NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1856 External electrical neuromuscular stimulation for urinary incontinence**

Your information

Name:	Mohammed Belal
Job title:	Consultant Urological Surgeon
Organisation:	University Hospitals Birmingham
Email address:	[redacted]
Professional organisation or society membership/affiliation:	BAUS
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 4582643

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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

☒ 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 am familiar with the technology and the principles of the procedure. I have extensive experience in percutaneous sacral nerve stimulation
	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	The technology is not widely used and would be performed in selected centres

	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 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):	Minor variation 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?	If used would be in addition to existing standard care

Current management

5	Please describe the current standard of care that is used in the NHS.	The standard of care is initial conservative, medical therapy followed by invasive procedures such as botulinum toxin injections or percutaneous sacral neuromodulation

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?	None

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?	
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	
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?	
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)	
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)?	
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	

13	Is any specific training needed in order to 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	
15	Please list the key efficacy outcomes for this procedure/technology?	
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	
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):	Most or all district general hospitals. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK.

		Cannot predict at present.

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.	

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)?	
22	Are there any issues with the usability or practical aspects of the procedure/technology?	

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?	
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	
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:

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
Choose an item.			
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:	**Mohammed Belal**
Dated:	**07/01/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1856 External electrical neuromuscular stimulation for urinary incontinence**

Your information

Name:	Sheilagh Reid
Job title:	Consultant Urological Surgeon
Organisation:	Sheffield Teaching Hospitals
Email address:	[redacted]
Professional organisation or society membership/affiliation:	BAUS (I am the chair of the FNUU section of BAUS completing my term as chair January 2022
Nominated/ratified by (if applicable):	BAUS
Registration number (e.g. GMC, NMC, HCPC)	407966

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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 no experience with this technology however as a urologists who specialises in the treatment of incontinence and neuropathic conditions I have extensive experience in the management of conditions for which this is supposed to treat
	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

	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):	
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 an alternative to intravaginal devices but sine established as being superior to this or the gold standard which would be pelvic floor muscle training 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?	It will be an adjunct probably to pelvic physiotherapy

Current management

5	Please describe the current standard of care that is used in the NHS.	Stress incontinence is treated in the first instance conservatively by sensible fluid management, weight loss and referral to pelvic floor therapy when this fails surgical treatments are considered

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?	Pelvic floor muscle training supervised by pelvic floor physiotherapy is the gold standard, intravaginal devices are also available There is a Cochrane review from 2015 which looked at adding PFMT to other procedures such including electrical stimulation and showed if you added the PFMT the patients did better but it isn't clear whether they would have done just as well with the PFMT alone (Cochrane Database Syst Rev. 2015 Nov 3;2015(11):CD010551. doi: 10.1002/14651858.CD010551.pub3) I am not aware if electrical devices are offered on the NHS this is the remit of the pelvic floor physiotherapists however there has been a randomised control trial in 2009 of the Neo Control chair which gave electromagnetic stimulation to the pelvic floor and was not found to be better than sham (BJUI 2009 May;103(10):1386-90)

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 think it needs careful evaluation to justify its use compared to pelvic floor physio or potentially as an adjunct to it, it is unlikely to have adverse effects so cost will be a major factor
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	As above Also is there a role in men who develop post prostatectomy incontinence who are poorly served with pelvic floor therapists compared to women
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 if it were found to be as good as physiotherapy lead pelvic floor therapy
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 don't know as PFMT needs clinical supervision
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)?	I don't know
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	I don't know

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	Apart from discomfort unless there is a potential danger form anything electrical I cant see this causing harm except for the harm of cost if the device is not effective There is a randomised controlled trial comparing EES with intravaginal stimulation showing equivalent effect with a lower risk of UTI which might be relevant Neurourol Urodyn 2019 Sep;38(7):1834-1843. doi: 10.1002/nau.24066
15	Please list the key efficacy outcomes for this procedure/technology?	Decreas pad usage, improvement in ICIQ short form Improvement in quality of life Although urodynamic improvement would be a good technical assessment it probably isn't justified for a device like this
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	As above
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not convinced it works

18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Cannot predict at present. – if it worked and was affordable then it would have widespread community use

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.	Listed throughout this form Also a very interesting paper from IJUN 2014 'Electrical Stimulation for Post Prostatectomy urinary incontinence: is it useful in patients who cannot learn muscular excercises'
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Not aware

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)?	No idea There must be a huge number referred for pelvic floor physio

22	Are there any issues with the usability or practical aspects of the procedure/technology?	I am not aware of any
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?	Its efficacy has to be established
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Randomised controlled trial PFMT ve EES
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 Adverse outcome measures: As above

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	This is an expensive gadget that needs good evidence that it works for it to be adopted

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial personal	I am chair of the FNUU section of BAUS (British Association of Urological Surgeons)	**January 2020**	**January 2022**
Choose an item.			
Choose an item.			

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Print name:	**Sheilagh Reid**
Dated:	**30th November 2021**