

Professional Expert Questionnaire

Technology/Procedure name & indication:

Your information

Name:	<input type="text" value="Click here to enter text."/> Gordan Grahovac
Job title:	<input type="text" value="Click here to enter text."/> Consultant Neurosurgeon
Organisation:	<input type="text" value="Click here to enter text."/> King's college Hospital
Email address:	<input type="text" value="Click here to enter text."/> gordan.grahovac@nhs.net
Professional organisation or society membership/affiliation:	<input type="text" value="Click here to enter text."/> GMC
Nominated/ratified by (if applicable):	<input type="text" value="Click here to enter text."/> N/A
Registration number (e.g. GMC, NMC, HCPC)	<input type="text" value="Click here to enter text."/> 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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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:

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

<p>1</p>	<p>Please describe your level of experience with the procedure/technology, for example:</p> <p>Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none">- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?- Is this procedure/technology performed/used by clinicians in specialities other than your own?- If your specialty is involved in patient selection or referral to another specialty for this	<p>I have been 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	<ul style="list-style-type: none"> 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	<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>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.</p> <p>A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.</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?	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

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>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>
20	<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

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

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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:

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="Winston.rennie@gmail.com"/>
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"/>

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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

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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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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.			

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Print name:	<input type="text" value="Dr W J Rennie"/>
Dated:	<input type="text" value="04/02/2021"/>