NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP746/3 Intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure caused by high spinal cord injuries

Your information

Name:	Ben Messer
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Nominated/ratified by (if applicable):	British thoracic society
Registration number (e.g. GMC, NMC, HCPC)	4742971

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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.

☐ Y 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:

Not applicable

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 am familiar with the technology only in so far as my organisation was a recruiting site for DIPALS though I was not involved in this study. We have one patient under our home ventilation service with diaphragm pacing. This is not commonly used in the UK. Patients are often very interested in this technology and its potential to reduce ventilator dependence. The main specialities would be home ventilation and spinal injuries physicians. Where applicable, we would refer to local surgeons. However I am aware that there is no expertise in this procedure in the North East and Cumbria.

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have had no involvement in research on this procedure. 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 has been around as a concept for some years but is not widely used and would therefore be a significant innovation. Definitely novel and of uncertain safety and efficacy.
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?	My very small experience would suggest that in patients with very high spinal cord injury levels, existing gold standard treatment with ventilation (either invasive or non-invasive) would still be required but ventilator dependency may be reduced.

Current management

5	Please describe the current standard of care that is used in the NHS.	Ventilation either invasive or non-invasive.

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?	a reduction in ventilator dependency and consequent improvement in independence and quality of life.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	just those listed above who are ventilator-dependent with high cervical spine injuries.
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, it could reduce ventilator dependency. This may also reduce the complications of ventilation as well as improve quality of life. There is a significant burden of hospital admissions in this group which can be due to respiratory causes. In theory, this technology could help to reduce this.
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)	initially, there would be an increased cost and use of resource but this may be offset in the longer term.
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)?	see section 10 above.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	the key issues will be surgical familiarity with the technique and adequate training for home ventilation teams surrounding the equipment.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	yes see Section 12 above.

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	operative intervention will pose a small risk. The current evidence base for phrenic nerve stimulation is not positive. However, it is in a very different population.
15	Please list the key efficacy outcomes for this procedure/technology?	hours of ventilator dependence before and after the procedure. Hospital admissions. Quality of life metrics.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	it has not currently been well investigated in large randomised controlled trials in the proposed group of patients.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	see Section 17 above.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Fewer than 10 specialist centres in the UK. Cannot predict at present.

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.	DIPALS is the main trial but in a totally different population.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	not known

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)?	Small numbers, probably 5-10 patients in our region.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	unknown as I am not familiar with the equipment.
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?	currently lack of efficacy and safety data but if this changes with new evidence then it may very well be adopted.

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	large well conducted randomised controlled trial.
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: Quality of life, hours of ventilation in a 24 hour period, rate of decannulation of tracheostomy, hospital admissions, mortality. Adverse outcome measures: Perioperative adverse outcomes such as respiratory deterioration.
26	Is there any other data (published or otherwise) that you would like to share with the committee?	no

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	not applicable

NICE National Institute for Health and Care Excellence

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

☐ Y 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:	**Ben Messer**
Dated:	**16/08/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP746/3 Intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure caused by high spinal cord injuries

Your information

Name:	KESAVA REDDY MANNUR
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Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	2909785

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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 have expertise in laparoscopic surgery for 32years. I have operated and still do a lot of procedures near diaphragm including hiatus hernia and diaphragmatic hernia repairs. I have inserted wires/electrodes to stimulate the stomach a long time ago. But I don't have direct experience in the stimulators of the diaphragm.
	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	No Don't know. I am sure that this will be very beneficial in patients who could not be weaned off the ventilator or who have to be on ventilator for a long time, thus preventing the problems/ complications including respiratory infection of the ventilator assistance. Also in patients with cervical spinal cord injury (phrenic nerve injury), it helps them to move about without a mechanical ventilator. As these electrodes are not attached to phrenic nerve, phrenic nerve is not damaged. Now it is being used as synchronized diaphragmatic treatment of symptomatic heart failure. Once this is available, it would be taken up very quickly because of the vast advantage. By any experienced laparoscopic surgeon in close cooperation with the intensivists in the intensive care unit, respiratory physician or a rehabilitation specialist. No. it has to be referred to our speciality by others in intensive care set up

	procedure/technology, please 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 bibliographic research on this procedure. .
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):	At the moment, phrenic nerve stimulation is available, but the phrenic nerve would be damaged or the scar tissue formed and the stimulators may not be effective 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?	It would be used in addition to existing standard care

Current management

5	Please describe the current standard of care that is used in the NHS.	Mechanical ventilation

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?	Phrenic nerve stimulation of the diaphragm Phrenic nerve is stimulated and that may be damaged. Direct stimulation of the muscle has the advantage of damage to the phrenic nerve

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?	The whole stimulating electrodes are not that exposed and direct stimulation of the diaphragm could achieve the same objective in a better manner. Mechanical ventilator has the major problem of speech and also respiratory infections (pneumonia)
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Upper cervical spine injury patients, patients on ventilator for a long time and could not be weaned off quickly, patients with heart failure, Amyotrophic lateral sclerosis
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 will definitely benefit the healthcare system Yes. Of course mechanical ventilation may not be necessary after the initial period necessary, patients could be freely transported without the ventilators, patients could speak without any aids, patients could move about without being attached to ventilator
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)	It would definitely cost less, bringing a lot of saving to the health care, apart from convenience for the patients and the staff involved. The biggest benefit would be the marked reduction in respiratory infections
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)?	It would cost less. Need less staff once it is in place for the patient. Requirement of mechanical ventilators is less.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	It requires the normal operating theatres. The laparoscopic equipment is already there in every hospital. One requires an extra time for the experienced laparoscopic surgeon and also buying the unit of the stimulating electordes and the pacer.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Any experienced laparoscopic surgeon could do the procedure given the basic instructions of where and how the electrodes have to be inserted.an interaction with the device company is mandatory.

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	Injury to viscera and bleeding should be Extremely rare and were not reported in what I have read. As mentioned above. 1surgical device revision, 1 wire eruption , 1 Access site hemorrhage treated with transfusion oof blood, 1 pneumothorax requiring chest drain (can happen with Mechanical ventilators also). In another study, where the diaphragmatic stimulator was used in Amyotrophic lateral sclerosissALS patients, it accelerated the death in thes ALS patients probably from impairing the functional recovery of partially denervated muscles (impaired the compensatory reinnervation) and so one has to be cautious/avoid in using this in ALS setting.
15	Please list the key efficacy outcomes for this procedure/technology?	1. Able to speak which is not possible with mechanical ventilatore 2. Marked decrease in respiratory infections
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Accelerated death rate in ALS; so require more trials in this
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):	A minority of hospitals, but at least 10 in the UK. Cannot predict at present.

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.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	**Transcutaneous electrical diaphragmatic stimulation (TEDS) for the respiratory muscle strengthening: randomized and controlled clinical study** KM Cancelliero, D Ike, LM Sampaio, VL Santos, R Stirbulov, D Costa Fisioterapia e pesquisa, **2012**, 19(4), 303-308 | added to CENTRAL: 30 June 2014 | 2014 Issue 6 **TEDS in Prolonged Mechanical Ventilation** NCT04741724 https://clinicaltrials.gov/show/NCT04741724, **2021** | added to CENTRAL: 28 February 2021 | 2021 Issue 02 **Prospective Randomised Study Of Full Length Compression Stocking And Anti-Embolism Stockings (TEDS) After Varicose Vein Surgery** ISRCTN29102258 https://trialsearch.who.int/Trial2.aspx?TrialID=ISRCTN29102258, **2007** | added to CENTRAL: 31 March 2019 | 2019 Issue 3 **Propofol Target-Controlled Infusion in Emergency Department Sedation (ProTEDS): a multicentre, single-arm feasibility study** FM Burton, DJ Lowe, J Millar, AR Corfield, MJ Watson, MAB Sim Emergency medicine journal, **2020** | added to CENTRAL: 31 January 2021 | 2021 Issue 01 PubMed Embase **A study protocol for a feasibility study: propofol Target-Controlled Infusion in Emergency Department Sedation (ProTEDS)-a multicentre feasibility study protocol** FM Burton, DJ Lowe, J Millar, AR Corfield, MAB Sim

		Pilot and feasibility studies, **2019**, 5(1) | added to CENTRAL: 31 May 2020 | 2020 Issue 05 Embase **Geko Neuromuscular Stimulator vs Thromboembolism Deterrent Stockings (TEDS): DVT Prevention Study** NCT01935414 https://clinicaltrials.gov/show/NCT01935414, **2013** | added to CENTRAL: 31 May 2018 | 2018 Issue 5 **Effects of Inspiratory Muscle Training on Exertional Breathlessness in Patients With Unilateral Diaphragm Paralysis** NCT04563468 https://clinicaltrials.gov/show/NCT04563468, **2020** | added to CENTRAL: 31 October 2020 | 2020 Issue 10 **Transcutaneous Electrical Diaphragmatic Stimulation in Critically Ill Elderly Patients** NCT04565002 https://clinicaltrials.gov/show/NCT04565002, **2020** | added to CENTRAL: 31 October 2020 | 2020 Issue 10 **Effects of Respiratory Muscle Training on Respiratory Muscle Strength, Functional Capacity and Quality of Life in Pulmonary Hypertension** NCT03186092 https://clinicaltrials.gov/show/NCT03186092, **2017** | added to CENTRAL: 31 May 2018 | 2018 Issue 5 **Electrical Stimulation for Attenuating Muscle Atrophy** NCT02321163 https://clinicaltrials.gov/show/NCT02321163, **2014** | added to CENTRAL: 31 May 2018 | 2018 Issue 5 **Transcutaneous Electrical Diaphragmatic Stimulation and Inspiratory Muscle Training in Patients With COPD Exacerbated : https://clinicaltrials.gov/ct2/show/NCT03844711**

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)?	May be 50 -100 a year
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?	Only in ALS
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: 1. Quality of life measures including speech, mobility, transport 2. Hospital stay and readmissions 3. Respiratory infections Adverse outcome measures: 1.skin infection 2. bleeding requiring transfusion 3. pneumothorax, atelectasis

		4. device revision 5. electrode dislodgement 6. intermittent upper airway obstruction in the initial period
26	Is there any other data (published or otherwise) that you would like to share with the committee?	1. https://emedicine.medscape.com/article/1970348-overview?icd=ssl_login_success_221011#a6 2. Le Pimpec-Barthes F, Legras A, Arame A, Pricopi C, Boucherie JC, Badia A, et al. Diaphragm pacing: the state of the art. *J Thorac Dis*. 2016 Apr. 8 (Suppl 4):S376-86. [QxMD MEDLINE Link]. 3. https://www.karger.com/Article/FullText/517401: European study 4. Synchronized diaphragmatic stimulation for heart failure using the VisONE system: a first-in-patient study: https://eprints.gla.ac.uk/271826/1/271826.pdf 5. Synchronized Diaphragmatic Stimulation for the Treatment of Symptomatic Heart Failure: A Novel Implantable Therapy Concept: https://www.jacc.org/doi/10.1016/j.jacbts.2022.02.012 6. Transcutaneous electrical diaphragmatic stimulation reduces the duration of invasive mechanical ventilation in patients with cervical spinal cord injury: retrospective case series: https://www.nature.com/articles/s41394-021-00396-4 7. Intramuscular diaphragmatic stimulation for patients with traumatic high cervical injuries and ventilator dependent respiratory failure: A systematic review of safety and effectiveness: https://www.sciencedirect.com/science/article/abs/pii/S0020138315008414 8. Phrenic nerve stimulation prevents diaphragm atrophy in patients with respiratory failure on mechanical ventilation: https://bmcpulmmed.biomedcentral.com/articles/10.1186/s12890-021-01677-2

		9. Effects of transcutaneous electrical diaphragmatic stimulation on respiratory function in patients with prolonged mechanical ventilation: https://pubmed.ncbi.nlm.nih.gov/35198044/

Further comments

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

Declarations of interests: none

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

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

Print name:	**Kesava reddy mannur**
Dated:	**7 october 2022**