NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1953 Radiofrequency ablation as an adjunct to balloon kyphoplasty or percutaneous vertebroplasty for palliation of painful spinal metastases**

Your information

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

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

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

Click here to enter text.

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

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	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 (see below). 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. Can be performed by Spine surgeons or pain management specialists. This has been adopted in some overseas countries.
2	− Please indicate your research experience relating to this procedure	I have done bibliographic research on this procedure.

	(please choose one or more if relevant):	I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research.
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):	RF ablation has been performed in mainstream clinical practice in the UK for osteoid osteomas for at least 30 years. Current innovations include: -Developments in the instruments used, higher temperatures achieved under more controlled local environments with no specific and better focused heated nucleus. - Thermopotective 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. Established practice and no longer new. 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?	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. Furthermore, RF can be performed without precluding the ability to offering more invasive standard of care interventions such as surgery.

Current management

5	Please describe the current standard of care that is used in the NHS.	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
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/cryoablation Inducing necrosis of malignant cells by extreme cooling (-40celcius) rather than heating up to 87Celcius with RF.

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?	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. Furthermore, RF can be performed without precluding the ability to offering more invasive standard of care interventions such as surgery. 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.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Single or oligometastatic. Small lesions Young patients with otherwise good response to other therapies Palliative patients in which surgery is no longer deemed safe.
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?	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.
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)	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.

		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. This procedure is performed in radiology departments which have existing image- guidance equipment. 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
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 be come part of training for future generations and reduce the upfront cost of training as a consultant.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:	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. Incidence of major complications is extremely low, supported by literature evidence.

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	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.
15	Please list the key efficacy outcomes for this procedure/technology?	Pain relief Patient satisfaction Cost benefits Hospital stays Reduced locoregional recurrence rates Improved morbidity rate and incidence, and mortality rates Improved patient mobility and activity levels. 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
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 procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	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 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. 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. 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. Please see attached comprehensive literature review I have performed
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)?	The incidence of spine metastasis is as high as 7 % of all patients presenting with metastatic disease according to cancer research uk. This translates to thousands of patients every year.

22	Are there any issues with the usability or practical aspects of the procedure/technology?	Training of staff and access to interventional IR suites for radiologists to perform the procedures.
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?	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.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Healthcare economics analysis.
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Pain relief Patient satisfaction Cost benefits Hospital stays Reduced locoregional recurrence rates Adverse outcome measures: Infection, bleeding, worsening of pain, instability of the spine at this level or adjacent levels. 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.

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
Non-financial professional	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:	**Dr Danoob Dalili**
Dated:	**01/09/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1953 Radiofrequency ablation as an adjunct to balloon kyphoplasty or percutaneous vertebroplasty for palliation of painful spinal metastases**

Your information

Name:	Richard Fawcett
Job title:	Consultant Musculoskeletal Radiologist
Organisation:	Leeds Teaching Hospitals, UK
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Royal College of radiologist, British Society of Skeletal Radiologists, European Society of Skeletal Radiologists, Medical Protection Society
Nominated/ratified by (if applicable):	NA
Registration number (e.g. GMC, NMC, HCPC)	6155492

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this	I have performed one radiofrequency ablation of a lumbar spine metastasis followed by vertebroplasty. I have performed a further radiofrequency ablation and osteoplasty for a pelvic bone metastasis. I have performed multiple (10 to 20) vertebroplasty/osteoplasties for metastatic infiltration of the spine and other bones. I am familiar with the procedure and technology as I regularly perform radiofrequency ablation for benign tumours such as osteoid osteoma. The procedure is fairly uncommonly used to my knowledge. I know of a handful of centres that perform this procedure, mainly teaching hospitals with a spinal surgery service on site. The procedure can be performed by radiologists or surgeons. The patient selection often comes from oncologists, haematologists (for myeloma) or spinal surgeons.

	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 had no involvement in 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):	This procedure is probably not the current standard of care in the UK with the majority of patients with vertebral metastases being treated with systemic therapies (chemotherapy) and radiotherapy for localised pain. Oral analgesia is also commonly used. Vertebroplasty alone for this without radiofrequency ablation is well established. As such I would describe this as a minor variation on an existing procedure. 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 would be used as an addition to existing standard of care. It is supplementary in that it can provide effective pain relief and local tumour control but would be in conjunction with established therapies such as chemotherapy or radiotherapy.

Current management

5	Please describe the current standard of care that is used in the NHS.	Radiotherapy, stereotactic radiotherapy. Pain management using oral analgesia. Possibly vertebroplasty without radiofrequency ablation in some centres.
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	No

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	The potential benefit is that it provides superior relief of pain to established therapies. The other huge potential benefit is for local tumour control. The reason why this is of importance is that patients with one or a few metastases could have this procedure performed to entirely kill the tumour and, if the primary tumour can be fully resected or treated, then the patient would effectively be cancer-free and this could significantly improve prognosis. There is a little in the way of evidence at this stage to support this scenario but it is potentially a very important alternative treatment arm for the future of cancer care.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	The main patient group is those with painful vertebral metastasis which significantly affects quality of life and who have not responded to established therapies.
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. Treating patients with vertebral fractures which are causing pain can mean that they are more mobile and less likely to get infections that could result in hospital admission. An improved prognosis from cancer has not yet been proven but thermal ablation in other parts of the body has been shown to be as effective in terms of clinical outcomes as previous established therapies and, as mentioned above, the increasing use of this procedure could very well result in the same being said for ablating bone lesions.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	I expect it would cost more than the current standard of care as rather than replacing current care it is likely to complement it.

11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	I expect it would cost more than the current standard of care as rather than replacing current care it is likely to complement it.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Very little is required in terms of additional clinical facilities. For example, in my trust we have interventional radiology theatres which are more than adequate to safely perform this procedure.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, clinicians needs to be adept in interventional radiology procedures for the skeletal system, including vertebroplasty.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	The main harm is that damage is done through excess heat to the spinal nerves. This could result in chronic pain or sensory disturbance in the lower limbs, weakness, paralysis. Anecdotally I have heard of a case of paralysis but this is not verified. Apparently during that case protective measures (the use of a thermocouple or thermometer device to monitor the temperature adjacent to the spinal nerves) was not used. Further adverse events include those that may come from the vertebroplasty which are very rare. These include nerve damage through cement extrusion, infection, bleeding, worsening pain.
15	Please list the key efficacy outcomes for this procedure/technology?	The outcomes are pain improvement, improved quality of life and survival rates.

16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The main issue with this procedure is where the radiofrequency ablation adds significant additional benefit compared to vertebroplasty/kyphoplasty alone. Limited evidence on this suggest that it does not significantly improve pain scores post procedure, however there is evidence to show that it reduces the rate of cement leakage, which can cause complications. There is also evidence to show that it improves local tumour control (i.e. the tumours are gone or are smaller than they were previously. There is, however, no current evidence to show that the overall prognosis improves but there is research lacking in this area due to the limited availability of the procedure.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The main area of controversy would be around monitoring the temperature around the spinal nerves during the radio frequency ablation procedure. Performing the procedure without doing this, to me, feels like an additional risk to damage the spinal nerves as the thermocouple provides a constant reading of the temperature next to the spinal nerves and ensures that it does not go high enough to cause damage.
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	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature	The Addition of Radiofrequency Tumor Ablation to Kyphoplasty May Reduce the Rate of Local Recurrence in Spinal Metastases Secondary to Breast Cancer. Ragheb A, et al. World Neurosurg. 2022.PMID: 35183797 Thermal-ablation of vertebral metastases prevents adverse events in patients with differentiated **thyroid** carcinoma. Barat M, et al. Eur J Radiol. 2019. PMID: 31525680

	searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Not that I know of

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)?	Very difficult to say. Maybe thousands
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Not that I know of
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?	Not that I know of
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Larger research studies looking at pain scores and safety of radiofrequency ablation plus vertebroplasty/kyphoplasty versus vertebroplasty/kyphoplasty ablation alone.
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term	Beneficial outcome measures: Pain scores, survival rates, mobility

	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:	Adverse outcome measures: Infection and bleeding rates, nerve damage, mortality
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,	

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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.			
Choose an item.			
Choose an item.			

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Print name:	**Richard Fawcett**
Dated:	**17/8/22**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1953 Radiofrequency ablation as an adjunct to balloon kyphoplasty or percutaneous vertebroplasty for palliation of painful spinal metastases

Your information

Name:	Dr Steven Morgan
Job title:	Consultant Radiologist
Organisation:	North Bristol NHS Trust
Email address:	[redacted]
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

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

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I have extensive experience using RF systems to treat spinal metastases. From 2017-21 inclusive, we have performed RFA and VP/BKP on 161 cancer patients.
	Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this	Current user, as above. This is slowly growing across the UK – we have perhaps 15 or so interested individuals express interest for training/courses/webinars. There needs to be at least one specialist regional centre across the regions of the UK. Spinal met RFA will be performed by Radiologists and Spine Surgeons. All patients are discussed at our weekly Complex Spine MDT. I/we receive referrals from many different clinicians/specialities.

	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 undertaken extensive bibliographic research in this field. We are currently bringing together our 4 year database for publication. Nothing yet published.
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):	RFA has been successfully used to treat painful bony metastases for 20 years. First published by Dupuy in 2001. It is usually combined with augmentation (VA): (vertebroplasty/kyphoplasty) 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. RFA helps to provide local tumour control, and delay/prevent pathological fracture/instability, and Metastatic Spinal Cord Compression (MSCC) and the awful squelae thereof. Augmentation alone in metastases may result in tumour seeding/extravasation. Additionally, there is some evidence to suggest that RFA reduces cement leak. RFA also has a synergistic effect with radiotherapy, both improving degree of, and reducing time to achieve pain relief. 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%). 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. RFA is additional to RT, can be synergistic, and helps to treat those refractive to RT, or in whom more RT is not possible.

		For reasons given, my opinion is (where possible) not to undertake VP/BKP in isolation in a likely verterbral tumour. There are of course cases (very common) of osteoporotic fractures in cancer patients, in whom it is reasonable to omit RFA.
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?	RFA will work alongside RT. RFA should be used in conjunction with VA in the treatment of painful vertebral metastases.

Current management

5	Please describe the current standard of care that is used in the NHS.	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). RFA is performed concurrent to biopsy – essential treatment planning i.e. receptor/marker status.
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 Microwave MRI guided Ultrasound These are other thermal ablative modalities. Each has pros/cons. RFA is the safest modality for spine work. I can discuss.

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?	Pain reduction, local tumour control (reduces risk of MSCC), reduce fracture risk (both tumour and secondary to RT), reduce opioid use. Generally improve quality of life and keep ambulant. Reduction in LOS for patients/need for admission.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	It is entirely appropriate to treat osteoporotic fractures with VP/BKP. Evidence shows a good reduction in LOS for acute inpatients. Tumour cases require ablation pre cmeneting procedures whenever possible. Patients with painful +/-fractured (or large lytic) spinal metastases/myeloma.
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?	In addition to a tumour pathway, we need to incorporate the GIRFT guidance for OP VCF esp in tumour patients and especially inpatients. We are currently planning with Oncologists locally to highlight patients earlier – esp given # rate in SBRT approaching 15%. This will hopefully: Reduce rates of MSCC. Reduce inpatient Length of Stay. Improve local tumour and pain control, prolonging quality of life. We are working on a local guideline/pathway.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Cases of osteoporotic fractures in cancer patients need access to a VP/BKP service to care for those with extreme pain and non-ambulatory. This has shown to reduce LOS which offsets the cost of the procedure. When considering tumoural fractures, in isolation, VP/BKP is cheaper then RFA+VP/BKP. Given the cohort of risks, the addition for a relatively small increment is hugely beneficial.

		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.
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)?	Implementation should be focussed on initially 10-20 centres across the UK, perhaps with a regional catchment (as we have in Bristol) It will require interventional team training and provision.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	There needs to be dedicated access to interventional rooms 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.
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

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	I consent for pain, bleeding, infection, thermal nerve injury and cement leak Post ablation flare of pain – 20-50% (I cover with 5 days of steroids, much like RT). Thermal Nerve Injury: Myself, nil so far. Cement leak: I quote a cancer patient 100%. I always perform CT immediately after the procedure, and can usually find a small paravertebral leak. 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) 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) Even given relatively low quality data, RFA has shown to be safe and effective. Given significant pain in this palliative population, is worthwhile.

15	Please list the key efficacy outcomes for this procedure/technology?	Pain reduction. Lowering fracture risk for Oncologists. Local tumour control.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Regarding VP/BKP in general – previous RCT evidence is mixed, in my view mainly due to patient selection. If we initially concentrate on inpatients with high pain scores, there is good evidence to support benefit. There is nothing more detrimental to a patient than lying in a hospital bed. Bed rest is very harmful.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Regional set up. Spoke/wheel. Perhaps 10-15 specialist centres.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Pleaser also consult eht GIRFT data re OP VCF. Opinder Sahota, Nottingham. Guidelines: NCCN Adult Cancer Pain 2020. Oncologist 2015. Myeloma 2019 Key Names: Matt Callstrom, Jack Jennings, Sean Tutton Goetz et al. J Clin Oncol. 2004 Jan 15; 22(2):300-6. Opus One: J Vasc Interv Radiol 2020; 31:1745–1752 Cazzato et al, Tech Vasc Int Rad 2020; 23:100677. Wallace et al, J Neurooncol 2015; 124: 111-118 Wallace et al, AJNR 2016; 37:759-65

		Gevargez EJR 2008; 65: 246-52. David et al Ann Pall Med 2017; 6(2): 118-24 Prezzano et al Am J Hosp & Pall Med 2019 May; 36(5): 417-422 Greenwood et al Pain Phys 2015; 18: 573-81 Lea/Tutton Semin Int Radiol 2017; 34: 121-31 Bagla et al Cardiovasc Int Rad 2016; 391289-97 Proschek et al Anticancer Res 2009; 29: 2787-92 Anchala et al Pain Phys 2014; 17: 317-327 Hillen et al Radiology 2014; 273 (1): 263-7 Cruz et al J Neurosurg Spine 2014; 21: 372-77
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)?	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	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Pain, QOL scores, local recurrence, MSCC rates, LOS reduction Reduction in fracture rates following SBRT Adverse outcome measures: No change in pain, complication rates as above.
26	Is there any other data (published or otherwise) that you would like to share with the committee?	I would be happy to discuss my cohort/data/experience with the committee.

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	Again, happy to discuss the technologies and pros/cons of different systems and differing ablative modalities.

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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
Direct - financial	OncoV Ltd. Consultancy/Proctoring	**1.3.20**	
Direct - financial	Stryker. Consultancy/Proctoring	**3.7.20**	
Choose an item.			

YES 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:	**11.8.22**