NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1938 Alcohol-mediated perivascular renal denervation for resistant hypertension

Your information

Name:	Anthony Mathur
Job title:	Consultant Cardiologist
Organisation:	Barts Heart Centre
Email address:	[redacted]
Professional organisation or society membership/affiliation:	FESC, FRCP
Nominated/ratified by (if applicable):	n/a
Registration number (e.g. GMC, NMC, HCPC)	GMC 3484775

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

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 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consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I am familiar having performed just under 20 of these procedures.
	Have you used it or are you currently using it?	I am currently using Ablative Solution's system as part of an ongoing clinical trial.
	− Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	This procedure is not routinely used in the NHS, and will still need to go through commissioning if the trial data is favourable. It is unlikely to have a quick uptake as it requires cathlab resources which are currently stretched, and a complex assessment pathway.
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	Yes, interventional radiologists use this procedure.

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	My specialty is only involved in the delivery of treatment, not patient selection.
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done clinical research on this procedure involving patients or healthy volunteers.
3	Does the title adequately reflect the procedure?	Yes
	Is the proposed indication appropriate? If not, please explain.	Yes, the current indication is resistant hypertension
	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?	The current standard of care is pharmacological, this is therefore an innovation as it involves ablation of the renal autonomic nervous system using alcohol. Other systems exist that ablate the nerves using either radiofrequency ablation or temperature.
	Which of the following best describes the procedure (please choose one):	Definitely novel and of uncertain 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?	It is an addition to be used in patients who are resistant to the current standard of care.
5	Have there been any substantial modifications to the procedure technique or,	There have been no modifications to this alcohol-derived method of providing renal denervation. There is growing literature supporting the use of radiofrequency ablation that has led to clinically

	if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	significant reductions in blood pressure; however, this data is not transferrable to the alcohol-mediated approach. No

Current management

6	Please describe the current standard of care that is used in the NHS.	Diet, lifestyle and pharmacological management
7	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?	Yes, there are other methods of delivering autonomic modulation including radiofrequency, cryo-ablation, and direct autonomic stimulation. These are all currently undergoing research in clinical trials. The objective is the same (i.e. autonomic modulation); however, it is delivered through different methods (as described above).

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Control of blood pressure when pharmacological therapy has failed
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients in whom existing pharmacotherapy is either ineffective or is difficult to administer (i.e. compliance)
10	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, 10% of patients with high blood pressure remain resistant. This therefore constitutes an important number of people who could benefit from this treatment. The benefit of a reduction in blood pressure would lead to improved outcomes with fewer hospital visits, a reduction in drug expenditure and an improvement in outcome in other related conditions such as diabetes, ischaemic heart disease and cerebrovascular disease.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Dedicated hypertension clinics are needed to ensure adequate assessment and patient referral. The procedure is carried out in existing cardiac cathlabs, and therefore capacity would need to be identified.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, the procedure requires a small amount of additional training for an experienced interventional cardiologist/radiologist.

Safety and efficacy of the procedure/technology

13	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:	The procedure uses an invasive technique that requires vascular access followed by the insertion of a specialised catheter into the renal artery to deliver the alcohol ablation. The complications that result are either due to vascular access (bruising), haemorrhage and aneurysm formation (less than 0.5%), or due to trauma to the renal artery as a result of insertion of needles and alcohol injection. This can lead to small aneurysm formation as well as contain perivascular leaks. The incidence of this leading to a serious clinical complication is <0.5%.

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	In the initial study, 2/45 patients had major adverse events of periprocedural access-site pseudoaneurysms, with major bleeding in one. There were no deaths or instances of myocardial infarction, stroke, transient ischemic attack, or renal artery stenosis. Transient microleaks were noted in 42% and 49% of the left and right main renal arteries, respectively. There were 2 cases of minor vessel dissection that resolved without treatment. (doi: 10.1016/j.jcin.2019.10.048).
14	Please list the key efficacy outcomes for this procedure/technology?	Significant reduction in blood pressure leading to decreased use of anti-hypertensive medication (by 23% at 6 months).
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The main concern relating to this procedure is in the context of 'failure of medical therapy' which is often due to compliance issues for which there are other means to correct/rectify.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Yes, the results of the clinical trial are awaited.
17	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

18	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	None known

	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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Target BP (ongoing)
20	Please list any other data (published and/or unpublished) that you would like to share.	N/A

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 target population is ~10% of those with hypertension (14 million), although it is unlikely that 1.4 million would be eligible for this treatment.
22	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	Beneficial outcome measures: (1) Increased time within target BP range as measured by ambulatory BP monitoring (4-6 weeks post procedure). (2) Decrease in anti-hypertensive medication use whilst fulfilling (1) (6 months – 1 year post-procedure). (3) Decreased hospital admissions and clinic appointments due to either uncontrolled hypertension or associated comorbidities (6 weeks – 1 year post procedure). (4) Decreased mortality compared to current standard of care (5 years post procedure). Adverse outcome measures: (1) Any procedural complication leading to prolongation of hospital stay and/or disability to patient (within 1 week of the procedure).

	procedure timescales over which these should be measured:	(2) Long term consequences of alcohol delivery to the renal artery (e.g. renal artery stenosis) (6 months – 1 year post-procedure).

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	One advantage of this method of delivering renal denervation is that it is a relatively quick procedure causing minimal discomfort to the patient and does not require substantial additional training for an interventional cardiologist/radiologist.

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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	I receive reimbursement for alcohol ablation procedures from Ablative Solutions as part of their clinical trial.	**2020**	**2023**
Direct - financial	I receive reimbursement for radio frequency ablation procedures from Recor Medical as part of their clinical trial.	**2020**	**2023**
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:	**Anthony Mathur**
Dated:	**24.05.23**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1938 Alcohol-mediated perivascular renal denervation for resistant hypertension

Your information

Name:	Click here to enter text. Christian Delles
Job title:	Click here to enter text. Professor of Cardiovascular Prevention; Head of School; Hon. Consultant Physician
Organisation:	Click here to enter text. School of Cardiovascular and Metabolic Health, University of Glasgow
Email address:	Click here to enter text. [redacted]
Professional organisation or society membership/affiliation:	Click here to enter text. Scottish Cardiovascular Forum; SHARP; Scottish Society of Physicians; British and Irish Hypertension Society; Association of Physicians (Treasurer); European Hypertension Society (Council member); European Council on Cardiovascular research (Treasurer); International Hypertension Society
Nominated/ratified by (if applicable):	Click here to enter text. British Cardiovascular Society
Registration number (e.g. GMC, NMC, HCPC)	Click here to enter text. GMC 6076989

How NICE will use this information:

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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 public

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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.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I have been involved in renal denervation (RDN) right from the beginning through a local trial with the original Symplicity catheter. I have been speaking on RDN at a few meetings and have recently conducted a study into genetic predictors of response to RDN. I think I know the field pretty well but have no direct links to trials or any association with a relevant industry partner.
	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?	We do not use RDN routinely in my institution. Across the UK it can be used in selected cases according to NICE IPG754. There has been a previous moratorium (https://heart.bmj.com/content/105/19/1456). I am looking at registry data and individual cases that undergo the procedure as part of trials or registry work. All of these refer to the ReCor and Medtronic devices. I have never worked with the alcohol-injection technology that is under discussion here but I have of course seen data at conferences and other occasion. I do not think there is currently an indication beyond resistant hypertension.

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. No – I have not systematically explored the literature. I have done research on this procedure in laboratory settings (e.g. device-related research). No. I have done clinical research on this procedure involving patients or healthy volunteers. Yes, but not on this specific technique but RDN in general. I have published this research. I am one of the authors of the 2023 ESH guidelines and have as such reviewed the available data. I have a paper under submission but this is on the Medtronic device (different technology). I have had no involvement in research on this procedure. Other (please comment)
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?	Yes. Yes. Established practice and no longer new. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. It is a variation of a general principle to conduct renal denervation. Safety is promising (PMID 37427416) but efficacy is less impressive (PMID 37427416) although longer-term data point towards efficacy as well (https://www.ahajournals.org/doi/10.1161/CIRCINTERVENTIONS.120.010075).

	Which of the following best describes the procedure (please choose one):	Definitely novel and of uncertain safety and efficacy. The first in a new class of procedure.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	No. It is an additional treatment in resistant hypertension if blood pressure control cannot be achieved with lifestyle and pharmacological measures. There may be a role in earlier stages or instead of pharmacotherapy in the distant future but so far all RDN techniques are only recommended for resistant hypertension in addition to other measures.
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	Not that I am aware of.

Current management

6	Please describe the current standard of care that is used in the NHS.	According to NICE CG127, staged approach from lifestyle measures to pharmacotherapy. Specific interventions for specific causes of secondary forms of hypertension. Currently RDN is only considered in some cases (NICE IPG754). The latter refers to other techniques. The alcohol-mediated technique has the same principle (renal denervation) but uses a different approach compared to radiofrequency (Medtronic) and ultrasound (ReCor).

7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Radiofrequency and ultrasound-based methods. These apply radiofrequency or ultrasound and do not inject e.g. alcohol into the renal arteries. They are, however, also catheter based. For patients it will be a very similar experience.

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	It could have the potential to reduce blood pressure in patients who are resistant to other approaches. It could also reduce the pill burden. In the longer term, in line with patient choice, the technology could also be used in less severe forms of hypertension but current data do not support this.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Probably those at highest risk of hypertension-mediated organ damage or with already established organ damage whose blood pressure cannot be controlled with existing measures. As outlined in IPG754, any decision about RDN (and this also applies to the new technology here) should be made by MDTs together with patient preferences.
10	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?	The current pathway applies to the vast majority of patients with hypertension and resistant hypertension. For some patients the new technology in particular and RDN in general could provide benefits. This is also the recommendation of the ESH Hypertension Guideline (2023). Indeed, better blood pressure control will lead to better outcomes and fewer visits to especially secondary care clinics where these patients are often seen.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Interventional radiology but nothing too fancy. For departments that can for example do renal artery angioplasty the procedure should be quite straightforward.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, training in the specific use of the catheter is required. It is suggested that only a small number of interventionalists conduct the procedure to ensure best possible discussions in MDTs prior to the procedure and consistent approaches during intervention – especially as only a relatively small number of patients will undergo the procedure.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology?	Angiography related complications such as haemorrhage, rupture of arteries, cholesterol emboli etc. Specific complications such as renal artery thrombosis and renal artery stenosis, loss of a kidney etc. are theoretically possible. There is no signal in this direction from current

	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	clinical trials yet but clearly these would be underpowered to detect side effects and are powered towards efficacy. Adverse effects so far relate to pain but to the best of my knowledge no more serious adverse effects have been reported so far. RDN in general, and this applies to the two currently used techniques (radiofrequency and ultrasound) appears to be safe and not associated with major complications. See above.
14	Please list the key efficacy outcomes for this procedure/technology?	Blood pressure difference pre/post procedure. Or: target blood pressure achieved. Or: reduction in pill burden (especially if they come with side effects) at similar BP control.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	There are currently advances in pharmacotherapy (new MR antagonists, siRNA-based therapies against angiotensinogen, dual endothelin receptor antagonists) specifically for hypertension and other new pharmacological approaches (SGLT2i, GLP-1 agonists) that also have a blood pressure-lowering effect. Given these recent advances the role of RDN in any future algorithm is less clear but it will certainly play a role as one tool among many.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	It needs its own nice in the spectrum of RDN to explain which patients will be best suited for which RDN procedure.
17	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. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK. Cannot predict at present.

Abstracts and ongoing studies

18	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.	Nothing that I am aware of at this time. You may want to screen abstracts submitted for the ESH conference in Berlin, May/June 2024 though.
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	I guess these are listed in relevant registries. I have no insights into any not registered trials.
20	Please list any other data (published and/or unpublished) that you would like to share.	n/a

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 definition of resistant hypertension is evolving. Many patients will have intolerances or limited adherence to therapy as one of the reasons for (pseudo)resistance. Formally about 10% of patients with hypertension have resistant hypertension. Of these some will qualify for RDN but the “some” depends on to-be-established pathways and the “some” will be shared between different RDN technologies. Not easy to predict I am afraid.
22	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	Beneficial outcome measures: Blood pressure lowering effect. Pill burden. QoL.

	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: Bloor pressure increase or no effect. Adverse effects of the procedure, e.g. haematoma, haemorrhage, pain, renal artery stenosis, embolism/thrombosis.

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	Whilst there are data on efficacy and safety the whole area of RDN is currently only relevant to a smaller number of patients with resistant hypertension. In the longer term this may change. A registry of patients undergoing the treatment (and maybe even more importantly, a registry of those who were considered for it but didn't make it because of e.g. variants in renal arterial anatomy) would be crucial.

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial professional	I am member of guideline committees namely the ESH guideline committee	**2021**	**ongoing**
Direct - financial	I think I may get some speaker honorarium for moderating a workshop sponsored by an RDN device manufacturer (ReCor) at ESH 2024 in Berlin but no contracts have been set up yet. It is a symposium approved by the ESH and is mainly an expert panel discussion without biased recommendations. I have not received any payment for any RDN-related work so far and have in fact done very little in this field other than having it on my agenda.	**2024**	**2024**
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:	**Click here to enter text. Christian Delles**
Dated:	**Click here to enter text. 2 May 2024**

View results

Respondent

76 Anonymous

68:43
Time to complete

1. Project Number and Name - (Can be found on email) *

Alcohol-mediated perivascular renal denervation for resistant hypertension (IP1938)

Your information

2. Name: *

Indranil Dasgupta

3. Job title: *

Consultant nephrologist

4. Organisation: *

University Hospitals Birmingham NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

UK Kidney Association

7. Nominated/ratified by (if applicable):

Nominated

8. Registration number (e.g. GMC, NMC, HCPC) *

4177773

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, which have been communicated by Zoe Jones.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

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 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: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

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

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

Yes

12. 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.

As far as I know it is not used in the NHS outside research studies

13. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [x] I have done research in renal denervation using technology other than alcohol-mediated deneravation other than alcohol

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes

16. Does this have a multi-indication?

Potentially there are indications in the field of hypertension, e.g. multiple antihypertensive intolerance, patients reluctant to take long-term medication.

17. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

It is variation in renal denervation using a different technology. Percutaneous transluminal renal denervation using radiofrequency or ultrasound technology for treatment of resistant hypertension was approved by NICE in March 2023 (IPG754)

18. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- (●) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ( ) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

19. 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 technology is unlikely to replace the radiofrequency or ultrasound renal denervation. This is because the recently published primary results of TARGET BP I trial, a sham controlled trial of this technology, demonstrated a very modest improvement in BP control in people with uncontrolled hypertension on 2-5 antihypertensive agents (https://doi.org/10.1161/CIRCULATIONAHA.124.069291). In comparison, pivotal trials of the other two technologies demonstrated more impressive BP reduction.

20. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

Not to my knowledge

21. Do you think guidance would be helpful on this topic?

- ○ Yes
- ◉ No

Current management

22. Please describe the current standard of care that is used in the NHS.

Resistant hypertension is currently treated with multiple antihypertensive medications or renal denervation using radiofrequency or ultrasound waves in centres where the technology and expertise are available within the NICE recommendations.

23. 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?

Percutaneous transluminal renal denervation using radiofrequency or ultrasound technology as already described (see NICE RPG754)

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

Controlling BP in people with treatment resistant hypertension or multiple antihypertensive drug intolerance. However, as already stated, the recent pivotal trial of this technology have demonstrated very modest benefit.

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Treatment resistant hypertension, multiple antihypertensive drug intolerance, reluctance to take long-term medication

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

    No based on current evidence

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

    Interventional radiology suite, expertise in carrying out renal artery interventions under fluoroscopy

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

    Training in using the technology which shouldn't be difficult for an experiences interventional radiologist

Safety and efficacy of the procedure/technology

29. 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

    Accessory renal artery dissection reported in one case in the TARGET BP I trial and in two cases in a previous trial (Mahfoud et al JACC Cardiovascular Intervention 2020). The latter trial also reported transient microleaks of alcohol in around 45%.

30. Please list the key efficacy outcomes for this procedure/technology?

    Reduction in systolic BP of around 6 mmHg

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

    As already stated, the primary results of the pivotal trial (TARGET BP I) using this technology demonstrated a very modest BP lowering effect (-3.2 mmHg difference between the arms) at 3 months in people with uncontrolled hypertension on 2-5 antihypertensive medications. A previous sham-controlled trial of this technology in less severe hypertension (those on 0-2 agents) showed no significant benefit at 8 weeks (between group difference -1.5 mmHg) but similar BP lowering between the intervention and sham-controlled arms at 12 months although medication burden was lower in the intervention group (TARGET BP, Pathak A, et al Eurointervention 2023). These findings raise concerns about efficacy, but the procedure was safe in both of these trial and previous studies.

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

    Efficacy

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) Most or all district general hospitals.
- ( ) A minority of hospitals, but at least 10 in the UK.
- ( ) Fewer than 10 specialist centres in the UK.
- (•) Cannot predict at present.

Abstracts and ongoing studies

34. 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.

BP Target I Trial: https://doi.org/10.1161/CIRCULATIONAHA.124.069291
BP Target Trial: doi: 10.4244/EIJ-D-23-00088.
Mahfoud et al: https://doi.org/10.1016/j.jcin.2019.10.048

35. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

Not to my knowledge

36. Please list any other data (published and/or unpublished) that you would like to share.

None

Other considerations

37. 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)?

Not applicable as the efficacy of this procedure has not been established yet

38. 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.

BP controlled to target
SBP lowering by at least 6 mmHg
Reduction in pill burden

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Renal artery dissection peri-procedurein/ short term and renal artery stenosis in the long-term

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

None

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.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

NA

43. 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. *

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Indranil Dasgupta

45. Date: *

02/05/2024

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1938 Alcohol-mediated perivascular renal denervation for resistant hypertension

Your information

Name:	Luca Faconti
Job title:	Consultant (Honorary(in Hypertension at Guy's and ST Thomas' NHS Foundation Trust and Clinical Lecturer at King's College London
Organisation:	King's College London
Email address:	[redacted]
Professional organisation or society membership/affiliation:	British and Irish Hypertension Society
Nominated/ratified by (if applicable):	Professor Ian Wilkinson
Registration number (e.g. GMC, NMC, HCPC)	GMC number 7503498

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☒ Please tick this box if you would like to receive information about other NICE topics.

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 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.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	As part of my job as hypertension consultant, I treat patients with resistant hypertension for which interventional procedures including renal denervation can be considered. Currently the procedure is not performed in my Trust.
	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?	I'm not currently using it

	− 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.	The procedure is indicated for the treatment of resistant hypertension As part the management of resistant hypertension, I can select and refer patients to interventional procedures including renal denervation. Currently in my Trust alcohol-mediated perivascular renal denervation is not used.
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on renal denervation and I co-authored a statement from the BIHS Statement on Renal Denervation (RDN) following publication of the NICE Interventional Procedures Guidance IPG754: Percutaneous transluminal renal sympathetic denervation for resistant hypertension. 1st March 2023.
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. 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):	Yes Yes Chemical renal denervation has been investigated over the last few years as an alternative to catheter-based renal denervation. Interventional trials have already explored its effect on blood pressure Established practice and no longer new.

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?	Addition
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	Not aware of No

Current management

6	Please describe the current standard of care that is used in the NHS.	Currently percutaneous transluminal renal sympathetic denervation for resistant hypertension should only be used with special arrangements for clinical governance, consent, and audit or research
7	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?	transluminal renal sympathetic denervation which used different modalities to destroy the nerves in the renal arteries

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	
10	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?	
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	

Safety and efficacy of the procedure/technology

13	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	
14	Please list the key efficacy outcomes for this procedure/technology?	
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	
17	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. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK. Cannot predict at present.

Abstracts and ongoing studies

18	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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	
20	Please list any other data (published and/or unpublished) that you would like to share.	

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)?	
22	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	Beneficial outcome measures: Adverse outcome measures:

	procedure timescales over which these should be measured:	

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

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

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

Print name:	**Click here to enter text.**
Dated:	**Click here to enter text.**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1938 Alcohol-mediated perivascular renal denervation for resistant hypertension

Your information

Name:	Peter Haworth
Job title:	Consultant Interventional Cardiologist
Organisation:	Portsmouth Hospitals University NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	British Cardiovascular Intervention Society, British Cardiac Society, Royal College of Physicians London
Nominated/ratified by (if applicable):	BCIS
Registration number (e.g. GMC, NMC, HCPC)	4738688

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☒ Please tick this box if you would like to receive information about other NICE topics.

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 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.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I have not personally used the alcohol denervation system but have experience in using other methods of renal denervation. I first was involved in renal denervation in 2012 whilst on my fellowship in New Zealand. At this time we utilised the Vessix balloon deliverable RF device which is no longer available. Most recently I have been using the radio frequency ablation catheter from Medtronic (Spyral). We undertook 11 renal denervation procedures in Portsmouth last year. All the patients who underwent the procedure in Portsmouth were enrolled in the Global Symplicity registry run by Medtronic. At the minute we have several patients on the waiting list to have this procedure undertaken for resistant hypertension but unfortunately there is no funding for this at the minute.
	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?	I do not know of any centres in the UK carrying out the alcohol renal denervation. There is a clear need for treatment of resistant hypertension as it remains the biggest worldwide cause of mortality and morbidity. If there were wider access to funded technologies that had clinical evidence of success then I am sure that there would be more widespread uptake of the technologies. This procedure is usually carried out by either interventional cardiologists or interventional radiologists.

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	Patient selection in our centre is from my hypertension clinic although we also received direct referrals from the nephrologists and referrals from throughout the Wessex region.
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure.I have been involved in clinical research in renal denervation although not with the alcohol ablation technique. I have published on other technology used to perform the same procedure. (*Ormiston JA, Watson T, van Pelt N, Stewart R, Haworth P, Stewart JT, Webster MW. First-in-human use of the OneShot™ renal denervation system from Covidien. EuroIntervention. 2013 Jan 22;8(9):1090-4. doi: 10.4244/EIJV8I9A166. PMID: 23339814.)* We are contributing the the GSR Global define registry using the Medtronic Symplicity renal denervation catheter and have recruited 11 patients with resistant or uncontrolled hypertension in to this trial.
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. 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):	The title adequately reflects the procedure. This is a developing field and this technology is not widely adopted throughout the UK. In technique it invoves the same access site and delivery of a catherere but the method of denervation is novel. There is published data showing that this technology is effective in controlling BP in limited clinical trials and more data is needed. There is a scattering of use of alternative technologies (including RF therapy and US delivered therapy). We are hoping to join a clinical trial using the ultrasound delivered technology in the near future. The technology sits between these two statements - A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy in terms of access but is a new technology and initial use should be as part of ongoing trials and registries.

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 technology will be as an adjunct to ongoing pharmaceutical therapy.
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	No No

Current management

6	Please describe the current standard of care that is used in the NHS.	Patients with hypertension are managed initially with pharmaceuticals which are effective in controlling BP in the majority of patients. In patients who still have uncontrolled BP and no evidence of secondary causes of this then we offer renal denervation.
7	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?	Medtronic symplicty RF renal ablation ReCor Medical U/S renal denervation. Access is the same (via femoral artery) but mechanism of renal denervation is different.

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Improved blood pressure control translating into reduced mortality and morbidity.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with restistant hypertension or patients who are intolerant to pharmaceutical management of hypertension.
10	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?	There is theoretical benefit in obtaining better blood pressure control as we know that this reduces chance of mortality and morbidity. There is potential that this could translate into reduced burden on the NHS in terms of hospital visits and admissions.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Provision of either cardiac cath lab facilities or interventional radiology suites. We are already at capacity for cath lab usage and so it may be that nationally more facilities are required.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes

Safety and efficacy of the procedure/technology

13	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:	The potential harms included immediate complications, renal damage, vascular damage, contrast reactions and long term risks include renal dysfunction (although this has not been evident in previous studies. There is also a theoretical risk of development of renal artery stenosis although, again, in previous trials this has not been significant.

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	Reducing BP to reduce mortality and morbidity. Theoretical reduction in the amount of pharamceuticals the patient will require.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Effects of alcohol infusion on surrounding tissues.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Yes
17	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 20 in the UK.

Abstracts and ongoing studies

18	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	Schwaerzer, G. Alcohol-mediated renal denervation is a safe and efficient treatment for uncontrolled hypertension. Nat Cardiovasc Res (2024). https://doi.org/10.1038/s44161-024-00476-2 Pathak A, Rudolph UM, Saxena M, Zeller T, Müller-Ehmsen J, Lipsic E, Schmieder RE, Sievert H, Halbach M, Sharif F, Parise H, Fischell TA, Weber MA, Kandzari DE, Mahfoud F. Alcohol-mediated renal denervation in patients with hypertension in the absence of

	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.	antihypertensive medications. EuroIntervention. 2023 Sep 18;19(7):602-611. doi: 10.4244/EIJ-D-23-00088. PMID: 37427416; PMCID: PMC10493775. David E. Kandzari, Michael A. Weber, Atul Pathak, James P. Zidar, Manish Saxena, Shukri W. David, Roland E. Schmieder, Adam J. Janas, Christoph Langer, Alexandre Persu, Farrell O. Mendelsohn, Koen Ameloot, Malcolm Foster III, Tim A. Fischell, Helen Parise and Felix Mahfoud Originally published8 Apr 2024https://doi.org/10.1161/CIRCULATIONAHA.124.069291Circulation. 2024;0
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Target 1 has jus published (see above)
20	Please list any other data (published and/or unpublished) that you would like to share.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	In a population the size of portsmouth (1 million) we undertook 11 procedures last year. This could significantly increase with better availability and funding of the technique.
22	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.	Beneficial outcome measures: Reduction in office and ambulatory BP Reduction in number of pharmaceutical agents taken to control BP Reduction in cardiovascular mortality including stroke (MACCE) Adverse outcome measures: Procedural complications including bleeding, vascular damage and renal damage. Failure to control BP.

	– Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	These would be recorded as immediate complications then follow up at 1 yearly intervals to assess response to treatment.

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	

NICE National Institute for Health and Care Excellence

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	Contract with Medtronic for teaching regarding use of Medtronic Symplicity renal denervation catheter	**21/03/2024**	**Ongoing**
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:	**Peter Haworth**
Dated:	**14/05/2024**

View results

Respondent

75 Anonymous

75:12
Time to complete

1. Project Number and Name - (Can be found on email) *

Alcohol-mediated perivascular renal denervation for resistant hypertension (IP1938)

Your information

2. Name: *

Dr Philip S Lewis

3. Job title: *

Consultant Cardiologist & Clinical Hypertension Specialist

4. Organisation: *

Stockport NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

British Cardiovascular Society; British & Irish Hypertension Society (Executive Member); European Society of Hypertension; International Society of Hypertension; National

7. Nominated/ratified by (if applicable):

British Cardiovascular Society

8. Registration number (e.g. GMC, NMC, HCPC) *

GMC 1522404

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, which have been communicated by Zoe Jones.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

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 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: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

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

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

I am familiar with the technology and have in the past referred patients for other forms of renal artery nerve denervation. I have attended and chaired meetings discussing renal artery nerve denervation.

12. 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.

Renal artery nerve denervation procedures use thermal or radiofrequency energy are performed in a few centres in the UK but have not gained universal acceptance. The technology has been usually applied to patients resistant to other forms of therapy and has not been trialled as an alternative to pharmacotherapy.

13. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [x] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes

16. Does this have a multi-indication?

Current indications would currently be for resistant hypertension only.

17. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

This is a variation on renal artery nerve denervation by thermal and radiofrequency energies and not novel in concept or design.

18. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- (●) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ( ) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

19. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

There is insufficient data to show that this is superior to other forms of renal artery denervation already in use and there is no reason to believe at present that any superiority would be expected. It might be used an as alternative but that would probably depend on financial incentives> Procedural time and efficacy is not superior to other similar techniques.

20. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

None of which I am aware.

21. Do you think guidance would be helpful on this topic?

- (●) Yes
- ( ) No

Current management

22. Please describe the current standard of care that is used in the NHS.

Drug treatment for resistant hypertension with investigation and exclusion of "secondary" causes, referral to a Hypertension Specialist, exclusion of drug non-concordance, multi-disciplinary team discussion and trial of other oral agents, weight reduction, treatment of sleep apnoea, reduction in weight, salt and alcohol intake, increase in physical activity. Rarely if all of the above have been addressed, then referral for renal artery denervation might be made.

23. 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?

This is similar to renal artery denervation using other approaches including radio-frequency and ultrasonic ablation which is already better accepted through familiarity

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

None over existing therapies unless there were contraindications to radiofrequency ablation.

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

At present only patients very resistant or intolerant of other anti-hypertensive therapies.

26. 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?

    Not at present. This would require long-term outcome studies and comparisons with other renal artery nerve denervation techniques and being applied in trials to untreated hypertensives as an alternative to drug medication.

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

    Interventional radiology laboratory with trained interventional radiologists or cardiologists.

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Safety and efficacy of the procedure/technology

29. 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

    At 30 days, the proportion of patients with MAEs was 4.7% for the RDN group and none for the sham control group (P=0.007). In the RDN group, there was 1 (0.7%) hypertensive crisis event, and most adverse events (6 patients, 4.0%) were related to hypotension requiring intervention or medication change. During the procedure, an arterial dissection occurred of uncertain relationship to the guiding catheter or study device in 1 patient, although antegrade flow was maintained at procedure completion. By 6 months, cumulative occurrence of major adverse events was similar between treatment groups (5.3% RDN versus 4.0% sham control, P=0.224). One death occurred in the RDN cohort unrelated to the study procedure, device or drug (narcotic overdose). At imaging performed at 6 months post-procedure, there was no evidence of renal artery stenosis identified except for the 1 patient with accessory renal artery dissection occurring during the index procedure. In this patient, occlusion of the branch was identified at follow-up imaging, although the patient was asymptomatic and with no clinically relevant change in renal function. Kandzari DE et al. Effect of Alcohol-Mediated Renal Denervation on Blood Pressure in the Presence of Antihypertensive Medications: Primary Results from the TARGET BP I Randomized Clinical Trial; https://doi.org/10.1161/CIRCULATIONAHA.124.069291Circulation. 2024;0

30. Please list the key efficacy outcomes for this procedure/technology?

    Long term blood pressure reduction and control; reduction in therapy, follow up costs and procedural costs, complications short and long term

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

    Benefit versus expertly prescribed oral pharmacotherapy, long term efficacy and safety

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

    Yes, renal artery denervation has yet to accepted as a routine part of blood pressure control.

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) Most or all district general hospitals.
- ( ) A minority of hospitals, but at least 10 in the UK.
- (•) Fewer than 10 specialist centres in the UK.
- ( ) Cannot predict at present.

Abstracts and ongoing studies

34. 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.

Kandzari DE et al. Effect of Alcohol-Mediated Renal Denervation on Blood Pressure in the Presence of Antihypertensive Medications: Primary Results from the TARGET BP I Randomized Clinical Trial; https://doi.org/10.1161/CIRCULATIONAHA.124.069291Circulation. 2024;0 already quoted

35. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

Ablative Solutions Ltd. https://clinicaltrials.gov/ct2/show/NCT02910414

Medtronic: https://clinicaltrials.gov/ct2/show/NCT02439749

ReCor Medical: https://clinicaltrials.gov/ct2/show/NCT03614260

36. Please list any other data (published and/or unpublished) that you would like to share.

None that I am aware of

Other considerations

37. 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)?

If renal artery denervation wee to become a significant part of routine antihypertensive therapy then such procedures might be used in 2-5% of all hypertensives.

38. 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.

Quality of life versus prior therapy over 1 year. Long-term ease of blood pressure control (5-10 years) and cardiovascular outcomes 5-10 years+). Comparative costs versus conventional therapy with regard to Multiple Adverse Cardiovascular Events.

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Immediate procedural complications: including vascular dissection, pain, time in hospital, ease to list for procedure, retroperitoneal and extravascular haemorrhage (within 6 weeks). Late complications including renal dysfunction, stroke, concordance with subsequent treatment, and poor blood pressure control if patients BP elevates but follow up checks are not done routinely.

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

Long-term data neds to be collected. Current renal denervation outcome trial outcomes are difficult to interpret because of confounding changes in blood pressure pharmacotherapy which mean that the results are not fully blinded. Comparison with other renal artery denervation techniques would be required including long-term cost benefits and outcomes.

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.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

N/A

43. 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. *

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Dr Philip S Lewis

45. Date: *

30/04/2024

View results

Respondent

74 Anonymous

52:10
Time to complete

1. Project Number and Name - (Can be found on email) *

Alcohol-mediated perivascular renal denervation for resistant hypertension (IP1938)

Your information

2. Name: *

Dr. Spoorthy Kulkarni

3. Job title: *

Post-CCT Clinical Research fellow in Clinical Pharmacology and Therapeutics

4. Organisation: *

Cambridge University Hospitals NHS Foundation Trust and University of Cambridge

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

British and Irish Hypertension Society (BIHS)

7. Nominated/ratified by (if applicable):

BIHS

8. Registration number (e.g. GMC, NMC, HCPC) *

GMC: 7500045

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, which have been communicated by Zoe Jones.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

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 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: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

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

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

I am familiar with procedure and technology as this has been proposed as an alternative treatment for resistant hypertension and has been studied in clinical trials.

12. 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.

This procedure is vastly used as a research tool only and can be set up as an option for the management of resistant hypertension. Hypertension specialists across the country may have various backgrounds and cardiology, nephrology, endocrinology, and clinical pharmacology and therapeutics who would receive referrals from primary care or cross-specialties for resistant hypertension.

13. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [x] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- ( ) Yes
- (•) Transcatheter Alcohol-mediated perivascular renal denervation for resistant hypertension.

15. Is the proposed indication appropriate? If not, please explain

Yes

16. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

Resistant hypertension is managed by medications alone at the minute. Catheter-based renal denervation management has been proposed as an option for these patients, but the benefits are not completely proven as of yet. Alcohol-mediated perivascular renal denervation would be an approach within the catheter-based renal denervation.

17. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- (•) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ( ) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

18. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

Addition to existing standard care for specific population cohorts

19. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

None in my knowledge

20. Do you think guidance would be helpful on this topic?

- (●) Yes
- ( ) No

Current management

21. Please describe the current standard of care that is used in the NHS.

The standard of care is additional medications prescribed for resistant hypertension.

22. 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?

None

Potential patient benefits and impact on the health system

23. What do you consider to be the potential benefits to patients from using this procedure/technology?

Selected patients may respond to the procedure and have a reduction in their blood pressure and hence cardiovascular risks.

24. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Patients who are intolerant to medical therapy could potentially have an option for management of their hypertension.

25. 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?

Potentially in selected populations, it may lead to lower cardiovascular disease events.

26. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

Interventional radiological facilities

27. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Training to deliver the denervation technology will be needed

Safety and efficacy of the procedure/technology

28. 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

1. Vascular access aneurysms.
2. Risk related to no response.
3. Pain

29. Please list the key efficacy outcomes for this procedure/technology?

1. Blood pressure reduction at 6-12 months
2. Reduction in medication burden
3. Reduction in major adverse cardiovascular disease events (if available)

30. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

Larger studies demonstrating efficacy and safety are unpublished as of yet.

31. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

The benefits of the procedure are unclear on a population level.

32. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) Most or all district general hospitals.
- ( ) A minority of hospitals, but at least 10 in the UK.
- ( ) Fewer than 10 specialist centres in the UK.
- (•) Cannot predict at present.

Abstracts and ongoing studies

33. 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.

34. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

    TARGET BP I, TARGET BP OFF-MED

35. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

36. 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)?

    Among a clinic of 100 patients in specialist clinic, 10 might be truly resistant and ultimately 3-4 might be eligible/keen to undergo an invasive procedure

37. 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.

    Ensure that resistant hypertension is defined clearly at the start and adherence to said medications is measured objectively.
    Office Blood pressure measurement difference from baseline
    Ambulatory blood pressure measurement difference from baseline
    Home blood pressure measurement difference from baseline
    Number of medications required for blood pressure control
    Number of hospital visits related to hypertension or major cardiovascular adverse events
    These can be measured at 3 months, 6 months, and at 1 year.

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Adverse outcome measures.

    These should include early and late complications. Please state the post procedure timescales over which these should be measured:

    Development of aneurysms
    Lack of response might increase the risk of major cardiovascular adverse events

Further comments

39. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

There is a need for further research and the results of the wider studies will hopefully throw more light.

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.

40. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

41. Description of interests, including relevant dates of when the interest arose and ceased. *

None

42. 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. *

- (•) I agree
- ( ) I disagree

Signature

43. Name: *

Spoorthy Kulkarni

44. Date: *

25/04/2024

View results

Respondent

5 Anonymous

28:46
Time to complete

1. Project Number and Name - (Can be found on email) *

Alcohol-mediated perivascular renal denervation for resistant hypertension (IP1938)

Your information

2. Name: *

William McKane

3. Job title: *

Consultat Nephrologist

4. Organisation: *

Sheffield Teaching Hospitals NHSFT

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

UK Kidney Association

7. Nominated/ratified by (if applicable):

UK Kidney Association

8. Registration number (e.g. GMC, NMC, HCPC) *

3487390

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

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 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: https://www.nice.org.uk/privacy-notice

9. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

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

10. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

Familiar with percutaneous renal denervation, but no personal experience with the alcohol mediated catheter based delivery system to achieve this.

11. 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.

Only used in clinical trial setting or small numbers named patient basis in UK. Not used personally.

12. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [x] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [x] I have had no involvement in research on this procedure.
- [x] I have engaged with clinical research in radiofrec

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

14. Is the proposed indication appropriate? If not, please explain

Yes

15. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

There are two key questions:

1. Does renal denervation add anything to conventional care for resistant hypertension
2. Does the alcohol based technique have significant advantage over other methodologies (RF, US etc).

The evidence is growing that RDN does add value to the care of this patient population, but there is not good evidence that any one system is better than the alternatives.

16. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- (•) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

17. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

Addition.

Current management

18. Please describe the current standard of care that is used in the NHS.

Careful clinical assessment, exclusion of treatable secondary causes of resistant hypertension, assessment of adherence, attention to lifestyle aspects of hypertension and titration of multi-drug regimes.

19. 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?

A variety of catheter based systems for RDN exist, of which the leading three are radio-frequency, ultrasound and alcohol. There are no head to head comparisons so it is hard to make definitive comments about the relative efficacy/safety of the other systems. RF is the most mature, alcohol the least mature.

Potential patient benefits and impact on the health system

20. What do you consider to be the potential benefits to patients from using this procedure/technology?

Not clear that it has any benefits over RF and US based technologies yet.

21. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Resistant hypertension patients not meeting BP targets after specialist assessment and treatment

22. 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?

Too early to answer this question

23. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

A specialist hypertension service linked to an approriately trained and resourced interventional radiology/cardiology team

24. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Yes, and with other RDN technologies there has been a clear learning curve.

Safety and efficacy of the procedure/technology

25. 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 first in man study reported a 4% access site pseudoaneurysm rate with one major bleed. This may be a learning curve phenomenon but safety outcomes from future studies are important

26. Please list the key efficacy outcomes for this procedure/technology?

In the immediate future, the 6 month Systolic ABPM, but eventually one would want to see CV endpoint data from a large longitudinal study.

27. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

See above

28. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

29. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ Most or all district general hospitals.
- ○ A minority of hospitals, but at least 10 in the UK.
- ◉ Fewer than 10 specialist centres in the UK.
- ○ Cannot predict at present.

Abstracts and ongoing studies

30. 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.

Full published results from the 2 x Target BP studies will be important PMID: 34052211

31. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

See above

32. Please list any other data (published and/or unpublished) that you would like to share.

Nil

Other considerations

33. 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)?

Unknown as not clear whether this technology has any advantage/disadvantage over RF and US

34. 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.

Short/Medium Term Efficacy

Systolic ABPM
Proportion achieving target BP
Reduction in medication
QoL
Head to head with other technologies

Long term efficacy

CV endpoints (would need a much larger, longer trial)

35. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Safety

Procedure related complications (bleeding, aneurysm, late RAS)
eGFR

Further comments

36. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

See above

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.

37. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

38. Description of interests, including relevant dates of when the interest arose and ceased. *

N/A

39. 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. *

- (•) I agree
- ( ) I disagree

Signature

40. Name: *

William McKane

41. Date: *

23/05/2023