NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1877 Electrical stimulation of the pharynx for neurogenic dysphagia**

Your information

Name:	Catherine Blakemore
Job title:	Lead Speech and Language Therapist in Inpatient Neuro Rehabilitation
Organisation:	Northern Care Alliance, Salford Care Organisation
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Professional organisation or society membership/affiliation:	Royal College of Speech and Language Therapists
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g., GMC, NMC, HCPC)	HCPC: SL22116

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a MedTech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. Your advice and views represent your individual opinion and not that of your employer, professional society, or a consensus view. Your name, job title, organisation, and your responses, along with your declared interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I have experience in using this device with patients in inpatient neuro rehab settings both with and without tracheostomy. I have completed 5 treatments to date; 2 were with patients in the post-acute phase of rehab ad 3 have been with patients in the acute phase of Neuro rehab. I am keen to get approval to purchase the device to enable PES to be an ongoing treatment option.
	Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this	I was supported by the company Phagenesis in having access to a base station and catheters to trial the treatment with my caseload (hyperacute, acute, post-acute setting). Prior to this I had reviewed the literature and discussed the benefits of its use with colleagues working in AICU and Stroke. I am aware that there a few Hospitals in Greater Manchester that have access to PES and understand that it is more frequently used in the AICU and Stroke context currently but there is evidence in the literature for use in other Neurological aetiologies of dysphagia and in more chronic presentations of dysphagia. With the correct competency training and set up PES can be administered by professionals e.g. specialist nurses, however I strongly feel that Speech and Language Therapy should be very involved in the identification and monitoring of the patients involved, as it is the skillset of the SLT

	procedure/technology, please indicate your experience with it.	to assess and advise on appropriate functional management outcome from a swallow perspective, whether that relates to assessment of swallow recovery and secretion management to support tracheostomy weaning, or progression from NBM to oral intake. PES supports swallow rehabilitation through sensory stimulation of the vagus nerve and thereby swallow response, for a patient to require this they will most likely have sensory impairment posing them a greater risk of silent aspiration. The SLT has the skill set to perform objective assessments e.g., FEES and VFS which would help in some instance in the selection of appropriate patients, and in other's identify if the treatment has been successful from a functional perspective.
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research (see details below). *Blakemore C, Hunter J, Bhaskar B. Rapid swallow improvement following pharyngeal electrical stimulation in a COVID 19 patient with long term severe Neurogenic dysphagia: A case report. Journal of Rehabilitation Medicine Clinical Communications. 2021;4: 1000073. Published 2021 Dec 20*

3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	My clinical opinion is that PES is an innovative procedure which has growing recognition in the literature as a treatment option that can expediate outcomes of trache weaning, step down from AICU, progression with swallow and feeding outcomes for patients with Neurogenic dysphagia originating from both peripheral and central impairment. Established practice and no longer new.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	I believe that it is a brilliant resource to have in addition to standard care.

Current management

5	Please describe the current standard of care that is used in the NHS.	Currently standard care can include: -MDT led trache weaning approach, including ACV/ ESAF, resensitisation with cuff down (when safe to do so) - SLT led rehab programmes including targeted exercises (ideally informed by FEES/ VFS), manoeuvres and strategies, therapeutic tastes and advised oral intake.
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?	Some teams do have access to surface electrical stimulation devices for treatment of swallow e.g., NMES. This approach is not invasive but relies on accuracy of pad placement on appropriate muscles to ensure correct muscles are targeted to support contraction and swallow. I am not familiar with the evidence base for this device. The PES device like the Phagenesis device is invasive but can also be used as a functional feeding tube which is very helpful and appropriate in the acute phase of care. This treatment also

	If so, how do these differ from the procedure/technology described in the briefing?	has very clear guidance on the maximum number of treatments requires (x6) and the duration of this.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	- Reduced length of stay in AICU and HDU, due to faster recovery of swallow and possibility of decannulation from Trache- benefits patient wellbeing and has financial saving potential. - Faster recovery of swallow and return to oral intake- improving both functional and quality of life outcomes for patients. Also reduces care support needs and costs in supporting a patient with enteral feeding routes.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	- AICU - Stroke - Neuro- surgical - Neuro Rehab
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	This device has the potential to support patient flow and step down from AICU/ HDU and reduce length of stay. Faster decannulation from trache can (especially within the context of the COVID pandemic) can reduce risk of need for AGP's which has potential to cause exposure risk to professionals and other patients, it also enables patients to be moved to the right places for their care more quickly e.g., can be transferred to rehab more quickly, or other specialist areas that are not as familiar with trache management. Faster recovery of swallow can ensure increased independence and quality of life, optimise patient nutrition and hydration through requiring less modification and fewer restrictions. It can also reduce the length of stay caused by aspiration related illness and readmission due to improved swallow function and safety. Improved swallow function and oral intake can also reduce the limitations needed for placement as PEG feeding not required and specialist care support with enteral feeding no longer required. This also has a significant financial saving implication in both the Hospital setting and Community setting.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	I believe that for the whole pathway having access to PES (like Phagenesis) would support reduced costs overall in terms of; reduced bed stay days in AICU/ HDU, and Hospital stay overall. It would require less clinical care time from both nursing and SLT if recovery is expediated.

11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	There is an initial outlay for purchase, and time needed for training. Consideration is also needed for some settings to ensure the right structure of SLT cover and skill mix is in place to support with selection, assessment, additional rehab, and management approaches. Access to FEES and VFS would be essential to enable monitoring and guidance. When established the cost would be less overall with scope for savings on, less need for clinical reviews and monitoring of chest from MDT (including costs for CXR, antibiotics etc), less need from additional high costing specialist services/ beds e.g., AICU, faster recovery would enable reduced need for repeated reviews from specialist services.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	It would be important to ensure that the SLT establishment is resourced and skilled to be involved in this treatment approach, team education and patient selection to ensure resource is used appropriately. Access to FEES and potentially VFS would be strongly advised. Access to staff member able to place NG catheter If catheter to be used as functional NG, then wider treating team would need to be trained in its function.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	In my experience the company offers competency training in how to use the device and if staff member is trained and a frequent user then they could be assigned as a trainer. I would advise that SLT are very involved with the implementation of this, as they are experts in the field of swallow impairment and rehabilitation. Appropriate education and expectation management is essential as like all treatments it is not always successful. Understanding of the indications/contraindications and signs to stop treatment needs to be fully understood by those involved in patient selection and treatment administration. The wider treating team also need education in terms of the catheter care (i.e., not getting the electrodes wet in the shower), understanding that the NG catheter must be removed if the patient requires an urgent MRI

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Adverse effects from teaching clinical discussions and experience: - Discomfort - Hypersalivation- which may require suction, typically ceases when as patient has had a little time to tolerate the treatment and stops shortly afterwards. - Reddening to mucosa- low risk - Pain in ear and eye if placement impacts on trigeminal nerve- low risk, if occurs repositioning the catheter slightly by may help reduce contact with the nerve. - Local oedema- low risk
15	Please list the key efficacy outcomes for this procedure/technology?	- Improved secretion management, with potential for; improved quality of life, reduce risk of aspiration events, potential for wean to uncuffed trache tube which may in turn support decannulation. - Reduced frequency of reintubation/ failed decannulations - Rapid/ timely decannulation from tracheostomy - Reduced prevalence of aspiration pneumonia - Reduced LOS - Improved independence with nutrition and hydration though faster recovery of swallow and return to oral intake. - Improved quality of life for patients and relatives
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Despite the evidenced benefits of PES, the invasive nature of this treatment and the need for patient tolerance and engagement in threshold and tolerance setting does mean that this treatment approach may not be possible for more agitated or cognitively impaired patients. I would also not wish to currently use this treatment option in low awareness patients or those with PSH in case sensory stimulation triggered significant episodes.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	

18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	As stated previously I would advocate for an appropriately resourced and skilled SLT service to support with the implementation of PES, feel that it should be considered in centres where there is an appropriate skill set and access to FEES and VFS. Centres that are most appropriate would be those that have; AICU/ HDU, high caseloads of Neuro patients e.g., Acute and rehab Stroke and Neuro units. Most or all district general hospitals.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Bath PM, Scutt P, Love J, et al. Pharyngeal Electrical Stimulation for Treatment of Dysphagia in Subacute Stroke: A Randomized Controlled Trial. Stroke. 2016;47(6):1562-1570. Michou E, Mistry S, Jefferson S, Tyrrell P, Hamdy S. Characterizing the mechanisms of central and peripheral forms of neurostimulation in chronic dysphagic stroke patients. Brain Stimul. 2014;7(1):66-73. Restivo DA, Casabona A, Centonze D, Marchese-Ragona R, Maimone D, Pavone A. Pharyngeal electrical stimulation for dysphagia associated with multiple sclerosis: a pilot study. Brain Stimul. 2013;6(3):418-423. Suntrup S, Marian T, Schröder JB, et al. Electrical pharyngeal stimulation for dysphagia treatment in tracheotomized stroke patients: a randomized controlled trial. Intensive Care Med. 2015;41(9):1629-1637. Dziewas R, Stellato R, van der Tweel I, et al. Pharyngeal electrical stimulation for early decannulation in tracheotomised patients with neurogenic dysphagia after stroke (PHAST-TRAC): a prospective, single-blinded, randomised trial. Lancet Neurol. 2018;17(10):849-859. Bath PM, Woodhouse LJ, Suntrup-Krueger S, et al. Pharyngeal electrical stimulation for neurogenic dysphagia following stroke, traumatic brain injury or other causes: Main results from the PHADER cohort study. EClinicalMedicine. 2020;28:100608. Published 2020 Nov 10.

		oestenberger M, Neuwersch S, Hoefner E, et al. A Pilot Study of Pharyngeal Electrical Stimulation for Orally Intubated ICU Patients with Dysphagia. Neurocrit Care. 2020;32(2):532-538. Muhle P, Labeit B, Wollbrink A, et al. Targeting the sensory feedback within the swallowing network-Reversing artificially induced pharyngolaryngeal hypesthesia by central and peripheral stimulation strategies. Hum Brain Mapp. 2021;42(2):427-438. Blakemore C, Hunter J, Bhaskar B. Rapid swallow improvement following pharyngeal electrical stimulation in a COVID 19 patient with long term severe Neurogenic dysphagia: A case report. Journal of Rehabilitation Medicine Clinical Communications. 2021;4: 1000073. Published 2021 Dec 20
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	PhEAST

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Would not be able to advise appropriately as the benefits are across specialities; AICU, Stroke, Neurosurgery, Neuro Rehab and in more chronic populations.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Not that I have experienced.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	Lack of SLT resource and skill mix to support this implementation, education, patient selection and associated assessments and monitoring.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	I understand that the current PhEAST study is looking at the difference between usual SLT care and intervention and usual care with PES.

25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures, and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: I would monitor measure before and after treatment over a period of 6 months/ or for as long as the patient is demonstrating positive change in assessment reviews. **Rating scales:** *Secretion rating scales:* Drooling severity scale New Zealand Secretion rating scale- with FEES *Aspiration risk:* Penetration and Aspiration Scale- FEES or VFS *Functional swallow rating scale:* FOIS DSRS TOMS for dysphagia *Additional functional outcome data:* Duration of trache and time to decannulation Time from cuffed trache to uncuffed trache/ decannulation Number of bed stay days in AICU/ HDU Time from NBM to oral intake Incidence of aspiration/ readmission to Hospital *Quality of life scales:* Eat 10 Swal- Qol HADS

		Adverse outcome measures: Occasions of no functional change Incidents of pain/ oedema and severity Number of incomplete treatments due to intolerance- may be an indication of inappropriate selection and incorrect resource use.

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	

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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial professional	The company Phagenesis supported with the loan of a base station and provided catheters to support trial of this device at Manchester Foundation Trust and Salford Royal Foundation Trust	**March 2020 (Loaned equipment for trial in MFT, then agreed to loan for SRFT in Aug 2020)**	**March 2022 (End of loan agreement)**
Non-financial personal	The company Phagenesis supported with the publication costs of a case report published in JRM-CC in Dec 2021	**Aug 2020 (Started Write up)**	**Dec 2021 (Case Report Published)**
Choose an item.			

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Catherine Blakemore**
Dated:	**14. 04.2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1877 Electrical stimulation of the pharynx for neurogenic dysphagia

Your information

Name:	Deborah Broadbent
Job title:	Clinical Specialist Speech and Language Therapist
Organisation:	Universities Hopsitals Dorset NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Royal College of Speech and Language Therapists and Health & Care Professions Council
Nominated/ratified by (if applicable):	N/A
Registration number (e.g. GMC, NMC, HCPC)	RC0008601 SL05269

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Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I am familiar with this technology and have used it frequently with patients on the stroke unit at Poole Hospital. Initially I was involved as part of a RCT and then a registry study. I have use dit with approximately 50 patients since 2014
	Have you used it or are you currently using it?	We are currently delivering Pharyngeal electrical stimulation (PES) at Poole Hospital as a stand-alone treatment.
	− Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	I do not believe this is widely used as yet in the NHS as further studies as planned to determine it's effectiveness.
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	I am not aware of many other professions using this equipment but it is possible for them to be trained to do so
	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please	We deliver this treatment so do not refer patients elsewhere for it.

	indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done clinical research on this procedure involving patients or healthy volunteers. I have been involved in the STEPs Phader, and PhEED studies and as a trust we are about to start PhEAST imminently. Other (please comment)
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	This is a new and innovative way to treat dysphagia that is very different to our usual forms of standard care. Definitely novel and of uncertain safety and efficacy. Safety levels have clearly been established with this treatment but further studies are planned to look at it's effectiveness.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	It would be used on selected patients in addition to standard care

Current management

5	Please describe the current standard of care that is used in the NHS.	Current care for dysphagia is varied but mostly consists of compensatory techniques, swallow exercises and some external muscle stimulation is sometimes used
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	No

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	I believe this treatment is effective in approximately 50-60% of the patients I have used it on. It can significantly improve post stroke dysphagia and in many cases patients can revert back to eating and drinking either normal or modified diet and fluids
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Stroke patients with dysphagia and potentially patients with other forms of neurogenic dysphagia
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	It does have the potential to reduce the incidence of aspiration pneumonia, need for NG and PEG feeding and reduce length of stay.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Overall with good patient selection I believe it could be a cost effective treatment and more importantly improve patients outcomes and quality of life
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Initial lay out of costs for equipment and training staff would be significant but there could be savings in the longer ter
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No specific changes are required.
13	Is any specific training needed in order to	Training in the delivery of the treatment would be required

	use the procedure/technology with respect to efficacy or safety?	

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	There are patients that cannot receive the treatment eg pregnant patients, those on oxygen or who have a pacemaker cannot receive the treatment. It is therefore imperative that the treatment is not delivered to these groups. I am not aware of any other risks
15	Please list the key efficacy outcomes for this procedure/technology?	Improved swallow function, increased pharyngeal sensation, reduced risk of aspiration
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Patients who are not eligible to receive the treatment
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	I am not aware of any controversy
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	STEPs study National Stroke Conference presentations over past 5 years
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	PhEAST study is about to start across the UK and Europe. UHD is taking part in this research

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	In my experience we deliver this treatment to 1-2 stroke patients per month on our stroke unit. We have approximately 500 admissions per year
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Once training is given there should not be any concerns
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	It is costly and as there is still current research in this field there may be a reluctance to purchase the equipment

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	This is currently planned with PhEAST
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Assessment of swallow, requirement of long term enteral feeding, incidence of aspiration pneumonia Adverse outcome measures: Tolerability of treatment by patients

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	I have been using this treatment and technology as part of clinical research but I am also advocating for this within my trust as part of general clinical. We have been delivering this as part of standard care to some of our stroke patients.

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Choose an item.			
Choose an item.			
Choose an item.			

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Print name:	**Deborah Broadbent**
Dated:	**14.04.22**

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Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1877 Electrical stimulation of the pharynx for neurogenic dysphagia**

Your information

Name:	Professor Philip M Bath
Job title:	Stroke Association Professor of Stroke Medicine
Organisation:	University of Nottingham
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Royal College of Physicians (RCP). British & Irish Association Stroke Physicians (BIASP)
Nominated/ratified by (if applicable):	
Registration number (e.g. GMC, NMC, HCPC)	2581530

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Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this	**Pharyngeal electrical stimulation (PES)** **Clinical**: I have occasionally used the procedure in patients with post stroke dysphagia. However, it is usually administered by speech & language therapists or nurses. I am very familiar with the technique. **Research, primary**: I have been/am: - Chief Investigator of the completed commercial Phagenesis Ltd-sponsored STEPS phase III t PES; this includes academic secondary publications: ○ Bath PM, Scutt P, Love J, Clavé P, Cohen D, Dziewas R, Iversen HK, Ledl C, Ragab Soda H, et al. Pharyngeal electrical stimulation for treatment of dysphagia in subacut stroke: A randomized controlled trial. *Stroke*. 2016;47:1562-1570 ○ Everton LF, Benfield JK, Hedstrom A, Wilkinson G, Michou E, England TJ, Dziewas Bath PM, Hamdy S. Psychometric assessment and validation of the dysphagia sever rating scale in stroke patients. *Sci Rep*. 2020;10:7268 ○ Everton LF, Benfield JK, Michou E, Hamdy S, Bath PM. Effects of pharyngeal electri stimulation on swallow timings, clearance and safety in post-stroke dysphagia: Analy from the swallowing treatment using electrical pharyngeal stimulation (steps) trial. *St Research and Treatment*. 2021;2021:5520657 - Deputy Chief Investigator of the completed commercial Phagenesis Ltd-sponsored PHADER phase IV study of PES: ○ Bath PM, Woodhouse LJ, Suntrup-Krueger S, Likar R, Koestenberger M, Warusevitane A, Herzog J, Schuttler M, Ragab S, Everton L, et al. Pharyngeal electrical stimulation for neurogenic dysphagia following stroke, traumatic brain

	procedure/technology, please indicate your experience with it.	injury or other causes: Main results from the phader cohort study. *EClinicalMedicine*. 2020;28:100608 - Deputy Chief Investigator of the completed commercial Phagenesis Ltd-sponsored PhEED phase III trial of PES: publication of this trial that was stopped early due to low recruitment is in progress. - Chief Investigator of the ongoing academic NIHR HTA-funded PhEAST phase IV trial of PES. PhEAST will involve 30-40 UK sites as well as some from Austria, Denmark and Germany. It uses a primary clinical outcome (DSRS) and has health economic outcomes: o https://fundingawards.nihr.ac.uk/award/NIHR132016 o https://www.isrctn.com/ISRCTNISRCTN98886991 o https://stroke.nottingham.ac.uk/pheast/ - Chair of Trial Steering Committee of the completed commercial Phagenesis Ltd-sponsored PhAST-TRAC trial: o Dziewas R, Mistry S, Hamdy S, Minnerup J, Van Der Tweel I, Schäbitz W, Bath PM, Investigators P-T. Design and implementation of pharyngeal electrical stimulation for early de-cannulation in tracheotomized (phast-trac) stroke patients with neurogenic dysphagia: A prospective randomized single-blinded interventional study. *Int J Stroke*. 2017;12:430-437. o Dziewas R, Stellato R, van der Tweel I, Walther E, Werner CJ, Braun T, Citerio G, Jandl M, Friedrichs M, Notzel K, et al. Pharyngeal electrical stimulation for early decannulation in tracheotomised patients with neurogenic dysphagia after stroke (phast-trac): A prospective, single-blinded, randomised trial. *Lancet Neurol*. 2018 - Chief Investigator of the academic real world phase IV register of PES: o https://stroke.nottingham.ac.uk/stroke_maps/ **Research, secondary research**: I have been/am: - Senior author of an individual patient data systematic review/meta-analysis of pilot academic of PES: o Scutt P, Lee HS, Hamdy S, Bath PM. Pharyngeal electrical stimulation for treatment poststroke dysphagia: Individual patient data meta-analysis of randomised controlled *Stroke Res Treat*. 2015;2015:429053 - Senior author of a Cochrane review of interventions for post-stroke dysphagia which includes PES; this was first published in 2000 and is being updated but the latest published version is o Bath PM, Lee HS, Everton LF. Swallowing therapy for dysphagia in acute and subacu stroke. *Cochrane Database Syst Rev*. 2018;10:Cd000323

		NHS use − PES has a CE Mark for neurogenic dysphagia which covers multiple causes including stroke, traumatic brain injury, multiple stenosis and critical illness polyneuropathy. Hence, PES is available in the UK. − PES is infrequently used after non-ventilated stroke due to the absence of definitive evidence, especially following the neutral STEPS trial. My own Trust is awaiting more evidence, e.g. from PhEAST, and NICE comment. − PES is increasingly being used in ICUs on the basis of PHAST-TRAC and single arm part of PHADER relevant to post-ventilation dysphagia. − We occasionally buy catheters for younger patients with particularly troublesome post stroke dysphagia.
2	− 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 clinical research on this procedure involving patients or healthy volunteers. I have published this research.
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	PES is a first in class device but is potentially wider in that there is no definitive treatment for post-stroke dysphagia (Cochrane review). Definitely novel and of uncertain safety and efficacy. The first in a new class of procedure.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	PES has the potential to be used on top of nurse/SLT care as defined below.

Current management

5	Please describe the current standard of care that is used in the NHS.	Post-stroke dysphagia is largely managed by nurses (screening tests) and speech & language therapists (SLTs, screening, instrumental tests with VFS and FEES). SLTs use a 'black box' of behavioural interventions which together appear to be effective (Cochrane review).
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	PES should not be confused with neuromuscular electrical stimulation (NMES) which applies to an overlapping group of patients (https://www.nice.org.uk/guidance/ipg634). NMES encompasses several techniques, and its evidence is primarily from multiple academic phase II trials. The Cochrane review suggests that NMES may be effective although there is significant heterogeneity. The Cochrane review has identified multiple other interventions encompassing potential drugs and devices (rTMS, TCDS). There is currently minimal evidence to support the use of any of these.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Reduced clinical dysphagia, aspiration pneumonia (and so death), need for long-term enteral nutrition via PEG/RIG, length of stay in hospital, and carer stress. Improved quality of life.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Neurogenic dysphagia: including stroke, traumatic brain injury, multiple stenosis and critical illness polyneuropathy. PES (and other techniques) have not been tested in and are probably not suitable for end-stage neurogenic dysphagia, e.g. dementia, motor-neuron disease.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Pathway: Although PES will not change hospital pathways, it has the potential to reduce length of rehabilitation and so hospital stay. Often, discharge from rehabilitation wards is delayed by the need to find a care home or set up homes from enteral nutrition, including training of carers. The company have discussed the potential for at home treatment using a short catheter that does not allow nutrition to be administered. Outcomes: improved as listed in 7.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	The cost of PES (training, catheter, delivery) has the potential to more-then-offset the costs of managing complications such as pneumonia, enteral nutrition costs, and length of stay.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Staff will need to be trained in administering PES. PES is controlled from a base station that needs to be bought (or rented). Overall, PES could be cost effective and reduce costs.

12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No extra facilities - treatment is administered by the bed-side.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, one-off training is needed for control of the base-station. Insertion and management of the catheter is similar to nasogastric tubes.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Hazards of insertion of a nasogastric tube. PES studies (as identified above) have not identified device-specific AEs. PES studies have not recorded serious device deficiencies.
15	Please list the key efficacy outcomes for this procedure/technology?	STEPS used radiological penetration/aspiration measured using the penetration aspiration scale score derived from videofluoroscopy. PHAST-TRAC used readiness to decannulate following tracheotomy during ventilation based on FEES examination. PhEAST will use clinical dysphagia measured using the dysphagia severity rating scale. See question 7 for other outcomes.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	STEPS was neutral. There are multiple potential explanations: - Patients receiving PES were under-treated (15 mA) relative to the positive studies: PHAST-TRAC 34 mA, PHADER 20 mA, PhEED 28 mA.

		- The control group received PES testing for threshold and tolerability. Retrospectively, this amounted to significant treatment in patients with high tolerability levels. - Patients were too mild in dysphagia severity.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Yes, safe, potentially efficacious. Most or all district general hospitals.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Not aware of any.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Yes, see PhEAST and MAPS above. PhINEST is an EU trial in ICUs.

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	5-10% of hospitalised strokes.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	No.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	No.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Ongoing trials likely to provide definitive data on effectiveness or lack of.
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late	Beneficial outcome measures: - Clinical dysphagia (DSRS, FOIS) - Aspiration pneumonia - Death - Need for long-term enteral nutrition via PEG/RIG - Length of stay in hospital - Carer stress - Quality of life (EQ-5D-5L, EQ-VAS) Adverse outcome measures: - Trauma from catheter insertion (as for nasogastric tube insertion) - Removal of catheter during 6 days of treatment

	complications. Please state the post procedure timescales over which these should be measured:	- Incomplete treatment (<6 treatment days)

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	A promising treatment which needs definitive trial and health economic evidence.

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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Direct - financial	Retainer by Phagenesis to provide advice.	**2011**	**Ongoing**
Non-financial professional	Travel if presenting at a company-sponsored educational symposium	**Ad hoc**	
Choose an item.			

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Click here to enter text.Philip Bath**
Dated:	**Click here to enter text.12/4/22**

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Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1877 Electrical stimulation of the pharynx for neurogenic dysphagia**

Your information

Name:	Sarah Wallace OBE
Job title:	Consultant Speech and Language Therapist
Organisation:	Manchester University NHS Foundation Trust (Wythenshawe Hospital)
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Royal College of Speech and Language Therapists, Health Care Professions Council
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	HCPC SL05492

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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

x☐ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this	I have been using pharyngeal electrical stimulation since 2017 as clinical treatment for dysphagia in patients in intensive care and on the stroke unit at Wythenshawe hospital. I started this because I am always looking for proactive ways to treat swallowing problems rather than waiting for things to resolve. I had 15 years of working experience in ICU as an SLT at this time. When I initiated this we were the first hospital in the UK to use it in ICU. I had seen many patients on ICU with very severe dysphagia due to ICU neuromyopathy/ acquired weakness and desensate swallows due to prolonged cuff inflation and was curious as to whether this treatment could be applied to this form of neurogenic dysphagia in the ICU setting. I was appraised of the literature at the time and discussed this with my MDT/medical colleagues prior to implementation. I approached the company supplying the equipment in the UK and was loaned the equipment for a trial which I carried out on 10 patients collecting data on clinical outcomes very carefully. I instigated this treatment with the full support of the ICU medical team and assistance of the hospital nutrition specialist nurse who was then fully trained to place the catheter. I used instrumental assessment (Fibreoptic Endoscopic Evaluation of Swallowing FEES) to evaluate the pre and post treatment changes and feeding outcome and monitored any adverse effects. I documented all the outcomes and presented these at the UKSRG conference and ESSD conference and at RCSLT Clinical Excellence network study days and reported back to the ICU and stroke teams. On this basis of largely very positive outcomes we were able to secure funding to purchase the base station and catheters to continue offering this treatment. During this pilot phase I devised patient selection criteria for ICU patients based on my experience and took a cautious open-minded approach.

	procedure/technology, please indicate your experience with it.	My SLT team are trained to use this treatment at Wythenshawe (catheters are purchased by the ICU) and we have trained the SLTs at Manchester Royal Infirmary to also use it on their ICU. Our Wythenshawe trained SLTs also now provide this treatment at Trafford hospital where they relocated to work on the stroke unit. My team at Wythenshawe use this treatment routinely and always measure outcomes immediately pre and post treatment with FEES or videofluoroscopy to be accurate. We collect outcome data on all these patients. I am very aware of the current situation in the UK NHS as I have spoken about my use of PES at many forums and this has led to other SLTs being keen to trial it and contacting myself for advice. I think a few centres use it for stroke (Notthingham, Poole, Trafford) and a few are starting to trial it in ICU on the back of our work. I have also spoken with the team in Germany who use it routinely and discussed future research gaps. Many other SLT teams are interested. At Wythenshawe we (SLT) select the patients but find that now the ICU intensivists also suggest it as they are very interested and have seen first hand the benefits to patients. I have found that using PES in severely dysphagic patients leads to better secretion management scores, reduced aspiration risk scores and earlier restoration of oral feeding which speeds up decannulation. This consequently supports reduced length of ICU stay. It seems to kick start the swallow in patients who are essentially desensate and not swallowing. I have seen patients start to swallow when the stimulation is switched on and go from NBM to full oral intake in 5 treatment sessions. Currently only SLT have the equipment to deliver this. I think that patient selection is very important and requires a thorough understanding of the swallowing aetiology and severity and physiology which is the remit of the SLT assessment.
2	– 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 clinical research on this procedure involving patients or healthy volunteers. I have published this research – an abstract at the European SSD conference which won first prize

		I also have a current submission to a peer reviewed journal IJLCD on the outcomes of PES on 25 ICU patients. This reports good progression with oral feeding and decannulation in the majority of our patients. All were severely dysphagic on ICU and Nil By Mouth pre treatment.
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	It is innovative. Sensory impairments impacting swallow are difficult to treat but have a profound impact. They lead to silent aspiration, delayed ventilator and tracheostomy weaning and psychological trauma to patients if they remain nil by mouth for longer than necessary. This is a proactive treatment which is a way to expedite recovery in ICU of laryngeal function I think ad I have seen this in my clinical experience of using it. I hav collected data to demonstrate this outcome. This is a new class of procedure to the UK although it has many years of research behind it. The reason it is not widely adopted is not lack of interest from clinicians but lack of funding to purchase equipment. I have no safety concerns about this device from my experience.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	In addition to standard care. We need to use many different tailored treatments in ICU patients due to complex aetiologies, this is another tool in the toolkit. If used more widely it might reduce the need for more treatment interventions because dysphagia resolves more quickly, hence more efficient care.

Current management

5	Please describe the current standard of care that is used in the NHS.	Treatments for dysphagia include using cuff deflation and one-way valves to restore laryngeal airflow and function. Sensory stimulation is key to recovery of swallowing and secretion management, which is key to tracheostomy/ventilator weaning and

		decannulation. Practice on early cuff deflation is variable across ICUs and can be delayed if there is a lack of SLT and lack of an MDT approach. Also one-way valves cant be used in patients who lack a patent upper airway whereas PES can be used. Dysphagia exercises are routinely used but their efficacy is unclear from the research on this cohort of patients. Variation is a key factor in rehabilitation of swallowing problems and without tools such as FEES to detect aspiration there tends to be a cautious approach which means patients remain NBM longer than they might need to be.
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	No other intraluminal electrical stimulation technology as far as I know. Surface electrical stimulation (NMES, Ampcare) but I have not used these. Above Cuff Vocalisation (ACV) and Passy Muir Valves provide laryngeal airflow which stimulates laryngopharyngeal sensory and subsequent motor responses. I use both of these routinely and have published research into ACV effects on swallowing and have a current NIHR device development study grant. For this project we are developing an ACV device and will study the effects of stimulation on swallowing and will be measuring the sensory response amongst other things. Pharyngeal electrical stimulation is a unique treatment technique I understand.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Earlier restoration of oral intake and earlier decannulation. It offers a treatment option for severe patients
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Tracheostomised patients. ? intubated patients as a preventative approach – prevent desensitisation of the laryngeal mechanism/sensorium
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes, potentially less severe dysphagia following intubation, shorter duration of dysphagia and shorter decannulation leads to reduced ICU length of stay and reduced economic and psychological burden. I think if the treatment were started earlier it could prevent some of the deconditioned swallowing problems and could prevent aspiration pneumonias which increase mortality and duration of ventilation and less need for PEG and NG feeding
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	In the ICU setting it has the potential to be very cost effective given the high costs of an ICU bed day. Improved swallowing on ICU could lead to less need for SLT intervention at step down to the ward and community discharge. In this scenario it costs less than standard care.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	There is resource impact in the need to deliver daily treatment. I think SLT assessment of the dysphagia is important to establish need for the treatment in the first place but this happens anyway. If it were used for example on a confused/delirious patient then they may pull out the catheter which is a cost impact. This is one of my selection criteria (no hyperactive delirium) It is likely to cost less than standard care in the ICU scenario – see above
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Mainly good MDT communication and documentation, and SLT/Dietetic input and Medical and Nutrition team/Sp Nurse support and clinical governance procedures. There are no extra facilities I can think of as such.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes but it is very straightforward to do the training and deliver the treatment. The important skilled aspect is in the dysphagia assessment and appropriate patient selection prior to treatment and assessment of the treatment effect in the context of the patient's holistic dysphagia care - which as SLTs is our role in the UK. These patients are referred to us anyway and are under our care so I see this tool as part of our treatment tool kit. Other professionals such as nurses can be trained to deliver the treatment itself and use the kit and to insert the catheter (medics/ ACCPs)

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	We have carefully recorded any adverse effects on all the patients we have used it with. These are minor and have included discomfort, and pain and on once case oedema which may not have been related. We have had some patients who were anxious but careful explanation and patient information is part of our routine practice when introducing this treatment option so they can make an informed decision whether to proceed. I reported all above adverse effects to phagenyx whenever we experienced these. I have had catheters fall out /become dislodged and issues with the catheter position which meant the treatment could not be delivered.
15	Please list the key efficacy outcomes for this procedure/technology?	Catheter stays in place. Patient tolerates the treatment and cooperates. Days to commencing oral feeding Days to full oral intake Chest infections/VAP/aspiration pneumonias Days to decannulation Length of ICU stay Length of hospital stay Need for NG or Peg feeding

		FEES outcomes – secretions ratings, aspiration ratings
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	None with the procedure itself, more to do with application in terms of patient selection and using it in patients where it has been established that they are definitely dysphagic No concerns regarding safety Can also be used in covid patients in ICU Efficacy – I am convinced it is efficacious
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	See above – I would have concerns if there was a lack of SLT involvement
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Cannot predict at present. The pandemic has led to resource difficulties and high clinical workloads which may lead to delays to implementing a new treatment.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	https://www.isrctn.com/ISRCTN87110165 https://pubmed.ncbi.nlm.nih.gov/32353976/ https://clinicaltrials.gov/ct2/show/NCT03840395 https://www.thelancet.com/pdfs/journals/eclinm/PIIS2589-5370(20)30352-7.pdf https://gut.bmj.com/content/63/Suppl_1/A31.1 https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0190608 https://pubmed.ncbi.nlm.nih.gov/31313142/ https://www.research.manchester.ac.uk/portal/en/publications/efficacy-of-pharyngeal-electrical-stimulation-treatment-pes-for-dysphagia-in-critical-care-patients(7e84bef6-f487-49cb-80c9-8e39a04ecc43).html

		Management of dysphagia using pharyngeal electrical stimulation in the general intensive care population – a service evaluation. Thomas Williams, Elizabeth Walkden, Brendan A McGrath,. Sarah Wallace. Under review by IJLCD
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	See above PHinest PHEED

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Some examples - At least 15,000 patients undergo a tracheostomy in ICU and the vast majority have dysphagia . Up to 60% of intubated patients also have post extubation dysphagia A third of ARDS patients remain dysphagic at hospital discharge
22	Are there any issues with the usability or practical aspects of the procedure/technology?	No
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	Resources and funding
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	No. More research will refine the patients cohorts who most benefit
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe:	Beneficial outcome measures: See above

	− Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Days to commencing oral feeding Days to full oral intake Chest infections/VAP/aspiration pneumonias Days to decannulation Length of ICU stay Length of hospital stay Need for NG or Peg feeding FEES outcome measures – secretions ratings, aspiration ratings Patient satisfaction and tolerance ICNARC and other ICU databases can report length of stay and tracheostomy ventilation durations Adverse outcome measures: Patient reported and staff reported side effects No change or worse swallow /feeding outcome Failed decannulations post treatment Staff reported difficulties with use

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	I have found it beneficial to use this treatment and am supportive of its wider adoption as I have used a robust method to measure outcomes and seen positive results. Instigating earlier oral feeding is life changing for patients and this treatment supports this

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	Clear opinion as the conclusion of a research project, about the clinical effectiveness – see article submission mentioned above.	**2022**	
Choose an item.			
Choose an item.			

x ☐ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Sarah Wallace**
Dated:	**08.04.22**