

## Professional Expert Questionnaire

Technology/Procedure name & indication:

### Your information

<b>Name:</b>	<input type="text" value="Jim Zhong"/>
<b>Job title:</b>	<input type="text" value="Clinical Research Fellow and Interventional Radiology Fellow"/>
<b>Organisation:</b>	<input type="text" value="University of Leeds/ Leeds Teaching Hospitals NHS Trust"/>
<b>Email address:</b>	<input type="text" value="[REDACTED]"/>
<b>Professional organisation or society membership/affiliation:</b>	<input type="text" value="British Society of Interventional Radiology (BSIR)"/>
<b>Nominated/ratified by (if applicable):</b>	<input type="text" value="BSIR"/>
<b>Registration number (e.g. GMC, NMC, HCPC)</b>	<input type="text" value="7329130"/>

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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

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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"> <li>- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?</li> <li>- Is this procedure/technology performed/used by clinicians in specialities other than your own?</li> <li>- If your specialty is involved in patient selection or referral to another specialty for this</li> </ul>	<p>Experience of image-guided ablative therapies (as an Interventional Radiology trainee) mainly for other tumour types such as liver, lung and kidney tumours. Out of the ablative technologies, including radio-frequency, microwave and cryoablation, IRE is one of the newest technologies with less data available particularly on long term outcomes. It has been used as a treatment also for local advanced pancreatic tumours. The early data suggests IRE is safe and may offer good short-term oncological outcomes with a lower risk of poor functional outcomes compared to other similar therapies.</p> <p>I am currently also doing a PhD and further research looking at personalising the treatment of prostate cancer. I am familiar with focal therapies (which includes IRE) from previous research studies I have been involved with.</p> <p>Traditionally, radical prostatectomy (RP) or radiotherapy (RT) (brachytherapy or external beam radiotherapy) were used to treat all men with localised prostate cancer regardless of their risk. Both RP and RT can still have significant risks of post-treatment side effects such as erectile dysfunction, urinary incontinence and gastrointestinal toxicity. With the advent of focal therapies, focusing treatment on a specific area of the prostate gland, the aim of these treatments are to achieve similar oncological outcomes compared to radical treatment while preserving functional outcomes and decreasing the rates of adverse effects effects.</p> <p>IRE is a novel ablative and non-thermal method.</p>
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	<p>procedure/technology, please indicate your experience with it.</p>	<p>IRE is currently being used in our institution (Leeds Teaching Hospitals NHS Trust). IRE is not widely used in the UK, because there are still many centres with a lack of interventional oncology infrastructure (the subspecialty of Interventional Radiology that delivers these image guided treatments). The speed of uptake is limited by few centres with the experience and capacity to train more IR doctors in this treatment method.</p> <p>IRE is mainly used by interventional radiologists. Surgeons may also use this technology with the assistance of IR but using this for laparoscopic and open surgical cases e.g. for pancreatic cancer.</p> <p>IR is involved in patients selection in all other areas of ablative treatment (as part of MDT).</p>
<p>2</p>	<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 published this research (on ablative technologies and also on prostate cancer therapies).</p> <p>Other (please comment):</p> <ol style="list-style-type: none"> <li>1. Wah TM, Zhong J, Wilson M, Vasudev NS, Banks RE. An Exploratory Analysis of Changes in Circulating Plasma Protein Profiles Following Image-Guided Ablation of Renal Tumours Provides Evidence for Effects on Multiple Biological Processes. <i>Cancers (Basel)</i>. 2021 Nov 30;13(23):6037. doi: 10.3390/cancers13236037. PMID: 34885149</li> <li>2. Zhong J, Slevin F, Scarsbrook AF, Serra M, Choudhury A, Hoskin PJ, Brown S, Henry AM. Salvage Reirradiation Options for Locally Recurrent Prostate Cancer: A Systematic Review. <i>Front Oncol</i>. 2021 Sep 9;11:681448. doi: 10.3389/fonc.2021.681448. PMID: 34568012</li> <li>3. Zhong J, Palkhi E, Ng H, Wang K, Milton R, Chaudhuri N, Lenton J, Smith J, Bhartia B, Wah TM. Long-Term Outcomes in Percutaneous Radiofrequency Ablation for Histologically Proven Colorectal Lung Metastasis. <i>Cardiovasc Intervent Radiol</i>. 2020 Dec;43(12):1900-1907. doi: 10.1007/s00270-020-02623-1. Epub 2020 Aug 18. PMID: 32812121</li> <li>4. Zhong J and Wah TM. Renal ablation: current management strategies and controversies. <i>Chinese Clinical Oncology</i>. Dec 2019. 8(6):63. PMID: 31968983.</li> <li>5. Zhong J, Bambrook J, Bhambra B, Smith J, Cartledge J, Ralph C, Vasudev N, Whiteley S, Wah T. Incidence of Post-Ablation Syndrome Following Image-Guided Percutaneous Cryoablation of Renal Cell Carcinoma: A Prospective Study. <i>Cardiovascular and Interventional Radiology</i>. February 2018; 41(2): 270–276. PMID: 29185017.</li> <li>6. Zhong J, Atiiga P, Alcorn DJ, Kay D, Illing R, Breen DJ, Railton N, McCafferty IJ, Haslam PJ, Wah TM. Cross-sectional Study of the Provision of Interventional Oncology Services in the United Kingdom. <i>British Medical Journal (Open)</i>. October 2017. 22;7(10):e016631. PMID: 29061610.</li> </ol>

<p><b>3</b></p>	<p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p>	<p>Definitely novel and of uncertain safety and efficacy.</p>
<p><b>4</b></p>	<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>Many focal therapy options available for prostate cancer (brachytherapy, cryotherapy, high intensity focused ultrasound called HIFU, transurethral localized sonographic ablation (TULSA) and photodynamic therapy), unclear about long-term outcomes and side-effect profile of many of these treatments therefore need to identify which patients are best to use this technology. IRE may be best at treating tumours which are locally advanced as due to the theory of the mechanism of action, there should be less damage to surrounding structures to the ablated zone. This may mean it fits into the treatment paradigm alongside other focal therapies (including radiotherapy) rather than replace all other treatments. Patient selection will be key.</p>

### Current management

<p><b>5</b></p>	<p>Please describe the current standard of care that is used in the NHS.</p>	<p>Radical prostatectomy (RP) or radiotherapy (RT) brachytherapy or external beam radiotherapy)</p>
<p><b>6</b></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>Not the same technology as IRE but other focal therapies for prostate lesions are available such as brachytherapy, cryotherapy, high intensity focused ultrasound called HIFU, transurethral localized sonographic ablation (TULSA) and photodynamic therapy.</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?	As IRE is non-thermal ablation, theoretically there should be less risk of heat injury to surrounding organs such as bladder or rectum. This means locally advanced tumours close to these structures could still be treated with this technology (Rationale for using it for locally advanced pancreatic tumours). Other focal therapies are currently mainly used for lower-risk, localised types of prostate cancer.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Potentially locally advanced tumours and also patients with small lesions amenable to focal therapy.
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?	Focal therapies has the potential (if shown to have equivocal long term outcomes to radical prostatectomy) to reduce in a much less invasive treatment which would cause less side effects, shortened recovery and reduced hospital visits. A competitor that remains is external beam radiotherapy as technology improves to enhance delivery accuracy but currently there is still a risk of radiation toxicity to surrounding organs (bladder and rectum) which potentially focal therapies can mitigate as it is more accurately targeted with probe placement, patient movement less of an issue as procedure usually done under an anaesthetic and various methods such as hydrodissection can be used to move surrounding structures like rectum further away from the ablated area. IRE also allows for normal tissue to be preserved in theory.
<b>10 - MTEP</b>	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)	Unclear about net cost.  Upfront costs – equipment, training and cost of radiology room/ scanner time (if done under MRI).  Cost savings – reduced hospital stay, reduced hospital visit.
<b>11 - MTEP</b>	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)?	Cost greater than external beam radiotherapy but may be cheaper than surgical options due to reduced hospital stay as more minimally invasive. Staffing costs for intra-operative situation likely similar – both require theatre or equivalent space, similar anaesthetic and nursing support.

12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Need a space with imaging capabilities such as CT or MRI to do this procedure if done by IR. Need capacity within the department to offer the procedure.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, IRE is not widely adopted in the UK amongst IR practitioners. Will need training to understand the set up for IRE and how to place IRE probes.

### 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>Adverse outcome measures:</p> <p>Early adverse effects (within 3 months) include mild haematuria (6-24%), dysuria, urinary tract infections, pain, urgency, and temporary incontinence.</p> <p>Long term adverse events are urethral stricture requiring further procedure/ surgery (rare, 2-5%), urinary incontinence (rare) and disease recurrence (risk of any focal therapy, no higher with IRE)</p> <p><b>References:</b></p> <ol style="list-style-type: none"> <li>Ong, S.; Leonardo, M.; Chengodu, T.; Bagguley, D.; Lawrentschuk, N. Irreversible Electroporation for Prostate Cancer. <i>Life</i> 2021, 11, 490. <a href="https://doi.org/10.3390/life11060490">https://doi.org/10.3390/life11060490</a></li> </ol>
15	Please list the key efficacy outcomes for this procedure/technology?	<ol style="list-style-type: none"> <li>Oncological outcomes: Overall survival/ Recurrence free survival (biochemical free survival)/ Metastasis free survival</li> <li>Functional outcomes e.g. Prostate Quality of Life Survey, IPSS, EPIC-26 and EORTC QLQ-C30 questionnaires</li> <li>Long term risk profile is also important e.g. risk of urethral strictures, gut injury etc</li> </ol>
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	<p>Contraindications for IRE ablation include:</p> <ul style="list-style-type: none"> <li>Ablation of lesions in the thoracic area in the presence of implanted cardiac pacemakers or defibrillators</li> <li>Ablation of lesions in the vicinity of implanted electronic devices or implanted devices with metal parts</li> </ul>

		<ul style="list-style-type: none"> <li>• Ablation of lesions of the eye, including the eyelids</li> <li>• Recent history of epilepsy or cardiac arrhythmia</li> <li>• Recent history of myocardial infarction</li> </ul> <p>Reference:</p> <p>Angiodynamics [Internet].c 2010: The first surgical ablation system based on Irreversible Electroporation Technology. Available from: <a href="http://www.erickortzmd.com/wp-content/uploads/2011/04/NanoKnife.pdf">http://www.erickortzmd.com/wp-content/uploads/2011/04/NanoKnife.pdf</a>.</p>
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Unclear about long term oncological outcomes (limited data)
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>	<ol style="list-style-type: none"> <li>1. Ong, S.; Leonardo, M.; Chengodu, T.; Bagguley, D.; Lawrentschuk, N. Irreversible Electroporation for Prostate Cancer. <i>Life</i> 2021, 11, 490. <a href="https://doi.org/10.3390/life11060490">https://doi.org/10.3390/life11060490</a></li> <li>2. Ramsay CR, Adewuyi TE, Gray J, Hislop J, Shirley MD, Jayakody S, MacLennan G, Fraser C, MacLennan S, Brazzelli M, N'Dow J, Pickard R, Robertson C, Rothnie K, Rushton SP, Vale L, Lam TB. Ablative therapy for people with localised prostate cancer: a systematic review and economic evaluation. <i>Health Technol Assess</i>. 2015 Jul;19(49):1-490. doi: 10.3310/hta19490. PMID: 26140518; PMCID: PMC4781236.</li> </ol>
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<p><b>20</b></p>	<p>Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.</p>	<p>The Clinical Research Office of the Endourological Society (CROES ClinicalTrials.gov identifier: NCT02255890)</p> <p>IRE vs radical prostatectomy (ClinicalTrials.gov identifier: NCT04278261).</p> <p>Australasian IRE database: Blazevski, A.; Scheltema, M.J.; Amin, A.; Thompson, J.E.; Lawrentschuk, N.; Stricker, P.D. Irreversible electroporation (IRE): A narrative review of the development of IRE from the laboratory to a prostate cancer treatment. BJU Int. 2019, 125, 369–378</p> <p>Irreversible Electroporation Versus Standard Medication for Benign Prostatic Obstruction: NCT03448510</p> <p>Non-prostate studies: PANFIRE Study: Irreversible Electroporation (IRE) to Treat Locally Advanced Pancreatic Carcinoma (PANFIRE) (ClinicalTrials.gov Identifier: NCT01939665)</p>
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**Other considerations**

<p><b>21</b></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>30-50 patients for a tertiary oncology centre (eligible for focal therapy)</p> <p>Based on this study: Nassiri N, Chang E, Lieu P, Priester AM, Margolis DJA, Huang J, Reiter RE, Dorey FJ, Marks LS, Natarajan S. Focal Therapy Eligibility Determined by Magnetic Resonance Imaging/Ultrasound Fusion Biopsy. J Urol. 2018 Feb;199(2):453-458. doi: 10.1016/j.juro.2017.08.085.</p>
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22	Are there any issues with the usability or practical aspects of the procedure/technology?	Learning curve with skillset – how and where to place IRE probes. As these cases are usually done under general anaesthetic, also need experience from anaesthetic team so they are away of procedural risks.
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?	Capacity with Interventional Radiology departments/ Skillsets available locally in ablative therapies. Availability of MRI scanners an PET-CT scanners to accurately stage these patients.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Registry of all IRE treated prostates and also a prospective RCT to compare IRE with other focal therapies including brachytherapy and external beam radiotherapy.
25	<p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> <li>- 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.</li> <li>- Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:</li> </ul>	<p>Beneficial outcome measures:</p> <p>Short terms outcomes should be side effect profile of treatment and include quality of life measures. These tools should also assess symptoms of urinary and gastrointestinal toxicity (e.g. using the IPSS, EPIC-26 and EORTC QLQ-C30 questionnaires).</p> <p>Long term risk profile is also important e.g. risk of urethral strictures, gut injury etc</p> <p>Overall survival/ Recurrence free survival (biochemical free survival)/ Metastasis free survival</p> <p>Adverse outcome measures:</p> <p>Early adverse effects include mild haematuria, dysuria, urinary tract infections, pain, urgency, and temporary incontinence.</p> <p>Long term adverse events are urethral stricture requiring further procedure/ surgery and disease recurrence (risk of any focal therapy, no higher with IRE)</p>

## Further comments

**26**

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

### 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.**

<b>Print name:</b>	<input type="text" value="Jim Zhong"/>
<b>Dated:</b>	<input type="text" value="16/06/2022"/>

## Professional Expert Questionnaire

Technology/Procedure name & indication:

### Your information

<b>Name:</b>	<input type="text" value="Mark Emberton"/>
<b>Job title:</b>	<input type="text" value="Dean UCL Faculty of Medical Sciences"/>
<b>Organisation:</b>	<input type="text" value="UCL and UCLH NHS Trust"/>
<b>Email address:</b>	<input type="text" value="[REDACTED]"/>
<b>Professional organisation or society membership/affiliation:</b>	<input type="text" value="Royal College of Surgeons; British Association of urological Surgeons; American Urological Association; American Association of Genito-Urinary Surgeons"/>
<b>Nominated/ratified by (if applicable):</b>	<input type="text" value="Click here to enter text."/>
<b>Registration number (e.g. GMC, NMC, HCPC)</b>	<input type="text" value="3098619"/>

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

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

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

**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"><li>- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?</li><li>- Is this procedure/technology performed/used by clinicians in specialities other than your own?</li><li>- If your specialty is involved in patient selection or referral to another specialty for this</li></ul>	<p>I have been using it since 2010 and treated over 300 patients and published early pahse studies on the procedure</p> <p>Only NHS site is UCLH</p> <p>Yes it is used by interventional radiology</p> <p>Yes I see patients who ask for this proceedure</p>
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	procedure/technology, please indicate your experience with it.	
2	<p>– Please indicate your research experience relating to this procedure (please choose one or more if relevant):</p>	<p>I have done bibliographic research on this procedure.</p> <p>I have done research on this procedure in laboratory settings (e.g. device-related research).</p> <p>I have done clinical research on this procedure involving patients or healthy volunteers.</p> <p><b>I have published this research.</b></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><b>Established practice and no longer new.</b></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?	Neither – it is merely one of many techniques for achieving the focal ablation of a cancer

## Current management

5	Please describe the current standard of care that is used in the NHS.	In the selective ablation of cancers using interventional oncology techniques
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 which kills cells by cooling to -40degrees centigrade. IRE kills cells by exposing cells to high voltage current which forces the cells into apoptosis

## 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?	It is quick, reliable, easy to learn, easy to quality control, and has a low carbon footprint (unlike cryotherapy)
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	In my area patients with uni-focal localised prostate cancer
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.  Yes, Yes, and Yes.
<b>10 - MTEP</b>	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)	Less cost, less theatre time, less stay in hospital.
<b>11 - MTEP</b>	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)?	Net reduction in resource utilisation
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None



<b>13</b>	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Very little for someone with the skills of putting needles into the prostate
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### Safety and efficacy of the procedure/technology

<b>14</b>	<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>Minimal – but as will all prostate cancer treatments - damage to surrounding structures.</p> <p>This procedure is exceedingly well tolerated.</p> <p>Very few compared to the high toxicity levels associated with standard of care treatments</p> <p>Some have reported rectal injury. I have no experience of this.</p>
<b>15</b>	Please list the key efficacy outcomes for this procedure/technology?	The benefit is treating the cancer with 85% freedom from progression at 5-years with 1% risk of incontinence (compared to 20% for surgery) and 5% risk of erectile dysfunction (compared to 80% for surgery)
<b>16</b>	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	I have none as I have been doing it for over a decade and should have seen any untoward effects by now.
<b>17</b>	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not that I am aware
<b>18</b>	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	<p>Most or all district general hospitals.</p> <p>A minority of hospitals, but at least 10 in the UK.</p> <p><b>Fewer than 10 specialist centres in the UK.</b></p>

		Cannot predict at present.
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### Abstracts and ongoing studies

<b>19</b>	<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>	All in the public domain
<b>20</b>	<p>Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.</p>	There was a registry, but this ran out of funds. We are starting a new registry that will be run out of UCLH and will aim to be the world wide registry

### Other considerations

<b>21</b>	<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>	20% of the men diagnosed with clinically significant cancer each year.
<b>22</b>	<p>Are there any issues with the usability or practical aspects of the procedure/technology?</p>	None

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?	None
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Other than registries, no.
25	<p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> <li>- 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.</li> <li>- Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:</li> </ul>	<p>Beneficial outcome measures:</p> <p>Resource use.</p> <p>Time that men are from symptoms and toxicity Q-TWIST</p> <p>Adverse outcome measures:</p> <p>Need for re-treatment</p>

### Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	This is just one small part of the focal therapy paradigm which dominates all of surgical oncology. Too much focus is placed on the energy source and not enough on the system of care that has as its aim the preservation of health tissue and, as a consequence, quality of life.
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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>	I have received reimbursement for travel and for training and lecturing from Angiodynamics	2010	To date
<i>Non-financial professional</i>	I have undertaken investigator led research sponsored by angiodynamics	2010	To date
<i>Direct - financial</i>	I have been treating patients who want and are eligible for this procedure on a private basis and therefore receive numeration at staddard insurance rates	2010	To date

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:	<input type="text" value="Mark Emberton"/>
Dated:	<input type="text" value="08 April 2022"/>