NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1906 Daytime intraoral neuromuscular electrical tongue stimulation using a removable device for obstructive sleep apnoea

Your information

Name:	Greg Knepil
Job title:	Consultant Oral and Maxillofacial Surgeon
Organisation:	Gloucestershire Hospitals NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	British Association of Oral and Maxillofacial Surgeons (BAOMS)
Nominated/ratified by (if applicable):	BAOMS
Registration number (e.g. GMC, NMC, HCPC)	GMC: 4639851

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NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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

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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 procedure/technology, please indicate your experience with it.	I am not familiar with this device. I have never used this device. I have not heard about it before. I don't know of anyone providing this treatment but it can be bought online so it is likely to be self administered.
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 appears to be relatively new. Cochrane library has only published 8 clinical trials since 1999. 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?	I can see it being used as an adjunct to existing standard care.

Current management

5	Please describe the current standard of care that is used in the NHS.	Behavioural lifestyle therapy, positional therapy, Continuous Positive Airway Pressure (CPAP) support, mandibular advancement devices, surgical treatments to enlarge/stabilise the soft tissue airways.
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?	No

	If so, how do these differ from the procedure/technology described in the briefing?	

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?	Minimally invasive, in principle it seems very safe. Claimed to be effective, but Cochrane Library trials are sparse.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	It is claimed to help patients at the mild end of the scale for severity of 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?	This would be of interest to patients who are approaching this condition in a stepwise manner, regarding risk, starting with devices that are low risk. If effectiveness is as good as claimed, it may lead to fewer hospital visits, reduced cost, less invasive treatment at the mind end of the spectrum of disease.
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 would see this device being introduced to patients in primary care, rather than in hospitals, therefor down stream costs should be reduced for a percentage of patients where it is found to be effective.

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 should considerably reduced costs where it is found to be effective.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	The device is placed in the mouth by the patient. No clinical facilities are necessary.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Not that I am aware of. It can be purchased online by anyone.

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	From what I have read, I believe it is an unpleasant sensation. In principle there seems to be very little possible long-lasting harm, however any hard object placed in the mouth may damage teeth, or place a strain on the jaw joints, although this is theoretical, and unlikely to be severe. The duration of the benefit appears to be limited, so may require using repeatedly, and may end up not being useful at all.

15	Please list the key efficacy outcomes for this procedure/technology?	I would want to see evidence of reduced daytime sleepiness, and improvements in sleep study metrics.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The effectiveness appears to be limited to mild sleep apnoea and snoring. The evidence for its effectiveness is limited, and the duration of effectiveness is not described in the literature that I have found.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Duration of effect, and patient selection (other than snoring and mild OSA).
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	I don't believe this is a suitable procedure for hospital setting at all. From what I have read it is only likely to be of benefit for mild disease, and can be self-administered, or provided under the care of a general dentist (probably ideally) or practitioner with training in Obstructive sleep Apnoea, or Sleep Disordered Breathing. The degree to which it helps, and duration of benefit is also lacking in evidence base (from my search of medical/surgical literature) 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.	I have undertaken a medline search.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	[redacted]

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)?	OSA affects 10-20% of the population. Snoring even more. This device claims to help snoring and mild OSA so maybe 10% of population would be eligible, although I don't believe anything like that number would be interested in seeking help.
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?	Cost: snoring and mild OSA are not diseases where interventions are normally funded.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Yes. Placebo controlled randomised clinical trials.
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: Sleep Study metrics Epworth sleepiness scores Social Return On Investment methodology Adverse outcome measures: Jaw joint problems - months Dental health - months Rate of relapse - months/years
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,	I have no experience of this treatment. In my view I expect that the benefits are likely to be limited to such mild disease that these patients are unlikely to be treated in a hospital.

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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
None			
Choose an item.			
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:	**Greg Knepil**
Dated:	**31st August 2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1906 Daytime intraoral neuromuscular electrical tongue stimulation using a removable device for obstructive sleep apnoea**

Your information

Name:	Tim Quinnell
Job title:	Respiratory and Sleep disorders physician
Organisation:	Royal Papworth Hospital Foundation NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Member British Thoracic Society, Past President British Sleep Society
Nominated/ratified by (if applicable):	British Thoracic Society
Registration number (e.g. GMC, NMC, HCPC)	GMC 4024198

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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?	I am familiar with literature on this treatment but have not used it in patients. It ried it once personally. I have over 20 years of experience working in a tertiary NHS sleep centre, including providing care to a large regional OSA population.
	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?	No. Potentially large uptake if found useful and approved. CPAP first line and very well evidenced but not tolerated by all so effective alternatives are always needed.
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	I expect so as various specialties are involved in OSA management
	− If your specialty is involved in patient selection or referral to another specialty for this	N/A

	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):	Novel approach 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?	Addition

Current management

5	Please describe the current standard of care that is used in the NHS.	CPAP therapy is first line for all levels of OSA severity, alongside lifestyle management (eg weight loss). Alternatives include mandibular advancement devices.

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?	No negative effects on overnight sleep Requires only brief compliance once a day
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those intolerant of CPAP Milder cases?
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 Possibly
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)	Unclear but will depend on effectiveness and device cost - Research needed
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)?	If effective would require less staff resource/care setting resource
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Not really

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	Unknown
15	Please list the key efficacy outcomes for this procedure/technology?	Adherence, objective OSA indices (from sleep studies), PROMs including Epworth sleepiness scale score and QoL
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Need more research on efficacy. My understanding is that SEs are rare/minimal
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Don't know
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.	Not aware of any
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Unknown

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)?	10-20% of mild OSA patients 5% of more severe (depending on effectiveness)
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Not really
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?	Cost

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Cost effectiveness Effectiveness in more severe cases Duration of effectiveness (ie longer term FU)
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: As above re outcome measures Incl longer term FU – eg 1-5 years Adverse outcome measures: Adherence Failure to respond to Rx SEs
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,	Apologies, haven't looked at evidence recently and limited time to complete this

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

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Print name:	**Tim Quinnell**
Dated:	**23 August 2022**

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Professional Expert Questionnaire

Technology/Procedure name & indication: IP1906 Daytime intraoral neuromuscular electrical tongue stimulation using a removable device for obstructive sleep apnoea

Your information

Name:	Click here to enter text.	ARI MANUEL
Job title:	Click here to enter text.	CONSULTANT
Organisation:	Click here to enter text.	LIVERPOOL NHS TRUST
Email address:	Click here to enter text.	ari.manuel@nhs.net
Professional organisation or society membership/affiliation:	Click here to enter text.	AASM RSM BTS
Nominated/ratified by (if applicable):	Click here to enter text.	N/A
Registration number (e.g. GMC, NMC, HCPC)	Click here to enter text.	6076363

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	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. I have done research on this procedure in laboratory settings (e.g. device-related research). I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research. 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):	Old technology but innovative to bring to NHS Established practice and no longer new. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. Definitely novel and of uncertain safety and efficacy. ✓ The first in a new class of procedure.
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?	would help patients intolerant of current treatments.

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?	Helps patients intolerant w current tx.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Claustrophia / Anxiety w masks.
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?	Potentially Potentially
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)	Cost more - device, training, monitoring
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)?	Cost more - as above
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Training, not sure

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Need large trial safety data

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	- Failure to work - Initial complications from use.
15	Please list the key efficacy outcomes for this procedure/technology?	Improvement in ESS / ODI / AHI
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	No large scale trials
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Cost / Long term effects
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. ~~A minority of hospitals, but at least 10 in the UK.~~ Fewer than 10 specialist centres in the UK.

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?	cost / training
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	large trials ± QALYs or cost outcomes
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: Adverse outcome measures:
26	Is there any other data (published or otherwise) that you would like to share with the committee?	

Further comments