NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1790 - Neurostimulation of lumbar muscles for refractory non-specific chronic low back pain

Your information

Name:	GIRISH VAJRAMANI
Job title:	CONSULTANT NEUROSURGEON
Organisation:	UNIVERSITY HOSPITAL SOUTHAMPTON
Email address:	Girish.vajramani@uhs.nhs.uk
Professional organisation or society membership/affiliation:	Royal college of Physicians and Surgeons of Glasgow, General Medical Council. BMA
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	6046929

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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

☐ **YES** 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 already implanted 10 patients with this device as a part of research trial –PMCF. Have lot of experience in assessment of patient is suitable for this device. I am absolutely family with this technology and have no concerns. This device would be extremely he will helpful in patients with chronic mechanical low back pain will not undergone any spinal surgical procedures. The assessment has to be multidisciplinary involving Pain consultants as well as implanted. The implants could not either be pain physicians or neuro surgeons.
	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	In my department, I am the main implanter. I am also involved in multidisciplinary assessment of patient is suitable for this device.

	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):	Procedure is a minor variation of the existing spinal cord stimulation technology. The major difference is with respect to the lead placement ~~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?	This would be in addition to the existing standard of care. Currently there is no real treatment for patients with chronic mechanical low back pain.

		This device does not replace any current standard care

Current management

5	Please describe the current standard of care that is used in the NHS.	Medical optimisation Pain management strategies
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?	There is enormous potential, as currently there is no treatment will of L4 these patients
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Chronic mechanical low back pain inpatient her not undergone any previous spinal surgical procedure
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 could certainly lead to reduced burden on the pain clinics, decreased the opioid consumption, and improved quality of life
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)	As in for structure is already available in the units where spinal cord stimulator is routinely performed, there is no additional intra structure needed to start using the multifidus stimulator
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)?	neutral
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Noted shall clinical facilities are needed apart from of course access to theatre time
13	Is any specific training needed in order to	Although implants have to undergo a training program before starting to implant independently

	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	The risks and complications are similar to any neuromodulation treatment. However the neurological risks are much less as the leads are extra-spinal The common risks include infection and bleeding
15	Please list the key efficacy outcomes for this procedure/technology?	Reduction in chronic low back pain Reduction in total opioid use age Reduction in total analgesic requirement
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	nil
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):	~~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)?	We are still waiting between 10-20 implants in each Centre per year
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Currently the devices MRI in compatible

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?	-
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: Pain score Disability score Quality of life score Total opioid consumtion pre and post Adverse outcome measures: Infection

Further comments

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

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.

NO CONFLICT OF ONTEREST

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
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:	**GIRISH VAJRAMANI**
Dated:	**17/03/2021**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1790 - Neurostimulation of lumbar muscles for refractory non-specific chronic low back pain**

Your information

Name:	Sam Eldabe
Job title:	Consultant in Anaesthesia and Pain Medicine
Organisation:	South Tees Hospitals NHS Trust
Email address:	seldabe@nhs.net
Professional organisation or society membership/affiliation:	Neuromodulation Society of the UK and Ireland
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	4148924

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?	Yes, I have conducted a number of these procedures as part of the Reactiv8-A and Reactiv8-B study
	Have you used it or are you currently using it?	Yes, it is used in UK centres that have taken part in the above studies
	− Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	It is used on a small scale (less than 50 devices /year) that is likely to continue
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	Pain Consultants and Spinal Surgeons
	− If your specialty is involved in patient selection or referral to another specialty for this	Patient selection and implants happen within the same specialty

	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. X I have done clinical research on this procedure involving patients or healthy volunteers. X I have published this research. X
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):	Definitely novel and of uncertain safety and efficacy. X The approach is novel but the neurostimulation principle is similar to other neurostimulator.
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 current standard of care at end of care pathway.

Current management

5	Please describe the current standard of care that is used in the NHS.	Oral analgesia, Physiotherapy, medial branch blocks and radiofrequency denervation

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?	Improved long term outcomes in a subsection of Chronic Low back pain (CLBP) patients with multifidus dysfunction with no response to conventional care.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with multifidus dysfunction as shown on prone instability test
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?	The technology is likely to produce improved outcomes for CLBP patients. This is unlikely to result in savings since it is positioned at the end of the care pathway,
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)	More
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)?	More than the current standard of care.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Can be provided by most pain clinics and spinal surgery departments using existing facilities.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Procedure training in positioning the leads for new implanters.

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	1. Infection (often resulting in device explants) 2. Lead fracture (requiring surgical lead revision) 3. Lead migration (rare but as above) 4. Pain over the (IPG) battery (managed conservatively) 5. Overstimulation of tissue (managed via programming) 6. Nerve damage (damage to spinal nerve root) this a theoretical harm that has not been reported in studies.
15	Please list the key efficacy outcomes for this procedure/technology?	Pain relief, improved function, improved health related quality of life, reduced analgesic intake, return to work.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Safety profile similar to or better than other neurostimulation devices. Efficacy documented in a number of studies.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Recently sham controlled study showing no statistical difference from sham at 120 days but clear improvement at 12 months
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.

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.	UK National Neurmodulation Registry. (Registry of the National Neuromodulation Society of the UK and Ireland) Reactiv8-A Post Marketing Continuing Follow up (Sponsored by Mainstay Medical) Reactiv8-B study two and five year follow up (Sponsored by Mainstay Medical)

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)?	50-75
22	Are there any issues with the usability or practical aspects of the procedure/technology?	None the technology is applicable in its current from.

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?	Research to assess outcomes in other groups such as those who have already undergone and back surgery with no improvement.
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: Average pain on NRS Function on ODI Quality of Life on EQ-5D Analgesic consumption Return to work Adverse outcome measures: Number of device revision with justification (lead migration, fracture, etc..) Number of devices explanted with justification (infection, device failure, no efficacy, need for MRI)

Further comments

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

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
Direct - financial	Consulting for Mainstay Medical (I have worked collaboratively with the manufacturer on study design and rollout in UK and internationally)	**2011**	**To date**
Non-financial professional	Study Design for Mainstay Medical	**2011**	**To date**
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:	**Sam Eldabe**
Dated:	**22/03/2021**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1790 - Neurostimulation of lumbar muscles for refractory non-specific chronic low back pain**

Your information

Name:	Simon Thomson
Job title:	Consultant in pain medicine and neuromodulation
Organisation:	Mid and South Essex University Hospitals
Email address:	Simon.Thomson@btuh.nhs.uk
Professional organisation or society membership/affiliation:	British Pain Society, Neuromodulation Society of UK and Ireland
Nominated/ratified by (if applicable):	Not applicable
Registration number (e.g. GMC, NMC, HCPC)	2844046

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?	I have implanted 12 patients with Reactiv8 by Mainstay Medical. 11 as part of the post marketing clinical follow-up study as requested by BSI for MHRA and one patient treated as a non-NHS patient. Yes, I am familiar with the technology, procedure and overall patient management. I have been aware of the technology from its early time at Proof of Concept stage
	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	Yes, as above We have just started our routine NHS Reactiv8 service at Mid and South Essex University Hospitals. At present only sites that have been involved in the trials are now using it within NHS. These sites will help with the further roll out once established The occasional spinal surgeon (orthopaedic and neurosurgeon) has been rarely involved

	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 clinical research on this procedure involving patients or healthy volunteers X 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):	It was a novel approach, concept and design Established practice and no longer new. The first in a new class of procedure. There is more to learn as regards its applications
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?	Yes, it will replace some repeat medial branch radiofrequency neurolysis procedures and primary lumbar fusion surgery for back pain

Current management

5	Please describe the current standard of care that is used in the NHS.	Once more conservative back pain management strategies such as physiotherapy offer only limited benefit a patient with chronic (>6 months) back pain is referred to specialist

		pain management for assessment. If localised pain of >5/10 then patient offered diagnostic medial branch local anaesthesia. If positive then medial branch radiofrequency neurolysis. If less than 12 months 50% benefit then offered Reactiv8
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, there is nothing similar available in NHS

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?	This is a restorative treatment that can achieve full remission of long term chronic back pain symptoms. It may reduce the long term sequalae of poorly managed low back pain. This reduces work absence, medication requirement, physical therapy requirement and minimal targeted interventional treatment such as repeat medial branch radiofrequency neurolysis
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Yes, patients with chronic pain whose progressive degenerative change can be halted/delayed by this treatment
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. Exactly that. Improved outcomes, lower accumulative cost over a 5 to 10-year time horizon. See above
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)	Over a 5-year horizon it will be about the same cost, but with better outcomes.
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 implementation costs. Hospital costs are about the same as spinal cord stimulation (A483). Device costs are in addition. Some costs for pain nurse specialist to assist with patient flows, before and after procedure
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No change to existing facilities. Procedure is done in specialist care setting

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, this can be provided by company, advanced pain management training, clinical fellowships with mentor training, professional society such as Neuromodulation Society of UK and Ireland

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	Device infection, probably in order of 1 to 2% Lead migration or corruption requiring lead replacement – 1 to 2% The leads are NOT within the spinal canal, so serious neurological harm is rare
15	Please list the key efficacy outcomes for this procedure/technology?	Reduced average pain rating, improved function, reduced medication, reduced physiotherapy, hospital visits and absence from work
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Procedure must be done by individual who is specifically trained. Procedure must be managed within a service who can provide expertise in selection, implant technique, Patient education and management and re-programming
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Low back pain is common. The precise population that will benefit can be difficult to identify. The ideal cohort has been identified by the clinical studies to date, but others will emerge. Important that emerging indications are developed through observational studies
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Eventually, most or all district general hospitals but during roll out at least 10 in the UK.

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.	North American Neuromodulation Society Neuromodulation society of UK and Ireland
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Reactiv8PMCF has a 5-year follow-up. My patients are just passing through the 3-year follow-up point

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)?	We estimate at Mid and South Essex (serves about 1.2 million) that about 60 new patients per year
22	Are there any issues with the usability or practical aspects of the procedure/technology?	No issues
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?	The main issues will be NHS capacity issues. However, procedure is likely to reduce demand for other less effective procedures

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Further work needs to be done to understand clinical and cost effectiveness. Comparison with standards of care. Exploration of wider indications
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: Mean daily pain, annual back pain episodes, medication requirement, work status, days of work, function, PROMS-29 Adverse outcome measures: Explant due to infection, lack of efficacy Revision due to lead migration or problem with implantable pulse generator

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	Awaiting whole body MRI conditional approval – this is needed

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
Non-financial professional	My hospital is funded to carry out Reactiv8 PMCF trial. We have 11 patients in trial. Recruitment finished in 2018. 5-year data collection is ongoing. I have presented interim data of my cohort at clinical meetings		
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:	**Dr Simon Thomson**
Dated:	**23 March 2021**