2 Personal pecuniary interests

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

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

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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:

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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.

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Interventional Procedures Programme

Specialist Adviser questionnaire

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Please respond in the boxes provided.

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

Procedure Name:	Transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia
Name of Specialist Advisor:	Lise Sproson
Specialist Society:	Royal College of Speech and Language Therapists and NIHR Devices for Dignity MTC

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:

It will be important to distinguish between different approaches used – different companies use different approaches. The earliest developed and better known device was VitalStim – their treatment protocol, electrode shape and placement and directions on whether or not patients should attempt to swallow anything during stimulation are very different to the Ampcare equipment and protocol.

It will also be important to clarify research findings on electrical stimulation used in isolation and research carried out using electrical stimulation in combination with exercises.

Finally, a number of acronyms are used to refer to this procedure in the literature; NMES, TNMES, TNES, TES and trademarks as reference; Estim, VitalStim and Ampcare ESP. Clarification on an agreed terminology or acronym would help clinicians with literature searching.

2 Your involvement in the procedure

I have been trained in and used the Ampcare ESP protocol but I have not used the VitalStim equipment. That approach has much more variable electrode placement.

I took part as treating clinician in a RCT of Ampcare ESP together with my colleagues Professor Sue Pownall and Professor Pam Enderby which has recently been published in IJLCD (March-April 2018, Vol 53.No2, 405-417)

I have also made oral and poster presentations of our RCT results

I have co-authored a chapter, entitled "Electrical Stimulation for the Treatment of Dysphagia", again with Professor Pownall and Professor Enderby, which was in the book Electroceuticals, edited by professor Arshad Majid (Springer International Publishing AG 2017 137 A. Majid (ed.), *Electroceuticals*, DOI 10.1007/978-3-319-28612-9_6). This covered transcutaneous electrical stimulation, and also intra pharyngeal electrical stimulation, and transcranial stimulation.

I am now in a different work role – as a Senior Research Associate with NIHR Devices for Dignity MTC. I am therefore not treating patients but remain linked to the SLT department in Sheffield who are currently using the Ampcare ESP protocol for TNMES with dysphagic patients and collating audit forms to submit to NICE.

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 procedure is usually carried out by appropriately qualified Speech & Language Therapists.

Controversy exists, not about who should carry out the procedure, but about how effective it is, since the evidence base has been conflicted on this.

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

☐ I have never done this procedure.

☐ I have done this procedure at least once.

☒ I do this procedure regularly. – See below

Comments:

I have done this procedure many times in the past but am currently in a full time research role and therefore not currently using this procedure with patients.

I am involved with supporting therapists in Sheffield who are recently trained and also in training events to train other SLTs.

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

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

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

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

Comments:

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

☒ I have done bibliographic research on this procedure.

☐ I have done research on this procedure in laboratory settings (e.g. device-related research).

☒ I have done clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

I took part as treating clinician in a RCT of Ampcare ESP together with my colleagues Professor Sue Pownall and Professor Pam Enderby which has recently been published in IJLCD (March-April 2018, Vol 53.No2, 405-417)

I have also made oral and poster presentations of our RCT results

I have undertaken literature reviews on this topic to inform a book chapter which I co-authored, also as background for our recent IJLCD article.

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

☐ Established practice and no longer new.

☐ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

☒ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

This is definitely a novel procedure in that most SLT departments do not currently use it, however if used according to manufacturers' directions, it has proven to be acceptably safe. There are conditions which are contraindicated (e.g. patients with pace makers, patients with active neck lesions or cancer etc.)

Its efficacy is still under investigation and there have been conflicting research findings, depending on the particular equipment/protocol used (some use stimulation at frequency levels which trigger sensory stimulation alone and others at higher frequencies to cause motor contractions).

There are also differing results depending on the client group as some diagnoses respond better than others – for example stroke patients appear to respond better than head and neck cancer patients. Effect also differs depending on whether the stimulation is used as an adjunct to exercise or used alone.

If helpful, please see summary of the literature which I included as part of my recent paper reporting the RCT I did using TNMES as an adjunct to exercises. Please note that this is the literature on Stroke only, there are other papers for treatment of patients with other diagnoses:

Table 1: Summary of current literature on NMES in dysphagia rehabilitation post-stroke

There is conflicting evidence that NMES *alone* is effective in treating dysphagia post stroke
In favour: 1. Freed ML, Freed L, Chatburn RL, Christian M. Electrical stimulation for swallowing disorders caused by stroke. Respiratory Care 2001; 46(5) pp466-474. 2. Permsirivanich W, Tipchatyotin S, Wongchai M, Leelanmit V, Setthawacharawanich S, Sathirapanya P, et al. Comparing the effects of rehabilitation swallowing therapy vs. neuromuscular electrical stimulation therapy among stroke patients with persistent pharyngeal dysphagia: a randomized controlled study. J Med Assoc Thai 2009; 92 (2): 259-65 3. Gallas S, Marie JP, Leroi AM. Sensory transcutaneous electrical stimulation improves post-stroke dysphagic patients. Dysphagia 2010; 25: 291-29

Against:

1. Bulow M, Speyer R, Baijens L, Woisard V, Ekberg O. Neuromuscular electrical stimulation (NMES) in stroke patients with oral and pharyngeal dysfunction. Dysphagia 2008; 23:302-309

There is evidence that NMES *as an adjunct* is more effective than traditional post stroke dysphagia therapy alone

1. Lim KB, Lee HJ, Lim SS, Choi YI. Neuromuscular electrical and thermal-tactile stimulation for dysphagia caused by stroke: a randomized controlled trial. J Rehabil Med 2009; 41: 174-178
2. Park JW, Kim Y, Oh JC, Lee HJ. Effortful swallowing training combined with electrical stimulation in post stroke dysphagia: A randomized controlled study. Dysphagia 2012; 27: 521-527
3. Kushner DS, Peters K, Eroglu St, Perless-Carroll M, Johnson-Greene D,. Neuromuscular electrical stimulation in acute stoke feeding tube-dependent dysphagia during inpatient rehabilitation. Am. J. Phys. Med. Rehabil 2013; 92(6): 486-495
4. Sun SF, Hsu CW, Lin HS Sun HP, Chang PH, Hsieh WL, Wang JL. Combined neuromuscular electrical stimulation (NMES) with fibreoptic evaluation of swallowing (FEES) and traditional swallowing rehabilitation in the treatment of stroke-related dysphagia. Dysphagia 2013 December; 28(4): 557-66
5. Lee KW, Kim SB, Lee JH, Lee SJ, Ri JW, Park JG. The effect of early neuromuscular electrical stimulation therapy in acute/subacute ischaemic stroke patients with dysphagia. Ann Rehabil Med 2014; 38 (2): 153-159
6. Chen YW, Chang KH, Chen HC, Liang WM, Lin YN. The effects of neuromuscular electrical stimulation on post-stroke dysphagia: a systematic review and meta-analysis. Clin Rehabil 2016, 30 (1) 24-35

Our group was the first to report on the Ampcare Electrical Stimulation protocol, plus exercises against resistance. Most previous literature refers to the use of VitalStim.

We found that the intervention group (receiving TNMES plus exercise was more effective than usual care. This is therefore consistent with the studies above which find TNMES is effective when used as an adjunct. (Sproson, Pownall, Enderby, Freeman. Combined electrical stimulation and exercise for swallow rehabilitation post Stroke: a pilot randomised control trial. IJLCD March-April 2018, Vol 53.No2, 405-417).

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

Traditional exercises for dysphagia.

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

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

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

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

☐ Cannot give an estimate.

Comments:

Speech & Language Therapists, rather than doctors deliver this procedure.

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

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

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

I am not aware of significant adverse events reported in any of the published literature.

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

Since TNES involves the use of electric current at higher levels than occur naturally within the body, it's use is contraindicated in patients with pacemakers, metal implants, those with cancer or skin breakdown, and patients who are pregnant or who have peripheral nerve conduction problems (Baker, 1993).

Complications could theoretically include: chemical burn, due to electrode paste application, heat burn due to current intensity, electric shock from mains type current and wet skin, spread of infection from muscle-pumping effect and muscle soreness after prolonged use (Leelamanit et al., 2002).

In addition there may be specific risks pertaining to the placement of electrodes near the larynx and carotid bulb: laryngospasm, arrhythmia and hypotension (Lim et al., 2009)

In our trial, participants in the intervention arm judged that the Ampcare ESP treatment was tolerable and no immediate/long-term adverse effects of the intervention were found.

4.2 What are the key efficacy outcomes for this procedure?

- Physiological changes in swallow physiology function, for example improved range and strength of movement of oropharyngeal structures
- Reduced laryngeal penetration and/or aspiration – as determined under videofluoroscopy
- Functional improvement in safe swallowing ability – as determined by outcome measures such as FOIS, Rosenbek PAS and SWALQOL (these outcome measures are explained in section 5.1)

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

Please see literature summary in section 3.1 regarding the conflicting findings of previous studies. There remains uncertainty around effectiveness with different patient groups, differing results due to heterogeneity of electrode placement and treatment protocols.

There is also uncertainty around cost effectiveness as the treatment is designed to be delivered intensively.

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

Speech and Language Therapists must become certified and registered either with VitalStim or Ampcare.

The procedure can be carried out in a hospital or domiciliary setting, using the regulated equipment; stimulator unit, sterile wipes, electrodes and – for Ampcare - a specially designed postural resistance neck brace.

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

I am not aware of any currently, apart from the audit of Ampcare ESP which Professor Sue Pownall is collating in Sheffield, the results of which she will provide to NICE.

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

Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

Please see literature summary table above (re Stroke only).

A recent publication is: Sproson, Pownall, Enderby, Freeman. Combined electrical stimulation and exercise for swallow rehabilitation post Stroke: a pilot randomised control trial. IJLCD March-April 2018, Vol 53.No2, 405-417.

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, the VitalStim method has very disparate electrode placement guidance and current intensity settings.

ViatlStim allow food/fluid bolus swallows during stimulation whereas Ampcare ESP does not, it is an indirect therapy. This is based on evidence by Humbert et al 2006 and Ludlow et al 2007 that VitalStim over the laryngeal and submandibular areas lowered the larynx and hyoid during stimulation, placing some healthy volunteers and patients at risk of aspiration.

5 Audit Criteria

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

Sheffield Teaching Hospitals are currently collating audit data from NHS Trusts who are trialling the Ampcare protocol.

Professor Sue Pownall and those of us in Sheffield who are trained in the procedure adapted a NICE audit tool for this purpose. This is attached separately. questionnaire.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures). Please suggest the most appropriate method of measurement for each:

FOIS – Functional Oral Intake Scale – to show treatment effect in terms of the quantity and range of oral intake safely manageable pre and post treatment

Rosenbek Penetration-Aspiration Scale – to show any changes in severity of laryngeal penetration and/or aspiration and other physiological changes under videofluoroscopy

SWALQOl – Swallow-related Quality of Life

5.2 Adverse outcomes (including potential early and late complications). Please state timescales for measurement e.g. bleeding complications up to 1 month post-procedure:

Please see section 4.1.3 re theoretical adverse outcomes.

In our recent RCT we followed up patients one month post end of treatment and there were no adverse effects. I do not know of any complications which are likely to develop after treatment has stopped.

6 Trajectory of the procedure

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

This will depend upon training of therapists and staffing resources locally, given that the therapy is meant to be delivered intensively and many SLT departments are not sufficiently resourced for this.

Health economic evaluation and larger scale trial of efficacy could help determine whether cost offsetting of being able to discharge patients from protracted follow up would merit service re-design.

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:

There is potential for much greater application – but dependent on resource allocation and training. Research into the most cost efficient ways of delivering this treatment is required.

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?

Larger scale trials would be helpful in clarifying advice for clinicians as there have been conflicting results from earlier trials and many of the studies are small scale.

Clarification will also be required on which treatment protocol and electrode placements are suitable for particular oropharyngeal dysphagia symptoms, also as to whether food/fluid boluses are to be given while stimulation is underway as VitalStim and Ampcare give different guidance on this.

Health economic evaluation is also required as implementation of many of the protocols requires some SLT service redesign and so evaluation of the cost offsets would be helpful to add to efficacy data.

8 Data protection and conflicts of interest

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

8.1 Data Protection

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

be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

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

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

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

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

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

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

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

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 have presented oral and poster presentations and published a paper on an RCT trial evaluating the Ampcare ESP protocol, however this research was independently designed and carried out by NHS staff.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

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

Jan 2016

Conflicts of Interest for Specialist Advisers

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

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

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

2 Personal pecuniary interests

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

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

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

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

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

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

2.2 No personal interest exists in the case of:

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

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

3 **Personal family interest**

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

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

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

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

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

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

3.2 No personal family interest exists in the case of:

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

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

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

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

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

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

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

5 Non-personal interests

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

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

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

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

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