

Professional Expert Questionnaire

Technology/Procedure name & indication:

Your information

Name:	<input type="text" value="Devendra Mahadevan"/>
Job title:	<input type="text" value="Consultant Orthopaedic Foot and Ankle Surgeon"/>
Organisation:	<input type="text" value="Royal Berkshire Hospital NHS Foundation Trust"/>
Email address:	<input type="text" value="Devendra.mahadevan@royalberkshire.nhs.uk"/>
Professional organisation or society membership/affiliation:	<input type="text" value="British Orthopaedic Foot and Ankle Society (BOFAS)"/>
Nominated/ratified by (if applicable):	<input type="text" value="Nominated by BOFAS Scientific Committee"/>
Registration number (e.g. GMC, NMC, HCPC)	<input type="text" value="GMC 6054859"/>

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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	procedure/technology, please indicate your experience with it.	
2	<p>– Please indicate your research experience relating to this procedure (please choose one or more if relevant):</p>	<p>I have done bibliographic research on this procedure.</p> <p>I have done research on this procedure in laboratory settings (e.g. device related research).</p> <p>I have done clinical research on this procedure involving patients or healthy volunteers.</p> <p>I have published this research.</p> <p>I have had no involvement in research on this procedure.</p> <p>Other (please comment):</p> <p><u>I have researched and published on Morton's neuroma tests, prognostics and interventions.</u></p>
3	<p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p>	<p><u>It is a novel approach.</u></p> <p>Established practice and no longer new.</p> <p>A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.</p> <p>Definitely novel and of uncertain safety and efficacy.</p> <p>The first in a new class of procedure.</p>

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 do not believe this procedure would replace or add to the existing standard of care. There is very limited published evidence on this procedure.
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Current management

5	Please describe the current standard of care that is used in the NHS.	Corticosteroid injections – first line treatment Surgical excision of neuroma for patients who have not improved with conservative treatment
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?	I am not aware.

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?	Less invasive than surgery
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Unsure
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?	No as there is poor evidence to support this procedure.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	I believe this procedure is likely to cost more (unnecessary additional procedure) as I feel the results would probably be temporary and patients will eventually be referred to receive the current standard of care.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	As per 10
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Equipment for imaging (Ultrasound) and equipment to perform cryoablation.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Training to use the device and ultrasound probe.
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Safety and efficacy of the procedure/technology

14	<p>What are the potential harms of the procedure/technology?</p> <p>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:</p> <p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p>	<p>There is limited evidence about the efficacy or potential risks of this procedure.</p> <p>Anecdotally, worsening pain and fat necrosis around procedure site.</p> <p>Other theoretical adverse events include infection and bruising.</p>
15	Please list the key efficacy outcomes for this procedure/technology?	Pain relief from the neuroma
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	There are significant uncertainties about this procedure as there is very limited published evidence
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	As per 16
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	<p>Most or all district general hospitals.</p> <p>A minority of hospitals, but at least 10 in the UK.</p> <p>Fewer than 10 specialist centres in the UK.</p>

	Cannot predict at present.
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Abstracts and ongoing studies

19	<p>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).</p> <p>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.</p>	I am unaware of any.
20	<p>Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.</p>	Not aware

Other considerations

21	<p>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)?</p>	The approximate incidence of Morton's neuroma is between 50 – 90 / 100,000 but not all cases would need treatment.
22	<p>Are there any issues with the usability or practical aspects of the procedure/technology?</p>	Should only be undertaken by clinicians who are trained to perform imaging and cryoablation.

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?	I am not aware.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Yes as the current level of evidence is poor.
25	<p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> - 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: 	<p>Beneficial outcome measures:</p> <ol style="list-style-type: none"> 1) Clinical outcomes <ul style="list-style-type: none"> - pain relief or clinically significant pain improvement – Visual analogue scale 2) Quality of life measures <ul style="list-style-type: none"> - EQ5D 3) Patient reported outcomes <ul style="list-style-type: none"> - MOxFQ <p>Timescales: 6 and 12months post intervention</p> <p>Adverse outcome measures:</p> <ul style="list-style-type: none"> - Infection (within first 2 weeks) - Fat necrosis (within 3 months) - Recurrence or failure of treatment (any time point)
26	Is there any other data (published or otherwise) that you would like to share with the committee?	No

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Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	None
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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.	N/A		
Choose an item.	N/A		
Choose an item.	N/A		

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:	Devendra Mahadevan
Dated:	15/05/2022

Professional Expert Questionnaire

Technology/Procedure name & indication:

Your information

Name:	<input type="text" value="Click here to enter text."/> James Carmichael
Job title:	<input type="text" value="Click here to enter text."/> Consultant Orthopaedic Foot and Ankle Surgeon
Organisation:	<input type="text" value="Click here to enter text."/> North West Anglia NHS Foundation Trust
Email address:	<input type="text" value="Click here to enter text."/> jim.carmichael@nhs.net
Professional organisation or society membership/affiliation:	<input type="text" value="Click here to enter text."/> BOFAS, BOA, AOFAS, IBRA
Nominated/ratified by (if applicable):	<input type="text" value="Click here to enter text."/>
Registration number (e.g. GMC, NMC, HCPC)	<input type="text" value="Click here to enter text."/> 4435143

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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.

<p>1 Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none">- 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	<p><u>I have a passing awareness of the procedure but have no personal experience. I routinely treat patients with the condition however.</u></p> <p><u>In my geographical area, the procedure is not routinely performed by orthopaedic surgeons. It is offered privately by some podiatrists</u></p>
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	procedure/technology, please indicate your experience with it.	
2	<p>– Please indicate your research experience relating to this procedure (please choose one or more if relevant):</p>	<p>I have done bibliographic research on this procedure.</p> <p>I have done research on this procedure in laboratory settings (e.g. device-related research).</p> <p>I have done clinical research on this procedure involving patients or healthy volunteers.</p> <p>I have published this research.</p> <p><u>I have had no involvement in research on this procedure.</u></p> <p>Other (please comment)</p>
3	<p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p>	<p><u>The procedure has been available for some time. The current standard of care is excision of the neuroma. The described intervention is an entirely different approach.</u></p> <p>Established practice and no longer new.</p> <p>A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.</p> <p><u>Definitely novel and of uncertain safety and efficacy.</u></p> <p>The first in a new class of procedure.</p>
4	Does this procedure/technology have the potential to replace current standard care or	<u>Potentially replace</u>

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would it be used as an addition to existing standard care?	
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Current management

<p>5 Please describe the current standard of care that is used in the NHS.</p>	<p><u>Current standard of care is either:</u></p> <ol style="list-style-type: none"> 1) <u>Image guided steroid injection</u> 2) <u>Surgical excision of the neuroma</u>
<p>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?</p> <p>If so, how do these differ from the procedure/technology described in the briefing?</p>	

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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?	<u>Small incision</u> <u>Improved cosmesis</u>
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	<u>No</u>
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?	<u>Unlikely</u>
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)	<u>If found to be successful, might reduce costs through less surgical time. However accurate image guidance would likely cost more in initial training and resource allocation</u>
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)?	<u>If found to be successful – likely to lower resource, however additional training and resource for Ultrasound would be required</u>
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?	<u>Training in the use of ultrasound and the cryo-ablation technique</u>
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Safety and efficacy of the procedure/technology

14	<p>What are the potential harms of the procedure/technology?</p> <p>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:</p> <p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p>	<p><u>This procedure has very little research behind it and as such the risks and safety information is largely theoretical</u></p> <p><u>Uncontrolled thermal injury – this might generate more scar tissue and make revision surgery more challenging</u></p> <p><u>Persistent pain</u></p>
15	Please list the key efficacy outcomes for this procedure/technology?	<p><u>Pain relief over long term</u></p> <p><u>Recurrence rate</u></p>
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	<u>There is minimal prospective data available</u>
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	<u>There is minimal data available at this stage and further study is required</u>
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	<p><u>Most or all district general hospitals.</u></p> <p>A minority of hospitals, but at least 10 in the UK.</p> <p>Fewer than 10 specialist centres in the UK.</p>

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	Cannot predict at present.
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Abstracts and ongoing studies

19	<p>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).</p> <p>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.</p>	<p>Foot Ankle Surg. 2020 Oct;26(7):736-743. doi: 10.1016/j.fas.2019.09.009. Epub 2019 Nov 2. Non-surgical treatments for Morton's neuroma: A systematic review Lauren Thomson¹, Randeep S Aujla², Pip Divall³, Maneesh Bhatia² Affiliations expand</p> <ul style="list-style-type: none"> • PMID: 31718949 DOI: 10.1016/j.fas.2019.09.009
20	<p>Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.</p>	<p>Not known</p>

Other considerations

21	<p>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)?</p>	<p>Unclear – This is a common condition presenting to foot and ankle clinics across the country</p>
22	<p>Are there any issues with the usability or practical aspects of the procedure/technology?</p>	<p>Availability of trained sonographers difficult. Requires an available USS machine and user</p>

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?	<u>Lack of evidence, Availability of USS machine and expertise</u>
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	<u>Any Research!!!</u>
25	<p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> - 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: 	<p>Beneficial outcome measures: <u>Patient satisfaction and outcome scores including MOX FQ pre and post op with a minimum 3 year Follow up</u></p> <p>Adverse outcome measures:</p>
26	<u>Is there any other data (published or otherwise) that you would like to share with the committee?</u>	

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Further comments

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

Initial short term outcomes need to be compared not just to surgery but to steroid injection.
Longer term results are more relevant compared to surgery. The results of salvage surgery if recurrence occurs would also be very useful.

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.			

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.

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Print name:	<input type="text" value="Click here to enter text."/> James Carmichael
Dated:	<input type="text" value="Click here to enter text."/> 16/05/2022

Professional Expert Questionnaire

Technology/Procedure name & indication:

Your information

Name:	<input type="text" value="Ron McCulloch"/>
Job title:	<input type="text" value="Consultant Podiatric Surgeon"/>
Organisation:	<input type="text" value="The London Podiatry Centre"/>
Email address:	<input type="text" value="ron@london-podiatry.com"/>
Professional organisation or society membership/affiliation:	<input type="text" value="Royal College of Podiatry"/>
Nominated/ratified by (if applicable):	<input type="text" value="Click here to enter text."/>
Registration number (e.g. GMC, NMC, HCPC)	<input type="text" value="CH11409"/>

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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.

<p>1</p>	<p>Please describe your level of experience with the procedure/technology, for example:</p> <p>Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none"> - 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 	<p>I have been performing cryosurgery for Morton’s neuroma for about 10 years. I have been performing ablative radiofrequency for Morton’s neuroma for about 4 years. I have been performing open surgery for the same condition for about 20 years. I have completed a master’s degree in diagnostic ultrasound and as part of this, I undertook a cryosurgery audit where I reviewed cases performed at my practice.</p> <p>As far as I am aware, I am the only Consultant offering open surgery, cryosurgery and radiofrequency for Morton’s neuroma and as such, I am able to offer a balanced view on the pros and cons of each procedure.</p> <p>I was interested in establishing this at Homerton University where I was employed as a Consultant Podiatric Surgeon for 10 years but this never went further than the conceptual stage. I have since left the NHS and only work privately.</p> <p>I see patients from the UK and worldwide. I have dedicated websites promoting cryosurgery and Morton’s neuroma as I have a special interest.</p> <p>I undertook a fairly extensive audit on cryosurgery on 100 patients in 2013. It was always my plan to publish the results after a second longer-term audit but due to time constraints this never materialised.</p> <p>It was done as part of a master’s degree in MSK ultrasound and was credited with a distinction grade, demonstrating it was well constructed. The conclusion of the audit was as follows:</p>
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	<p>procedure/technology, please indicate your experience with it.</p>	<p>“The author is encouraged by the fact that 73% of respondents would have the procedure done again under similar circumstances, that 75% showed improvement in their post MOXFQ and that standards were met in relation to pain and standing / walking activity. Whilst the consent procedure requires rectification in some areas, no patient underwent cryosurgery without signing consent form A or B. The low incidence of complication and rapid recovery and ability to return to work are likely to generate continued appeal, when compared to an open procedure and the author will continue to make the procedure available to patients at LPC with a view to repeating the audit at 12-month post-surgery when the various recommended changes have been established.”</p>
<p>2</p>	<p>– Please indicate your research experience relating to this procedure (please choose one or more if relevant):</p>	<p>See previous comments.</p> <p>Other (please comment)</p>
<p>3</p>	<p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p>	<p>Patients with Morton’s neuroma are often (and should be) offered conservative treatment in the form of footwear advice and padding / insoles. A steroid injection may provide relief but often temporarily. Most patients who fail to respond to conservative care are offered surgery, most commonly excision of the neuroma via a dorsal approach. I am aware of at least one NHS service which offers radiofrequency for Morton’s neuroma but I am not aware of an NHS service offering cryosurgery for Morton’s neuroma. As far as I know, I am the only Consultant offering cryosurgery for Morton’s neuroma. There is one podiatrist (not surgically trained and not a podiatric surgeon) who also offers the treatment in the UK. In Europe, the procedure is also infrequently performed but it is more common in the USA where a number of Centres offer the treatment. I personally trained with Professor Wishnie in Newark (USA).</p> <p>I would class the procedure as more established in the USA but a new procedure for the UK. Having performed over a 1000 cryosurgery procedures for Morton’s neuroma, I would class it as a relatively safe procedure with far few risks than open surgery even steroid injection. Steroid injections cause atrophy and I have seen far more complications with steroid than cryosurgery. In all the cryosurgery surgery procedures I have performed, I am not convinced that I have ever made a patient worse with cryosurgery. The only complications to date have been infection but the infection rate is very low (as per my audit).</p> <ul style="list-style-type: none"> • Established practise 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?	No, in my experience open surgery has a higher success rate but also a much higher complication rate such as stump neuroma and a much longer recovery. I have never noted a stump neuroma with cryosurgery, nor have I seen this documented in the literature. It should be considered as a procedure prior to open surgery because of the low risk of complication, reduced costs and the fact that patients can return to work and activity (with care) 24-48 hours after the procedure. Open surgery requires a recovery period of at least 2 weeks, during which time the patient is resting and recovering at home.
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Current management

5	Please describe the current standard of care that is used in the NHS.	I am not aware that cryosurgery is used in the NHS. Standard of care is conservative care / insoles (more so if the patient is seen by Podiatry than Orthopaedics), footwear advice, steroid injection and finally open surgery. There are a few Centres who may offer radiofrequency.
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?	Radiofrequency (which I also perform) is available in the NHS partly because the equipment is often available and used by other specialists in pain clinics. I also offer ablative radiofrequency in my practice and have performed about 50 procedures. I prefer cryosurgery and usually offer radiofrequency if cryosurgery has not been successful. This is because, pain and swelling from ablative radiofrequency is more prevalent and patients often require a steroid injection post-surgery to settle this down. Given that patients have often already had a number of steroid injections (from other practitioners), when I see them, I try to avoid this treatment if possible given that there is often already established atrophy.

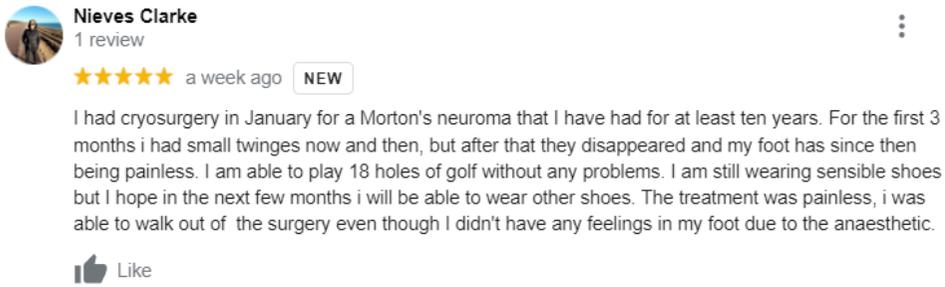
Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Reduced costs, reduced risk of complication, rapid recovery. Also, my threshold for performing the procedure in a high-risk patient is much lower than for open surgery. For example, I have performed cryosurgery on patients with circulatory compromise and those with immune suppression where I would have reservations with an open procedure.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Higher risk patients with various co-morbidities, those who cannot commit to the post-surgical recovery period for open surgery (self-employed etc), all patients who wish to avoid the additional risk of open surgery, particularly stump neuroma.
9	Does this procedure/technology have the potential to change the current pathway or	The procedure is technically challenging, but it should, in my view be an option for NHS patients. Costs are probably still relatively high because of the required ultrasound training, cost of

	<p>clinical outcomes to benefit the healthcare system?</p> <p>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?</p>	<p>equipment etc. but it would lead to reduced complication rates and associated costs. The number of visits would depend on Trust policy. At my previous NHS hospital, review appointments were often done by GPs in any case. In principle, follow-up care could certainly be done by the GP and one follow-up appointment is recommended.</p>
10 - MTEP	<p>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)</p>	<p>Specialist training would be required for practitioners already competent in performing interventional ultrasound and specialist machines and probes would need to be purchased. Probes can be disposable or reusable. The main cost benefit is that it would potentially free theatre space and avoid the need for an anaesthetist (open procedures are often still performed under GA or sedation). Reduced complication rates would incur a cost benefit.</p>
11 - MTEP	<p>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)?</p>	<p>The cost would be more than steroid injection but potentially less than open surgery. However, one would need to factor in that at best, cryosurgery has a success rate of about 70% as opposed to >90% for open surgery. The literature varies considerably, and this is particularly based on my personal experience.</p>
12	<p>What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?</p>	<p>A clean room would in my view be acceptable and a positive airflow theatre is not needed.</p>
13	<p>Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?</p>	<p>Yes. Furthermore, this is not readily available in the UK.</p>

Safety and efficacy of the procedure/technology

14	<p>What are the potential harms of the procedure/technology?</p> <p>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:</p>	<p>Very small risk of infection.</p> <p>Results from my audit of 100 patients showed no infections. From the 1000+ procedures I have performed, I would estimate no more than 10 infections (non-serious and settled with antibiotics).</p>
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	<p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p>	<p>Very few studies on the procedure. When I last reviewed the literature, no significant complications were noted from the procedure.</p>
15	<p>Please list the key efficacy outcomes for this procedure/technology?</p>	<p>I have treated the condition for very chronic neuromas and have more successful outcomes than not. Below is the latest Google review from a recent patient:</p> <div data-bbox="880 534 1825 821">  </div> <p>Please see Google for other positive reviews.</p>
16	<p>Please list any uncertainties or concerns about the efficacy and safety of this procedure/?</p>	<p>I have no concerns over the safety of the procedure. It is less likely to cause inadvertent damage to the surrounding tissues than steroid injection.</p>
17	<p>Is there controversy, or important uncertainty, about any aspect of the procedure/technology?</p>	<p>There is a general lack of awareness and knowledge of the procedure within the UK. As a result, I do on occasion receive indirect negative feedback from the consultants of NHS patients who question the value of the procedure. This feedback is generally conveyed by patients who wish to undergo cryosurgery.</p>
18	<p>If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):</p>	<p>Cannot predict at present.</p>

Abstracts and ongoing studies

19	<p>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).</p> <p>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.</p>	<p>Not aware of recent publications. However, I was asked to do this work at very short notice and have not had the opportunity to do an extensive literature search.</p>
20	<p>Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.</p>	<p>Not aware of any.</p>

Other considerations

21	<p>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)?</p>	<p>The presence of Morton's neuroma has been estimated to be as high as approximately 30% but such lesions are not always symptomatic. There is also confusion with regards to the presence of the neuroma versus a frequently present bursitis adjacent to the nerve. The condition is relatively common in podiatric practise and frequently seen by podiatric surgeons and orthopaedic surgeons alike. When caught early, the condition may respond to non-invasive treatment, particularly footwear change but otherwise it requires invasive treatment. We are seeing increasing numbers of neuroma in the younger population, although it remains particularly common in middle-aged woman wearing pointed or high heeled shoes.</p>
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22	Are there any issues with the usability or practical aspects of the procedure/technology?	No issues but extensive training is required.
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?	I introduced it into my practice 10 years ago. The main issue for NHS providers is the cost of training, purchase of equipment and willingness to introduce it for a condition which some would consider already has a number of satisfactory treatments.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	More research is required. However, cryoablation is used in various areas of medicine and it is accepted that the technology will cause tissue necrosis. This principle, together with positive feedback from patients who had the procedure in the USA, persuaded me to introduce it into my practice.
25	<p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> – 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. 	<p>Beneficial outcome measures benefit was seen in about 70% of patients based on an audit which I performed on 100 patients. I used the Manchester and Oxford Foot Health Status questionnaire for this audit.</p> <p>Adverse outcome measures:</p>

	<ul style="list-style-type: none"> - Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured: 	
26	Is there any other data (published or otherwise) that you would like to share with the committee?	

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	<p>I was asked to provide this information with very little notice just before a holiday and I have done my best to complete this questionnaire given the limited time frame. As stated, I am the only practitioner (as far as I am aware) to offer cryosurgery, radiofrequency and open surgery and as such, I am able to provide a balanced view on the procedure. My main reason for offering it to patients is the low risk of complication and rapid ability to return to work and normal activity, although not necessarily sport for several weeks. Open surgery is more effective, and I suspect that radiofrequency also has higher success rates. I base this on the premise that patients who have failed to respond to cryosurgery at my facility often then go on to respond to radiofrequency. However, cryosurgery is associated with less pain and less risk of complication and as such, is the first preference for my patients and myself should I ever be unfortunate enough to develop the condition.</p>
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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.			

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:	<input type="text" value="RON MCCULLOCH"/>
Dated:	<input type="text" value="13 MAY 2022"/>