

Professional Expert Questionnaire

Technology/Procedure name & indication:

Your information

Name:	<input type="text" value="Danoob Dalili"/>
Job title:	<input type="text" value="Consultant Musculoskeletal Radiologist and Interventional Spine lead"/>
Organisation:	<input type="text" value="Epsom and St Helier Hospitals- Southwest London Elective Orthopaedic Centre"/>
Email address:	<input type="text" value="[REDACTED]"/>
Professional organisation or society membership/affiliation:	<input type="text" value="Royal College of Radiologists, European Society of Skeletal Radiologists, British Society of Skeletal Radiologists, International Society of Skeletal Radiology"/>
Nominated/ratified by (if applicable):	<input type="text" value="Self"/>
Registration number (e.g. GMC, NMC, HCPC)	<input type="text" value="7084891"/>

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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</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 procedure/technology, please indicate your experience with it. 	<p>Trained and competent to perform this procedure since 2016. Actively performing this procedure since. Have accrued further experience by travelling to several centres in Europe and the USA to gain further insight to the outcomes and indications, as well as consolidated such knowledge by completing several peer review publications (I have more than 20 PubMed indexed publications on ablation technologies specifically to bone and spine disease)</p> <p>Performed in most sarcoma units across the country as well as in special centres which have trained radiologists. The outcomes and safety profile of this procedure render it amenable to fast roll out in the NHS if this is supported by institutions and the appropriate recommendations.</p> <p>Can be performed by Spine surgeons or pain management specialists. This has been adopted in some overseas countries.</p>
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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 clinical research on this procedure involving patients or healthy volunteers.</p> <p>I have published this research.</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>RF ablation has been performed in mainstream clinical practice in the UK for osteoid osteomas for at least 30 years. Current innovations include:</p> <ul style="list-style-type: none"> - Developments in the instruments used, higher temperatures achieved under more controlled local environments with no specific and better focused heated nucleus. - Thermoprotective techniques to improve the safety profile of the procedure and reduce co-morbidities in the surrounding vital structures thereby improved targeting of lesions and more precise delivery of heat whilst preserving more of the surrounding normal soft tissues and bones. - Innovations in anaesthesia and pain management techniques thereby allowing safer procedures to be performed faster, with shorter hospital stay and improved overall recovery trajectories. <p>Established practice and no longer considered new.</p> <p>A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.</p>
4	<p>Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?</p>	<p>Potentially offer a new first line therapeutic and palliative strategy for managing painful spine metastasis, which could also be used as an adjuvant therapeutic strategy alongside conservative therapies, chemotherapy, or radiotherapy. It could also be used to shrink metastatic foci or / and reduce their vascularity thereby rendering further surgery easier, safer, and possibly faster.</p> <p>Furthermore, RF can be performed without precluding the ability to offering more invasive standard of care interventions such as surgery.</p>

Current management

<p>5</p>	<p>Please describe the current standard of care that is used in the NHS.</p>	<p>A spectrum from: Do nothing, conservative therapy (pain killers, modify activities, spine brace and physiotherapy, acupuncture and other pain management techniques), Chemotherapy, targeted radiotherapy, and surgery. Where RFA is considered, patients are discussed in the relevant tumour MDM to confirm that it is appropriate and planning is agreed together with the oncologists, spine surgeons and radiologists. Some cases are performed with curative intent, others are performed prior to consideration of surgery, or to reduce tumour size and vascularity with the intent of performing surgery shortly after the procedure.</p>
<p>6</p>	<p>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>	<p>Cryotherapy/cryoablation</p> <p>Inducing necrosis of malignant cells by extreme cooling (-40 Celsius) rather than heating up to 87Celsius with RF.</p>

Potential patient benefits and impact on the health system

7	<p>What do you consider to be the potential benefits to patients from using this procedure/technology?</p>	<p>Potentially offer a new first line therapeutic and palliative strategy for managing painful spine metastasis, which could also be used as an adjuvant therapeutic strategy alongside conservative therapies, chemotherapy, or radiotherapy. It could also be used to shrink metastatic foci or / and reduce their vascularity thereby rendering further surgery easier, safer and possible faster.</p> <p>Furthermore, RF can be performed without precluding the ability to offering more invasive standard of care interventions such as surgery.</p> <p>Current evidence suggests higher patients and carers satisfaction rates, overall comparable or improved outcomes to standard care, fewer hospital visits, shorter hospital stay and shorter procedure times, less blood loss, reduced requirements for pain management and less invasive treatment.</p>
8	<p>Are there any groups of patients who would particularly benefit from using this procedure/technology?</p>	<p>Single or oligometastatic.</p> <p>Small lesions</p> <p>Young patients with otherwise good response to other therapies</p> <p>Palliative patients in which surgery is no longer deemed safe.</p>
9	<p>Does this procedure/technology have the potential to change the current pathway or 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>Current evidence suggests higher patients and carers satisfaction rates, overall comparable or improved outcomes to standard care, fewer hospital visits, shorter hospital stay and shorter procedure times, less blood loss, reduced requirements for pain management and less invasive treatment.</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>The equipment required is relatively low cost (average £1,000 per RFA probe). These procedures are often done as an OP procedure, and most patients can be sent home the same day thereby saving costs of hospital stay, pain management and recovery.</p> <p>The procedure is performed under image guidance and so early complications can be picked up at the time of the procedure, reducing the rate of procedural failure or complications and can be managed sooner than later if occur.</p>

		<p>This procedure is performed in radiology departments which have existing image- guidance equipment.</p> <p>As a non-surgical procedure this also saves blood loss, need for blood products, theatre time for the procedure as well as save up theatre time which can be used to perform other procedures that generate additional income and reduce NHS waiting times for theatre</p>
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)?	Will cost less than current standard of care – see answer 10.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None, in fact a better use of existing resources.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Upfront radiologist and HCA/ nursing training. Once this is performed in more centres across the UK it would become part of training for future generations and reduce the upfront cost of training as a consultant.

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>Vertebral fracture, minimal blood loss, pain, spinal cord or neural injury by heat or the metastasis. Complications associated with any percutaneous procedure such as infection.</p> <p>Incidence of major complications is extremely low, supported by literature evidence.</p> <p>Incidence of minor complications such as post procedure pain, nausea or transient increase blood pressure is low and is often managed efficiently by the anaesthetists who are performing the anaesthetic support for the procedure.</p>
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	Theoretical adverse events	
15	Please list the key efficacy outcomes for this procedure/technology?	<p>Pain relief</p> <p>Patient satisfaction</p> <p>Cost benefits</p> <p>Hospital stays</p> <p>Reduced locoregional recurrence rates</p> <p>Improved morbidity rate and incidence, and mortality rates</p> <p>Improved patient mobility and activity levels.</p> <p>Reduced costs of other interventions, and hospital visits e.g physio, pain management, orthopaedic, palliative care, ED visits as well as community care support needs and GP visits</p>
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Precise long term follow up is difficult to assess due to the inhomogeneity of the population studies, various prognostic factors linked to individual support, histological grade, comorbidities and therapeutic regimes offered.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No controversy. Uncertainty regarding specific quantification of cost benefits despite consensus from experts and medical professionals involved in offering this procedure and following up the patients.
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.

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	<p>33129427 Radiofrequency Ablation for the Palliative Treatment of Bone Metastases: Outcomes from the Multicenter OsteoCool Tumor Ablation Post-Market Study (OPuS One Study) in 100 Patients Levy J, Hopkins T, Morris J, Tran ND, David E, Massari F, Farid H, Vogel</p>
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	<p>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>A, O'Connell WG, Sunenshine P, Dixon R, Gangi A, von der Höh N, Bagla S. J Vasc Interv Radiol. 2020 Nov;31(11):1745-1752. doi: 10.1016/j.jvir.2020.07.014.</p> <p>34109573 Radiofrequency thermoablation (RFA) and radiotherapy (RT) combined treatment for bone metastases: a systematic review Piras A, La Vecchia M, Boldrini L, D'Aviero A, Galanti D, Guarini A, Sanfratello A, Venuti V, Angileri T, Daidone A. Eur Rev Med Pharmacol Sci. 2021 May;25(10):3647-3654. doi: 10.26355/eurrev_202105_25930.</p> <p>30307346 Percutaneous image-guided ablation of bone metastases: local tumor control in oligometastatic patients Luigi Cazzato R, Auloge P, De Marini P, Rousseau C, Chiang JB, Koch G, Caudrelier J, Rao P, Garnon J, Gangi A. Int J Hyperthermia. 2018;35(1):493-499. doi: 10.1080/02656736.2018.1508760. Epub 2018 Oct 11.</p> <p>Please see attached comprehensive literature review I have performed</p>
20	<p>Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.</p>	<p>BSSR is currently performing an national expert consensus paper (40+ total UK experts)</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 incidence of spine metastasis is as high as 7 % of all patients presenting with metastatic disease according to cancer research UK.</p> <p>This translates to thousands of patients every year.</p>
22	<p>Are there any issues with the usability or practical aspects of the procedure/technology?</p>	<p>Training of staff and access to interventional IR suites for radiologists to perform the procedures.</p>
23	<p>Are you aware of any issues which would prevent (or have prevented) this</p>	<p>Not specific to this procedure as equipment offered by various vendors. Limitations associated with most percutaneous image- guided interventions which include training, access to IR suite, anaesthetic support, access to recovery areas and staff.</p>

	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?	Healthcare economics analysis.
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> <ul style="list-style-type: none"> Pain relief Patient satisfaction Cost benefits Hospital stays Reduced locoregional recurrence rates <p>Adverse outcome measures:</p> <p>Infection, bleeding, worsening of pain, instability of the spine at this level or adjacent levels.</p> <p>In the immediate, periprocedural and post procedure period as well as 6 and 12 months follow up depending on the histological grade and overall prognosis of patients. Documenting carefully in patients any morbidity or mortality but also clarifying whether or not linked to the level treated or the procedure performed.</p>
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,	In my professional experience, that proven in the literature combined with extreme pressures on the NHS to free up theatre capacity, RFA of spinal metastasis may optimise the current patient pathways and improve the patients experience during their challenging oncological journey. This comment is supported by direct feedback from patients and carers who have undergone this procedure and is well documented in the literature. Given its excellent safety profile and promising initial results, there is a growing need to adopt such technologies to further benefit these patients for pain relief and local tumour control, which can only incur with robust and up to date guidelines.
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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
<i>Non-financial professional</i>	Consultant for Stryker		
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="Dr Danoob Dalili"/>
Dated:	<input type="text" value="01/09/2022"/>

Professional Expert Questionnaire

Technology/Procedure name & indication:

Your information

Name:	<input type="text" value="David McKean"/>
Job title:	<input type="text" value="Consultant Musculoskeletal Radiologist"/>
Organisation:	<input type="text" value="Buckinghamshire Healthcare NHS Trust"/>
Email address:	<input type="text" value="[REDACTED]"/>
Professional organisation or society membership/affiliation:	<input type="text" value="General Medical Council"/>
Nominated/ratified by (if applicable):	<input type="text" value="Royal College of Radiologists"/>
Registration number (e.g. GMC, NMC, HCPC)	<input type="text" value="7016184"/>

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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 procedure/technology, please indicate your experience with it. 	<p>I have extensive experience with radiofrequency procedures and the relevant technology.</p> <p>During my training at the Nuffield Orthopaedic Centre I received training in the use of percutaneous radiofrequency ablation, especially targeting the suprascapular nerve.</p> <p>I received training in radiofrequency ablation of spinal metastases using the Osteocool Medtronic device in Strasbourg in 2017 and have performed radiofrequency ablation for spinal and pelvic lesions in my NHS clinical practice since 2018. I also have experience using the OncoV radiofrequency ablation system</p> <p>We have performed over 60 cases of radiofrequency ablation in my NHS practice since then with excellent clinical outcomes. These cases are discussed at our Spinal MDT with input from the orthopaedic spinal surgery team, the local oncology team, radiology and palliative care. We also receive referrals for treatment from other NHS Trusts in our region.</p> <p>I am aware of several other centres in the UK who regularly perform radiofrequency ablation for painful spinal metastases. Radiofrequency ablation is a well understood technology which is established practice for the treatment of malignancy in numerous organs (lung, liver, renal, thyroid etc). The use of radiofrequency ablation of painful spinal metastases is widely recognised as a safe and effective treatment which can significantly improve patient's quality of life.</p> <p>This technology is most commonly performed by interventional or musculoskeletal radiologists but may also be performed by orthopaedic spinal surgeons and neurosurgeons.</p>
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2	<p>- Please indicate your research experience relating to this procedure (please choose one or more if relevant):</p>	<p>I have published case reports on the use of radiofrequency ablation. Data from my centre has presented at several national and international conferences. I am currently performing bibliographic research on this technique as part of a Delphi consensus study.</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>A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.</p> <p>Radiofrequency ablation is a well understood and widely used technology. Radiofrequency ablation involves heating tissues to a temperature at which cell death occurs. This technology has been widely used for many years for the treatment of primary and secondary lung cancer (https://www.nice.org.uk/guidance/ipg372), hepatocellular carcinoma (https://www.nice.org.uk/guidance/ipg2), colorectal liver metastases (https://www.nice.org.uk/guidance/ipg327), renal cancer (https://www.nice.org.uk/guidance/ipg353), and thyroid nodules (https://www.nice.org.uk/guidance/ipg562) as well as many other non-malignant conditions.</p> <p>Radiofrequency ablation of painful spinal metastases is based on the same technology as all ablation procedures. It uses an applicator to deliver high frequency alternating current (400 and 500 kHz) to the target tissue causing ionic agitation and frictional heat (to temperatures of 60–100 °C). In these palliative cases, the ablation is performed for pain relief (ablation will destroy the nerves innervating the infiltrated bone), local tumour control (ablation will destroy the targeted tumour and reduced the risk of local progression), and when combined with vertebroplasty will reduced the risk of pathological collapse and associated secondary neurologic compromise.</p> <p>There are several international guidelines which include RFA as an option in their metastatic spine disease treatment algorithm. This is well established clinical practice internationally.</p> <p>Cardiovascular and Interventional Radiological Society of Europe (CIRSE)- Ryan A, Byrne C, Pusceddu C, Buy X, Tsoumakidou G, Filippiadis D. CIRSE Standards of Practice on Thermal Ablation of Bone Tumours. <i>Cardiovasc Intervent Radiol</i>. 2022 May;45(5):591-605. doi: 10.1007/s00270-022-03126-x. Epub 2022 Mar 29. PMID: 35348870; PMCID: PMC9018647.</p> <p>American Society of Pain and Neuroscience (ASPN) - Aman MM, Mahmoud A, Deer T, Sayed D, Hagedorn JM, Brogan SE, Singh V, Gulati A, Strand N, Weisbein J, Goree JH, Xing F, Valimahomed A, Pak DJ, El Helou A, Ghosh P, Shah K, Patel V, Escobar A, Schmidt K, Shah J, Varshney V, Rosenberg W, Narang S. The American Society of Pain and Neuroscience (ASPN) Best Practices and Guidelines for the Interventional Management of Cancer-Associated Pain. <i>J</i></p>

		<p>Pain Res. 2021 Jul 16;14:2139-2164. doi: 10.2147/JPR.S315585. PMID: 34295184; PMCID: PMC8292624.</p> <p>European Society for Medical Oncology (ESMO) Clinical Practice Guidelines- https://www.annalsofoncology.org/article/S0923-7534(20)39995-6/fulltext</p> <p>National Comprehensive Cancer Network (NCCN) guideline- https://www.nccn.org/patients/guidelines/content/PDF/bone-patient.pdf</p> <p>American College of Radiology (ACR) guideline- https://www.jacr.org/article/S1546-1440(18)31161-X/fulltext#pageBody</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?	<p>Radiofrequency ablation does not preclude any conventional treatments for painful spinal metastases (including radiotherapy, chemotherapy, biologic therapy, opiate analgesia or vertebroplasty).</p> <p>However, in selected cases it can be an extremely effective adjunct to these treatments especially for patients who have failed to respond to standard care. For example, patients who have had the maximum available fractions of radiotherapy but are still in severe pain which is with uncontrolled with high dose opiates. This is often seen in radiosensitive tumour metastases (e.g. renal cell, melanoma, thyroid, colorectal).</p> <p>One other advantage of RFA is that it typically results in pain relief within 48 hours of treatment. While radiotherapy may be effective for some patients there is typically a delay in the onset of pain relief. Time to response may be a significant consideration for patients at the end of life.</p>

Current management

5	Please describe the current standard of care that is used in the NHS.	<p>The current standard of care for painful spinal metastases would involve treatment with surgery, radiation, and opiate analgesia. Surgical options are limited by significant morbidity and would usually only be considered for patients with significant life expectancy. In the absence of instability, radiotherapy and opioids are the mainstay of treatment. While radiotherapy can be effective for the treatment</p>
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		<p>of painful spinal metastases up to 30% of patients have no benefit at all from radiotherapy, the mean time to response is 3 weeks, and up to 50% of patients who do get pain relief represent with recurring pain 20-24 weeks following the end of treatment. While stereotactic radiotherapy is associated with improved pain responses, complete pain response is only seen in approximately 50% of cases. Stereotactic radiotherapy is also associated with high rates of pathologic vertebral collapse.</p>
<p>6</p>	<p>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>	<p>In patients with vertebral fragility fractures, vertebroplasty may be performed to stabilising the collapsing vertebral body. However, this may be a suboptimal treatment of pathological fractures for several reasons. There is the potential risk of PMMA cement displacing tumour cells into the circulation. In addition, vertebroplasty alone will not achieve local tumour control which may result in local progression and secondary neurological compromise. While it has been postulated that PMMA injection may have some minimal antitumoral effect from the exothermic reaction which occurs as the PMMA sets, there is no published data on rates of tumour progression following vertebroplasty alone. In addition, the flow of PMMA injected during vertebroplasty cannot be targeted to the site of tumour infiltration with the accuracy of RFA.</p> <p>The combination of ablation and cement augmentation allows for targeted tumour destruction and denervation prior to PMMA cement injection to augment vertebral stability.</p>

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?	Radiofrequency ablation of painful spinal metastases is a safe and effective way to palliate recalcitrant pain which is uncontrolled by conventional treatment options. This may have a huge impact on patient suffering at the end of life and may allow for more palliative patients to be cared for in the community.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	<p>This treatment would be of benefit to patients who have recalcitrant pain from spinal metastases which has not be controlled by conventional treatments.</p> <p>Vertebral metastases are very hard to treat with high risk of progression leading to pathological fractures, instability, and cord compression. Indeed, that the natural course of metastatic spinal lesions is fatal, often with intolerable pain. RFA of spinal metastases is minimally invasive with short procedure times and does not require the interruption of adjuvant therapies. There is very extensive data on the safety of RFA for spinal metastases and strong evidence for its efficacy.</p>
9	<p>Does this procedure/technology have the potential to change the current pathway or 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>In our clinical experience, radiofrequency ablation is a very useful adjunct to convention treatments (such as surgery, radiotherapy and opiate medication). In selected case it may have a significant impact on patient pathways. Specifically, we have had numerous instances of patient who had uncontrolled spinal pain despite maximum radiotherapy fractions, who were unable to be discharged home from the ward or from the local hospice despite high dose opiate medication. Targeted radiofrequency ablation was extremely successful at controlling these patients' pain, allowing them to mobilise and be discharged. They then received palliative care in the community (which was invariably these patients' preference) with significant cost savings to the NHS Trust.</p>
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)	<p>In my own clinical practice, radiofrequency ablation for painful spinal metastases is performed in a relatively small number of cases. In our NHS Trust we care for approximately 500,000 patients and we treat approximately 15-20 patients per year with RFA of painful spinal metastases.</p> <p>All potential referrals are discussed at our local Spinal MDT with input from the orthopaedic spinal surgeons, the local oncology team, radiology and palliative care. Having reviewed the cases, we discuss whether there are any surgical options, whether the patient has responded to radiotherapy or is likely to depending on the radiosensitivity of the tumour and how well the patient is tolerating their pain. We would only perform spinal ablation in cases where the MDT is certain that the site of pain generation has been identified and is amenable to RFA and cement augmentation.</p>

		Following RFA treatment, these carefully selected patients have often been able to be discharged home (from either the hospital ward or hospice), with significant cost savings to the local Trust. Given the effectiveness of this treatment in selected cases, our local management believe this has resulted in overall cost savings compared to the previous standard of care when these patients were often unable to be discharged to the community for prolonged periods of time.
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)?	There would likely be minimal resource impact from adopting this procedure. This procedure is indicated for a specific subset of patients. These would typically be patients with palliative disease, where no surgical option is advisable, who have intolerable pain despite radiotherapy and opiate analgesia. This procedure can only be performed by radiologists or surgeons trained to perform complex spinal procedures and would likely only be available in a small number of centres nationally which is unlikely to significantly impact resource allocation in the majority of care settings. However, treatment with RFA can allow for successful discharge of patients for palliative care at home, shortened inpatient stays and reduced analgesic requirements.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	These procedures are typically performed in a radiology interventional suite or theatre environment. In our centre, we perform our ablation procedures under conscious sedation with the support of our radiology sedation nurses. However, in many centres these will be performed under general anaesthesia with the support of the local anaesthetic department. Specific equipment, including ablation probes and generator are required and a thermocouple will often be used to monitor the temperature of sensitive tissues, such as nerve roots.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Specific training is required to perform RFA of spinal lesion safely. This would typically be performed by clinicians with experience of performing image guided spinal intervention. The essentials of the technique are similar to performing vertebroplasty. However, familiarity with the ablation generator and probes is necessary to be able to use these safely to minimise the risk of iatrogenic thermal injury. There are a number of UK centres with experience of performing radiofrequency of painful spinal metastases (Stoke Mandeville, Norwich, Bristol, Leeds etc) who could train clinicians in performing this procedure. There are regular training courses arranged by industry suppliers.

Safety and efficacy of the procedure/technology

<p>14</p>	<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>Clinically significant complications are not common following RFA of bone lesions (approx. 2.3%), fracture being the most common (1.8%). Other rarely encountered complications include infection, skin burn, peripheral sensory or motor neuropathy, arthropathy and haematoma. Factors associated with a higher complication rate are a tumour size > 3 cm and previous radiotherapy. Although rare, neural thermal injury is one of the more frequent complications following RFA. The majority of patients will recover completely; however, they must be appropriately advised regarding the likely duration of recovery (between 6 and 18 months).</p> <p>Cazzato RL, Palussière J, Auloge P, Rousseau C, Koch G, Dalili D, Buy X, Garnon J, De Marini P, Gangi A. Complications following percutaneous image-guided radiofrequency ablation of bone tumors: a 10-year dual-center experience. <i>Radiology</i>. 2020;296(1):227–235.</p>
<p>15</p>	<p>Please list the key efficacy outcomes for this procedure/technology?</p>	<p>The key efficacy outcome from radiofrequency ablation of painful spinal metastases is pain relief.</p> <p>For malignant lesions treated with palliative intent, bipolar radiofrequency ablation (b-RFA) with increased target temperature (> 70 °C) in combination with vertebroplasty has been reported to achieved pain relief (80% efficacy) and local tumour control in oligometastatic/oligoprogressive lesions (100% efficacy)</p> <ul style="list-style-type: none"> • Mayer T, Cazzato RL, De Marini P, Auloge P, Dalili D, Koch G, Garnon J, Gangi A. Spinal metastases treated with bipolar radiofrequency ablation with increased (>70 °C) target temperature: pain management and local tumor control. <i>Diagn Interv Imaging</i>. 2021;102(1):27–34. doi: 10.1016/j.diii.2020.04.012. <p>RFA was reported to be especially useful in patients with recalcitrant pain</p> <ul style="list-style-type: none"> • Mehta TI, Heiberger C, Kazi S, Brown M, Weissman S, Hong K, Mehta M, Yim D. Effectiveness of radiofrequency ablation in the treatment of painful osseous metastases: a correlation meta-analysis with machine learning cluster identification. <i>J Vasc Interv Radiol</i>. 2020;31(11):1753–1762. doi: 10.1016/j.jvir.2020.08.002. <p>For malignant lesions treated with curative intent, tumour-free survival has been reported to be 67% 1 year post-RFA or CA in oligometastases</p> <ul style="list-style-type: none"> • Deschamps F, Farouil G, Ternes N, et al. Thermal ablation techniques: A curative treatment of bone metastases in selected patients? <i>Eur Radiol</i>. 2014;24:1971–1980. doi: 10.1007/s00330-014-3202-1.

		<p>Secondary measures of efficacy would include reduce opiate analgesia requirements</p> <ul style="list-style-type: none"> Goetz MP, Callstrom MR, Charboneau JW, Farrell MA, Maus TP, Welch TJ, Wong GY, Sloan JA, Novotny PJ, Petersen IA, Beres RA, Regge D, Capanna R, Saker MB, Grönemeyer DH, Gevargez A, Ahrar K, Choti MA, de Baere TJ, Rubin J. Percutaneous image-guided radiofrequency ablation of painful metastases involving bone: a multicenter study. <i>J Clin Oncol.</i> 2004 Jan 15;22(2):300-6. doi: 10.1200/JCO.2004.03.097. PMID: 14722039.
<p>16</p>	<p>Please list any uncertainties or concerns about the efficacy and safety of this procedure/?</p>	<p>Vertebral metastases are very hard to treat with high risk of progression leading to pathological fractures, instability, and cord compression. Indeed, that the natural course of metastatic spinal lesions is fatal, often with intolerable pain. RFA of spinal metastases is minimally invasive with short procedure times and does not require the interruption of adjuvant therapies. There is very extensive data on the safety of RFA for spinal metastases and strong evidence for its efficacy.</p> <p>Dupuy DE, Liu D, Hartfeil D, et al. Percutaneous radiofrequency ablation of painful osseous metastases: a multicenter American College of Radiology Imaging Network trial. <i>Cancer</i> 2010;116(4):989–997. Crossref, Medline, Google Scholar</p> <p>Tanigawa N, Arai Y, Yamakado K, et al. Phase I/II study of radiofrequency ablation for painful bone metastases: japan interventional radiology in oncology study group 0208. <i>Cardiovasc Intervent Radiol</i> 2018;41(7):1043–1048. Crossref, Medline, Google Scholar</p> <p>Goetz MP, Callstrom MR, Charboneau JW, et al. Percutaneous image-guided radiofrequency ablation of painful metastases involving bone: a multicenter study. <i>J Clin Oncol</i> 2004;22(2):300–306. Crossref, Medline, Google Scholar</p> <p>Cazzato RL, Palussière J, Auloge P, Rousseau C, Koch G, Dalili D, Buy X, Garnon J, De Marini P, Gangi A. Complications Following Percutaneous Image-guided Radiofrequency Ablation of Bone Tumors: A 10-year Dual-Center Experience. <i>Radiology.</i> 2020 Jul;296(1):227-235. doi: 10.1148/radiol.2020191905. Epub 2020 Apr 28. PMID: 32343213.</p> <p>Cazzato RL, Garnon J, Caudrelier J, Rao PP, Koch G, Gangi A. Percutaneous radiofrequency ablation of painful spinal metastasis: a systematic literature assessment of analgesia and safety. <i>Int J Hyperthermia.</i> 2018 Dec;34(8):1272-1281. doi: 10.1080/02656736.2018.1425918. Epub 2018 Jan 17. PMID: 29308694.</p>

		<p>Rosian K, Hawlik K, Piso B. Efficacy Assessment of Radiofrequency Ablation as a Palliative Pain Treatment in Patients with Painful Metastatic Spinal Lesions: A Systematic Review. <i>Pain Physician</i>. 2018 Sep;21(5):E467-E476. PMID: 30282388.</p> <p>Levy J, Hopkins T, Morris J, Tran ND, David E, Massari F, Farid H, Vogel A, O'Connell WG, Sunenshine P, Dixon R, Gangi A, von der Höh N, Bagla S. Radiofrequency Ablation for the Palliative Treatment of Bone Metastases: Outcomes from the Multicenter OsteoCool Tumor Ablation Post-Market Study (OPuS One Study) in 100 Patients. <i>J Vasc Interv Radiol</i>. 2020 Nov;31(11):1745-1752. doi: 10.1016/j.jvir.2020.07.014. PMID: 33129427.</p>
17	<p>Is there controversy, or important uncertainty, about any aspect of the procedure/technology?</p>	<p>Where both vertebroplasty and radiotherapy are indicated, their relative timings are a matter of ongoing debate in the literature. The current Cardiovascular and Interventional Radiological Society of Europe (CIRSE) recommendations are as follows, however further study is required to determine the optimum timing of these treatments for different tumour types:</p> <ul style="list-style-type: none"> • In cases of solitary or oligometastases, it is recommended to perform thermoablation first, to effect local tumour control, followed by vertebroplasty to effect vertebral stabilisation and pain control. In radiosensitive lesions, subsequent radiation therapy can consolidate this treatment and improve the tumour response. • Where the risk of pathological fracture is high, e.g. in predominantly lytic lesions, particularly those with massive osteolysis, vertebroplasty should be performed first to diminish the risks of pathological fracture/collapse and secondary neurologic compromise, followed by radiotherapy to effect local tumour control. • Where a vertebral lesion is causing epiduritis, particularly with neurologic symptoms, radiotherapy should be performed first, followed by vertebroplasty. • Where SBRT is planned with curative intent, some centres prefer that this is performed before vertebroplasty, given the potential risk of cement displacing tumour cells into the circulation. • Where SBRT is used to treat small vertebral metastases to effect local tumour control and pain management, subsequent vertebroplasty is recommended to reduce the risk of collapse due to SBRT-related osteonecrosis. • If transarterial embolisation and RT are both indicated, embolisation should follow RT as the efficacy of the latter is reduced by hypoxia <p>Ryan A, Byrne C, Pusceddu C, Buy X, Tsoumakidou G, Filippiadis D. CIRSE Standards of Practice on Thermal Ablation of Bone Tumours. <i>Cardiovasc Intervent Radiol</i>. 2022</p>

		May;45(5):591-605. doi: 10.1007/s00270-022-03126-x. Epub 2022 Mar 29. PMID: 35348870; PMCID: PMC9018647
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK.

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>This is an area of ongoing research.</p> <p>The Opus One 12 month data has been presented as an abstract and I believe this will be published shortly. https://interventionalnews.com/sir-2021-abstract-of-the-year-opus-one-data-should-move-the-needle-more-on-radiofrequency-ablation-for-patients-with-painful-bone-metastases/</p> <p>I am aware of colleagues in Europe who are collaborating on a study looking at whether the rise in the level of circulating tumour cells seen in vertebroplasty can be prevented with RFA prior to cement augmentation.</p> <p>I am aware of two Delphi consensus papers which are currently being written on RFA of spinal metastases- one with members of the BSSR and one with members of the Interventional subcommittee of the ESSR.</p>
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)?	In our NHS Trust we care for approximately 500,000 patients and we treat approximately 15-20 patients per year with RFA of painful spinal metastases. While spinal metastases are common, there are relatively small numbers of patients who require this treatment. Typically, these are patients who have failed to respond to conventional radiotherapy and have uncontrolled recalcitrant pain despite high dose opiate analgesia.
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22	Are there any issues with the usability or practical aspects of the procedure/technology?	This procedure would be technically straightforward for a radiologist who has been trained in complex spinal procedures such as vertebroplasty.
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 of any issues which have prevented this procedure being adopted in our organisation.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	There are ongoing questions regarding the optimum timing of RFA and radiotherapy in patients with radiosensitive tumours (see section 17).
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> <p>Visual analogue pain score (VAS) – 1, 3, 6, 12 months</p> <p>Brief Pain Inventory (BPI) short form– 1, 3, 6, 12 months</p> <p>European Quality of Life–Five Dimensions– 1, 3, 6, 12 months</p> <p>Adverse outcome measures:</p> <p>Procedure-related complications according to the Clavien–Dindo Classification</p> <p>Vertebral related events (VRE)- defined as progressive fracture of a vertebral body, spinal cord compression or cauda equina syndrome requiring surgery and/or radiotherapy – 1, 3, 6, 12 months</p>
26	Is there any other data (published or otherwise) that you would like to share with the committee?	<p>We have had the following abstract accepted for presentation at the BIR Congress. We intend to submit the paper for publication shortly.</p> <p>Radiofrequency ablation of vertebral metastases to prevent adverse vertebral related events.</p>

		<p>Objectives: To evaluate the rates of local and distant adverse events in patients who had radiofrequency ablation of vertebral metastases.</p> <p>Methods: In this single-centre retrospective cohort study, we reviewed follow-up imaging of patients who had radiofrequency ablation of vertebral metastases between January 2018 and March 2022. Local failure (LF), distant failure, and overall survival (OS) were analysed. Follow up imaging was analysed for vertebral related events (VRE), defined as fracture of a vertebral body, spinal cord compression or cauda equina syndrome requiring surgery and/or radiotherapy. The rate of local tumour control, VRE at the treated level, VRE at untreated levels, and distant disease progression were recorded.</p> <p>Results: Radiofrequency ablation was performed on 60 lesions in 37 patients (mean age 62.5, range 24-87). Referral indications were for uncontrolled pain, reduced mobility and/or vertebral collapse. 25 ablated vertebral lesions underwent imaging follow up, 28% (7/25) with CT and 72% (18/25) with MRI. One VRE (4%, 1/25) was reported at a treated level, 36.8% (7/19) of patients had a VRE at untreated vertebral levels. Regression of epidural tumour at the posterior margin of the ablation zone was achieved in one patient. 57.9% (11/19) had distant disease progression, which included progression of osseous, hepatic, intracranial and lymph node metastases.</p> <p>Conclusion: Local tumour control of vertebral metastases using radiofrequency ablation is a feasible, safe and effective treatment which decreases the risk of local VRE, as well as achieving local pain control.</p>
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Further comments

<p>26</p>	<p>Please add any further comments on your particular experiences or knowledge of the procedure/technology,</p>	<p>This treatment uses well established and well understood technology. The data supporting RFA for painful spinal metastases is comparable to that for RFA treatment of several other cancer locations which NICE has previously approved such as RFA for primary and secondary lung cancer (https://www.nice.org.uk/guidance/ipg372), hepatocellular carcinoma (https://www.nice.org.uk/guidance/ipg2), colorectal liver metastases (https://www.nice.org.uk/guidance/ipg327), renal cancer (https://www.nice.org.uk/guidance/ipg353), and thyroid nodules (https://www.nice.org.uk/guidance/ipg562) as well as many other non-malignant conditions.</p>
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RFA for painful spinal metastases is well established clinical practice internationally and there are several international guidelines which include RFA as an option in their metastatic spine disease treatment algorithm.

Cardiovascular and Interventional Radiological Society of Europe (CIRSE)- Ryan A, Byrne C, Pusceddu C, Buy X, Tsoumakidou G, Filippiadis D. CIRSE Standards of Practice on Thermal Ablation of Bone Tumours. *Cardiovasc Intervent Radiol*. 2022 May;45(5):591-605. doi: 10.1007/s00270-022-03126-x. Epub 2022 Mar 29. PMID: 35348870; PMCID: PMC9018647.

American Society of Pain and Neuroscience (ASPN) - Aman MM, Mahmoud A, Deer T, Sayed D, Hagedorn JM, Brogan SE, Singh V, Gulati A, Strand N, Weisbein J, Goree JH, Xing F, Valimahomed A, Pak DJ, El Helou A, Ghosh P, Shah K, Patel V, Escobar A, Schmidt K, Shah J, Varshney V, Rosenberg W, Narang S. The American Society of Pain and Neuroscience (ASPN) Best Practices and Guidelines for the Interventional Management of Cancer-Associated Pain. *J Pain Res*. 2021 Jul 16;14:2139-2164. doi: 10.2147/JPR.S315585. PMID: 34295184; PMCID: PMC8292624.

European Society for Medical Oncology (ESMO) Clinical Practice Guidelines- [https://www.annalsofoncology.org/article/S0923-7534\(20\)39995-6/fulltext](https://www.annalsofoncology.org/article/S0923-7534(20)39995-6/fulltext)

National Comprehensive Cancer Network (NCCN) guideline- <https://www.nccn.org/patients/guidelines/content/PDF/bone-patient.pdf>

American College of Radiology (ACR) guideline- [https://www.jacr.org/article/S1546-1440\(18\)31161-X/fulltext#pageBody](https://www.jacr.org/article/S1546-1440(18)31161-X/fulltext#pageBody)

The number of patients who would be eligible for this treatment is relatively small and NICE approval of this technique is therefore unlikely to have a significant impact of resource allocation nationally. However, for palliative patients with recalcitrant pain from spinal metastases this technique can have a transformational effect on their quality of life which I have witnessed repeated in my own clinical practice.

Vertebral metastases are very hard to treat with high risk of progression leading to pathological fractures, instability, and cord compression. Indeed, that the natural course of metastatic spinal lesions is fatal, often with intolerable pain. RFA of spinal metastases is minimally invasive with short procedure times and does not require the interruption of adjuvant therapies. There is very extensive data on the safety of RFA for spinal metastases and strong evidence for its efficacy. I would strongly support its use ongoing use.

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
<i>Direct - financial</i>	I was a member of the Medtronic Interventional Advisory Board	January 2021	April 2022
<i>Direct - financial</i>	I have been invited to join the Advisory Board for OncoV	June 2022	Ongoing
<i>Non-financial professional</i>	I have been invited to chair an international webinar on RFA of spinal metastases in November 2022	November 2022	November 2022

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="David McKean"/>
Dated:	<input type="text" value="25/07/2022"/>

Professional Expert Questionnaire

Technology/Procedure name & indication:

Your information

Name:	Gordan Grahovac
Job title:	Consultant Neurosurgeon
Organisation:	King's college Hospital
Email address:	██████████
Professional organisation or society membership/affiliation:	GMC
Nominated/ratified by (if applicable):	N/A
Registration number (e.g. GMC, NMC, HCPC)	7473025

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.

<p>1 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 familiar with this radiofrequency ablation of vertebral body metastasis for several years and have been performing these procedures on regular basis since beginning of 2020.</p> <p>This procedure is already widely used in several centres in the UK by interventional radiologist, spinal neurosurgeons and spinal orthopaedic surgeons. This technology has potential to increase uptake in regular praxis in the NHS since the body of evidence is growing and supporting its application in managing painful vertebral body metastasis with rapid pain relief compared with current radiotherapy management.</p> <p>My speciality is directly involved in selection of this patients through MSCC MDT and during emergency work. Certain cases are direct referral from oncologist in cases of oligometastatic diseases to prevent possible pathological fracture during SRS management.</p>
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	procedure/technology, please indicate your experience with it.	
2	- Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure.
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):	Radiofrequency ablation is well established technology for management of metastatic deposits in long bones, solid organs. This is variation of current technology that enabled treatment of vertebral body metastatic deposits. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	This procedure will be used as addition to existing standard of care for management of metastatic vertebral body deposits such as surgical intervention and oncological management.

Current management

5	Please describe the current standard of care that is used in the NHS.	Radiotherapy, vertebroplasty, surgical stabilisation of the spine.
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<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>	<p>For minimal invasive management of vertebral body metastasis alternative methods are cryotherapy and microwave ablative therapy.</p> <p>Cryotherapy uses low temperature to ablate the metastatic deposits and is useful in osteoblastic metastatic deposits where radiofrequency is not so successful.</p> <p>Microwave ablation uses power of microwaves to ablate metastatic deposits.</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?	Rapid pain relief and increased safety of vertebroplasty/kypoplasty procedure in patients with metastatic deposits in the vertebral body.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with painful vertebral body metastasis
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?	Radiofrequency with vertebroplasty/kypoplasty has shown rapid pain relief and long-lived effect compared to radiotherapy that is current standard of care. This leads to less opioid consumption and better quality of life in patients with malignant metastatic disease, with less side effects of opioid. Also does not have any significant influence of continuation of oncological management due to minimal invasiveness of the 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)	This procedure requires additional cost due to use of radiofrequency probes and radiofrequency generator.
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)?	Don't think adoption of this procedure will have significant resource impact standard of care
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	none

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Training course would be sufficient to get versatile with machine and radiofrequency probes.
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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>Thermal lesion of spinal cord or nerve root as direct complication of radiofrequency ablation. Cement extravasation into spinal canal with subsequent neurological damage or into vasculature with possible pulmonary embolism. Possibility of visceral damage due to mistake of positioning needle and radiofrequency probe</p>
15	Please list the key efficacy outcomes for this procedure/technology?	Pain scores, infection rate, rate of cement leakage, ambulation
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	None
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not that I'm aware
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Cannot predict at present.

Abstracts and ongoing studies

<p>19</p>	<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>Levy J, Hopkins T, Morris J, Tran ND, David E, Massari F, Farid H, Vogel A, O'Connell WG, Sunenshine P, Dixon R, Gangi A, von der Höh N, Bagla S. Radiofrequency Ablation for the Palliative Treatment of Bone Metastases: Outcomes from the Multicenter OsteoCool Tumor Ablation Post-Market Study (OPuS One Study) in 100 Patients. J Vasc Interv Radiol. 2020 Nov;31(11):1745-1752. doi: 10.1016/j.jvir.2020.07.014.</p>
<p>20</p>	<p>Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.</p>	<p>Not that I'm aware</p>

Other considerations

<p>21</p>	<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>10-20%</p>
<p>22</p>	<p>Are there any issues with the usability or practical aspects of the procedure/technology?</p>	<p>none</p>
<p>23</p>	<p>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?</p>	<p>none</p>

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	none
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: Pain score (VAS), quality of life(EQ-5D), consumption of opioids on 1 week, 1 months, 3 months 6 months and up to one year.</p> <p>Adverse outcome measures: Infection rate 30 days after procedure, leakage rate of cement and thermal lesion of the cord immediate after procedure</p>

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	n/a
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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="Click here to enter text."/> Gordan Grahovac
Dated:	<input type="text" value="Click here to enter text."/> 7.2.2021

Professional Expert Questionnaire

Technology/Procedure name & indication: Radiofrequency ablation for palliation of painful spinal metastases IP1783

Your information

Name:	Dr Steven Morgan
Job title:	Consultant Radiologist
Organisation:	North Bristol NHS Trust
Email address:	██████████
Professional organisation or society membership/affiliation:	Royal College of Radiologists. BSSR. ESSR
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC: 6056381

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see [our privacy notice](#).

Y I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

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.

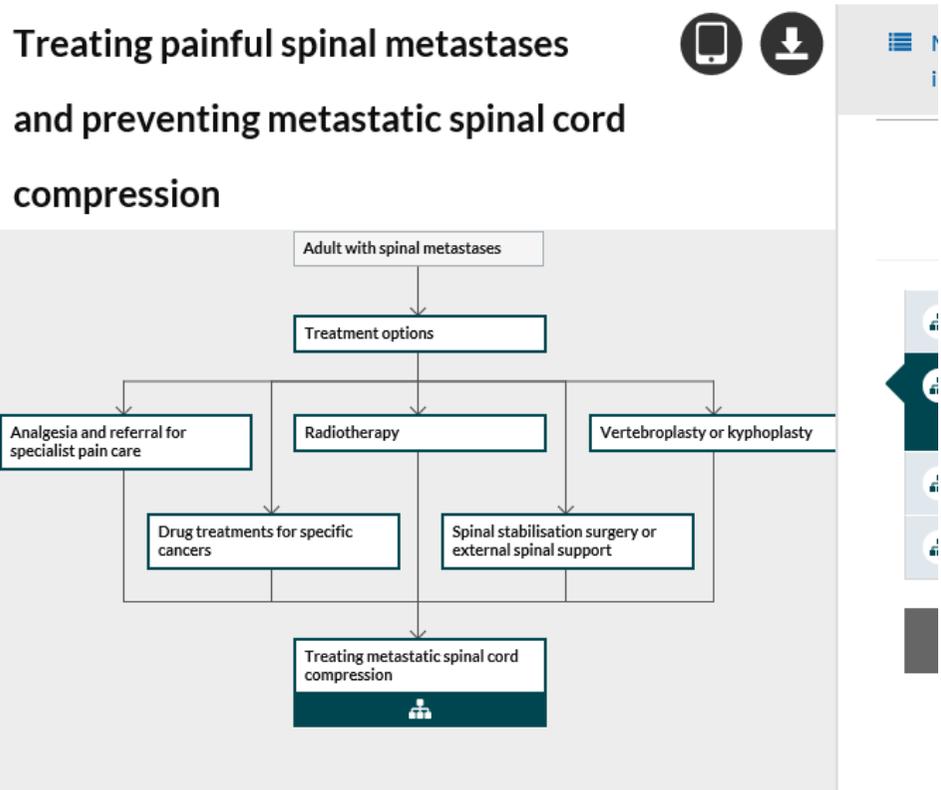
<p>1</p>	<p>Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none"> - Do you know how widely this procedure/technology is used in 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>I have extensive experience using RF systems to treat spinal metastases. We started our service in late 2016, and performed RFA on 42 patients in 2020.</p> <p>Current user, as above.</p> <p>This is slowly growing across the UK – we have perhaps 15 or so interested individuals express interest for training/courses/webinars.</p> <p>Spinal met RFA will be performed by Radiologists and Spine Surgeons.</p> <p>All patients are discussed at our weekly Complex Spine MDT. I/we receive referrals from many different clinicians/specialities.</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 undertaken extensive bibliographic research in this field.</p> <p>We are currently bringing together our 4 year database for publication. Nothing yet published.</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>RFA has been successfully used to treat painful bony metastases for 20 years.</p> <p>First published by Dupuy in 2001.</p> <p>It is usually combined with augmentation (VA): (vertebroplasty/kyphoplasty)</p> <p>It was first employed as an option for those who had failed standard therapies – analgesia and radiotherapy, and showed to significantly reduce pain. This is of major benefit in reducing opioid usage and side effects.</p> <p>RFA helps to provide local tumour control, and delay/prevent pathological fracture/instability, and Metastatic Spinal Cord Compression (MSCC) and the awful sequelae thereof.</p> <p>Augmentation alone in metastases may result in tumour seeding/extravasation.</p> <p>Additionally, there is some evidence to suggest that RFA reduces cement leak.</p> <p>RFA also has a synergistic effect with radiotherapy, both improving degree of, and reducing time to achieve pain relief.</p> <p>RFA is also a useful option in those whom cannot receive further RT, or where there is a high risk of vertebral fracture (EBRT 5%, SBRT 14%).</p> <p>Therefore, in comparison with VA alone, RFA represents a minor variation on an existing procedure, which is likely to improve the procedure's safety and efficacy.</p> <p>RFA is additional to RT, can be synergistic, and helps to treat those refractive to RT, or in whom more RT is not possible.</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?	<p>RFA will work alongside RT.</p> <p>RFA should be used in conjunction with VA in the treatment of painful vertebral metastases.</p>

Current management

<p>5</p>	<p>Please describe the current standard of care that is used in the NHS.</p>	<p>Current treatments are primarily palliative and include localized therapies (radiation and surgery), systemic therapies (chemotherapy, hormonal therapy, radiopharmaceuticals, and bisphosphonates), and analgesics (opioids and nonsteroidal anti-inflammatory drugs).</p> <p>RFA is performed concurrent to biopsy – essential treatment planning i.e. receptor/marker status.</p>
	<p>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>	<p>Cryotherapy Microwave MRI guided Ultrasound</p> <p>These are other thermal ablative modalities. Each has pros/cons. RFA is the safest modality for spine work. I can discuss.</p>

Potential patient benefits and impact on the health system

7	<p>What do you consider to be the potential benefits to patients from using this procedure/technology?</p>	<p>Pain reduction, local tumour control (reduces risk of MSCC), reduce fracture risk (both tumour and secondary to RT), reduce opioid use.</p> <p>Generally improve quality of life and keep ambulant.</p>
8	<p>Are there any groups of patients who would particularly benefit from using this procedure/technology?</p>	<p>Patients with painful +/-fractured (or large lytic) spinal metastases/myeloma</p>
9	<p>Does this procedure/technology have the potential to change the current pathway or 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>RFA needs to be added to the NICE MSCC pathway documents/flowcharts:</p> 

		<p>RFA can be undertaken at same sitting as biopsy/VA, treating pain/potential instability and obtaining tissue for planning patient centered treatment. This aids compliance with and reduces risks of RT.</p> <p>We are currently planning with Oncologists locally to highlight patients earlier.</p> <p>This will hopefully:</p> <p>Reduce rates of MSCC.</p> <p>Reduce inpatient Length of Stay.</p> <p>Improve local tumour and pain control, prolonging quality of life.</p> <p>We are working on a local guideline/pathway.</p>
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.)	<p>In isolation, RFA is more expensive than EBRT.</p> <p>Taken as a whole, the reduction in pain/hospital visits, need for surgery, and the devastating cost of MSCC to both the patient/family and health service, the benefit of RFA is enormous.</p>
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)?	<p>Implementation should be focussed on initially 10-20 centres across the UK, perhaps with a regional catchment (as we have in Bristol)</p> <p>It will require interventional team training and provision.</p>
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	<p>There needs to be dedicated access to interventional rooms</p> <p>Encouragement from senior NHS staff to see the global picture (i.e. not just within Radiology) as to why this is a very important role and to ensure staff are supported.</p>
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, operators/staff need to be trained.

Safety and efficacy of the procedure/technology

<p>14</p>	<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>I consent for pain, bleeding, infection, thermal nerve injury and cement leak</p> <p>Post ablation flare of pain – 20-50% (I cover with 5 days of steroids, much like RT).</p> <p>Thermal Nerve Injury: Myself, nil so far.</p> <p>Cement leak: I quote a cancer patient 100%. I always perform CT immediately after the procedure, and can usually find a small paravertebral leak.</p> <p>My leak rate was 48% in 2018 (2019/20 results pending). None symptomatic or needing further intervention. Literature rates will vary (depending how hard you look....and if CT used to check)</p> <p>I have 3 cases of small leak into a neural foramen, one symptomatic, settled with a nerve root block. Literature 11/583 post procedural pain increase/radicular pain (Pain Physician 2018; 21: E467. Rosian et al)</p> <p>Even given relatively low quality data, RFA has shown to be safe and effective. Given significant pain in this palliative population, is worthwhile.</p>
<p>15</p>	<p>Please list the key efficacy outcomes for this procedure/technology?</p>	<p>Pain reduction. Lowering fracture risk for Oncologists. Local tumour control.</p>
<p>16</p>	<p>Please list any uncertainties or concerns about the efficacy and safety of this procedure/?</p>	
<p>17</p>	<p>Is there controversy, or important uncertainty, about any aspect of the procedure/technology?</p>	
<p>18</p>	<p>If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):</p>	<p>Multiple centres across the UK to deal with the huge number of patients with painful spinal metastases.</p>

Abstracts and ongoing studies

<p>19</p>	<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>Guidelines: NCCN Adult Cancer Pain 2020. Oncologist 2015. Myeloma 2019</p> <p>Key Names: Matt Callstrom, Jack Jennings, Sean Tutton</p> <p>Goetz et al. J Clin Oncol. 2004 Jan 15; 22(2):300-6.</p> <p>Opus One: J Vasc Interv Radiol 2020; 31:1745–1752</p> <p>Cazzato et al, Tech Vasc Int Rad 2020; 23:100677.</p> <p>Wallace et al, J Neurooncol 2015; 124: 111-118</p> <p>Wallace et al, AJNR 2016; 37:759-65</p> <p>Gevargez EJR 2008; 65: 246-52.</p> <p>David et al Ann Pall Med 2017; 6(2): 118-24</p> <p>Prezzano et al Am J Hosp & Pall Med 2019 May; 36(5): 417-422</p> <p>Greenwood et al Pain Phys 2015; 18: 573-81</p> <p>Lea/Tutton Semin Int Radiol 2017; 34: 121-31</p> <p>Bagla et al Cardiovasc Int Rad 2016; 39:1289-97</p> <p>Proschek et al Anticancer Res 2009; 29: 2787-92</p> <p>Anchala et al Pain Phys 2014; 17: 317-327</p> <p>Hillen et al Radiology 2014; 273 (1): 263-7</p> <p>Cruz et al J Neurosurg Spine 2014; 21: 372-77</p>
<p>20</p>	<p>Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.</p>	

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)?	Within our local population, circa 700,000 (I think, Bristol and Bath) I would estimate our service to grow to 100+ cases, particularly in combination/helping RT and reducing risks thereof.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Once the operator is trained, and cases are selected carefully via an MDT approach, the tech is straightforward to use.
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?	We will hopefully get to see mets at an earlier stage to prevent fracture/complications. We could also combine this with SBRT data, vs SBRT alone.
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: Pain, QOL scores, local recurrence, MSCC rates, LOS reduction</p> <p>Adverse outcome measures: No change in pain, complication rates as above.</p>

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Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	I have gained much experience with RFA over the last 4 years, and think I would be the major user in the UK. Very happy to help the committee with the process.
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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
<i>Direct - financial</i>	OncoV Ltd. Consultancy/Proctoring	1.3.20	
<i>Direct - financial</i>	Stryker. Consultancy/Proctoring	3.7.20	
Choose an item.			

Y I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

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

Print name:	Dr Steven Morgan
Dated:	13.7.22

Professional Expert Questionnaire

Technology/Procedure name & indication:

Your information

Name:	<input type="text" value="Dr W J Rennie"/>
Job title:	<input type="text" value="Consultant Musculoskeletal Radiologist"/>
Organisation:	<input type="text" value="University Hospitals of Leicester NHS Trust"/>
Email address:	<input type="text" value="[REDACTED]"/>
Professional organisation or society membership/affiliation:	<input type="text" value="British Society of Skeletal Radiologists, Royal College of Radiologists"/>
Nominated/ratified by (if applicable):	<input type="text" value="N/A"/>
Registration number (e.g. GMC, NMC, HCPC)	<input type="text" value="GMC 4656845"/>

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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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	<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 am familiar with the procedure, technique and most of the commercially available devices since the early days of RF ablation</p> <p>I am currently using it – stopped due to COVID pandemic</p> <p>Currently very sporadically used in specialist centres. Speed of uptake maybe slightly increased once NICE Guidance is clear on its use.</p> <p>Some of the technology is used by clinicians in their surgical practice.</p> <p>I am heavily involved in patient selection and referral tends to be via a Multi Disciplinary Team approach in my practice. I perform all the cases once accepted.</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. Yes</p> <p>I have done research on this procedure in laboratory settings (e.g. device-related research). No</p> <p>I have done clinical research on this procedure involving patients or healthy volunteers. Yes</p> <p>I have published this research. Yes</p> <p>I have had no involvement in research on this procedure.</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>Novel approach in the NHS compared to standard of care.</p> <p>Established practice and no longer new.- In Specialist centres</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?	Has the potential to replace current standard of care.

Current management

5	Please describe the current standard of care that is used in the NHS.	Radiotherapy with or without stabilisation spinal surgery
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?	Cryotherapy – similar function but different mode of action.

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?	Greatly improved QoL, Markedly reduced pain and improved function. Obvites the need for major spinal surgery in most cases thereby reducing the burden to patients and the NHS in bed days.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Myeloma and patients with spinal metastasis.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes it does to the benefit of healthcare systems Yes see above 7
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Cost significantly Less if carefully managed pathway 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)?	About the same. Any costs incurred will be offset by reduced clinic visits and surgical/ITU bed stay.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Bi Plane fluoroscopy suites or Angiographic suite time- Radiology

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes. Fellowship of 6-9 months in accredited centres. I have trained people this way as they need to experience the whole gamut of complexity and attain sufficient hand eye coordination and radiology skills in cement/contrast extravasation
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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>Cement/ Filler Cortoss extravasation, Cement Pulmonary embolus, Lung infarction, spinal cord and nerve compression/ thermal burns.</p> <p>RF capacitance issues and cord burns.</p> <p>I have had none personally and have seen all the above from other units referred to me.</p> <p>Theoretical- pacemaker, implant effects and burns.</p> <p>Adverse effects of anaesthesia.</p>
15	Please list the key efficacy outcomes for this procedure/technology?	QoL outcome data for 6mths to 12 mths. Pain VAS scores.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Concerns are the lack of standardised training curricula. Random uptake by spinal surgeons with inadequate training or radiologists.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Controversy in Surgical literature as to the cause of vertebral pain and nociceptors anatomy. None about technology.
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. Yes</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>	
20	<p>Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.</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>	30 per year
22	<p>Are there any issues with the usability or practical aspects of the procedure/technology?</p>	Current issues with Anaesthetist availability and coordination of lists in CT/ Angiography suites

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?	As in 22. Lists, time and scanner/angiography suite availability
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Longitudinal standardised outcome measures in the UK population using EQ5D and VAS scores for 6mths and 1 year.
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> <p>QoL- EQ5D 3 time points, Pre procedure and 1month(clinic) and (6mths to 1 year- telephone)</p> <p>Adverse outcome measures:</p> <p>During procedure – image capture immediate post procedure CT</p> <p>1 month clinical assessment</p>

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	I have performed the procedure and established regular lists since 2006 using multiple technologies. I have seen complex cases and used much of the available technology in the NHS. The benefit to individual patients is significant with miraculous pain relief but the uptake has been sporadic across the NHS due to training issues, ignorance of the technology by oncologists, MDTs and hospital managers. Lack of procedure ownership with an orphan
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		<p>procedure that fits between multiple MDTs and by varying specialities does not help with referral. This should be a procedure offered via the Metastatic Bone service which should capture cases from Myeloma, Colorectal, Lung and Head and neck MDTs mainly. 96% of my work is from one single MDT and the service can cope with these numbers.</p>	
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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	None in the last 12 months		
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="Dr W J Rennie"/>
Dated:	<input type="text" value="04/02/2021"/>