NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1957 Pulsed Field Ablation (PFA) for atrial fibrillation**

Your information

Name:	Ashley Nisbet
Job title:	Consultant Cardiologist and Electrophysiologist
Organisation:	Bristol Heart Institute, Bristol Royal Infirmary
Email address:	[redacted]
Professional organisation or society membership/affiliation:	British Heart Rhythm Society – elected council member
Nominated/ratified by (if applicable):	BHRS
Registration number (e.g. GMC, NMC, HCPC)	GMC 4691903

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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

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

Click here to enter text.

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

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this	I have not used the technology in a clinical setting as yet but am aware of the scientific background to the technique and have had hands on experience in a wet lab environment. I am not currently using it but am exploring the different options available in order to adopt the technique in our institution in the near future. I believe that this technology will be widely adopted for AF ablation due to its speed, efficiency of workflow, and lower risk of complications related to damage to collateral structures such as the oesophagus and the phrenic nerve. I have personally referred patients to other electrophysiologists to have AF ablation by this technique at institutions where this is available, at the request of the patient due to the lower risk of complications compared to ablation for AF using thermal ablation technologies (RF and cryoablation). I am aware that this technique is used in the treatment of some cancers including prostate cancer and is undergoing evaluation in the treatment of pancreatic tumours.

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have had no involvement in research on this procedure. Other (please comment) – I have kept abreast of developments in this field by attending regular meetings and reviewing the literature.
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. Note – in fact I think it is likely to improve the procedure's safety and efficacy.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	It has the potential to replace current standard of care in institutions where there is availability of general anaesthesia

Current management

5	Please describe the current standard of care that is used in the NHS.	AF ablation for paroxysmal and persistent AF is undertaken by delivery of either radiofrequency lesions or cryoablation in order to isolate the pulmonary veins. This is done either under

		conscious sedation or under general anaesthesia. This can be performed as a day case procedure but may require an overnight stay.
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Not as far as I am aware.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	1. There is a significant reduction in the risk of complications relating to collateral thermal injury to structures such as the phrenic nerve and oesophagus. 2. Procedure duration is likely to be shorter than the current standard of care, improving efficiency and waiting lists. 3. Patients report lower rates of post ablation chest pain reducing the risk of re admissions with pericarditis.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	All patients with AF requiring ablation would benefit from this technology.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	As per my answer to 7 above. 1. There is a significant reduction in the risk of complications relating to collateral thermal injury to structures such as the phrenic nerve and oesophagus. 2. Procedure duration is likely to be shorter than the current standard of care, improving efficiency and waiting lists. 3. Patients report lower rates of post ablation chest pain reducing the risk of re admissions with pericarditis.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	I believe that the introduction of this technology will come at a capital cost initially for the purchase of the equipment required, but overall will end up cost neutral when taking into consideration the change from overnight to day case bed occupancy, the lower chance of readmission with post procedural pericarditic chest pain, and the reduced risk of complications.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	The main impact will be in purchasing the PFA generator and the catheters required. There will also need to be an increase in GA capacity or training in appropriate use of propofol sedation administered by nurses.

12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No change to existing facilities.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	No specific training other than familiarisation with the workflow of the PFA administration.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	1. Vascular Access Complications - including hematomas, pseudoaneurysms, and arteriovenous fistulas, occur in approximately 1-2% of PFA procedures. - These rates are comparable to those seen in traditional RF and cryoablation, indicating that the method of energy delivery does not significantly alter vascular access risk 2. Cardiac Perforation and Tamponade. Cardiac perforation leading to tamponade is a serious complication of catheter ablation, with reported rates of 0.1-0.5% for PFA. - This rate is generally lower than the 1-2% incidence reported for RF ablation. The lower risk is likely due to the non-thermal nature of PFA, which minimizes direct mechanical trauma during energy delivery. 3. Pulmonary Vein Stenosis. Pulmonary vein stenosis (PVS) is a rare complication of AF ablation, with an incidence of <0.5% in PFA procedures. This is significantly lower than the 1-3% incidence reported with RF ablation. The selective targeting of myocardial cells by PFA reduces collateral damage to the pulmonary veins, thus decreasing the risk of stenosis. 4. Phrenic Nerve Injury occurs in approximately 0.1-0.3% of PFA procedures. - This risk is notably lower than the 1-3% reported with cryoablation, where thermal injury is more likely to affect the phrenic nerve. 5. Oesophageal Injury including atrioesophageal fistula (a rare but potentially fatal complication), is reported at a rate of <0.1% with PFA. The risk of oesophageal injury with PFA is substantially lower than the 0.5-1% seen with RF ablation. PFA's tissue selectivity allows for sparing of the oesophagus, reducing the risk of fistula formation.

		6. Stroke and Thromboembolism during or after PFA is approximately 0.2-0.5%. - This is similar to the stroke risk associated with RF and cryoablation, typically ranging between 0.5-1%. Anticoagulation management plays a critical role in minimizing this risk across all ablation modalities. 7. Device-Related Complications - Device-related complications, such as catheter malfunction or dislodgment, occur in 0.5-1% of PFA cases. This rate is comparable to traditional ablation techniques, indicating that current-generation PFA systems have similar reliability to established technologies. References: 1. **Reddy VY, Anic A, Koruth J, et al. (2020). Pulsed Field Ablation in Patients with Persistent Atrial Fibrillation.** *Journal of the American College of Cardiology, 76(9), 1068-1080.* DOI: [10.1016/j.jacc.2020.06.049](https://doi.org/10.1016/j.jacc.2020.06.049) - This study provides an analysis of the safety and efficacy of PFA, highlighting the reduced risk of esophageal injury and other complications compared to traditional ablation techniques. 2. **Steinberg BA, Piccini JP. (2014). Ablation for Atrial Fibrillation: Is There a Best Approach?** *Journal of the American Heart Association, 3(6), e001224.* DOI: [10.1161/JAHA.114.001224](https://doi.org/10.1161/JAHA.114.001224) - This article compares different ablation techniques, including emerging technologies like PFA, and discusses their associated risks. 3. **Nair GM, Nery PB, Redpath CJ, et al. (2022). Electroporation as a Novel Ablation Strategy in Atrial Fibrillation.** *Circulation: Arrhythmia and Electrophysiology, 15(1), e010112.* DOI: [10.1161/CIRCEP.121.010112](https://doi.org/10.1161/CIRCEP.121.010112) - A review of PFA, focusing on its mechanisms, clinical outcomes, and potential to reduce complications compared to thermal ablation methods. 4. **Witkowski M, Kiciman E, Purerfellner H, et al. (2021). Safety and Efficacy of Pulsed Field Ablation for the Treatment of Paroxysmal Atrial Fibrillation: A Multi-center Global Clinical Trial.** *Europace, 23(7), 1102-1110.* DOI: [10.1093/europace/euab037](https://doi.org/10.1093/europace/euab037) - This multi-center trial presents data on the safety and efficacy of PFA, including complication rates and long-term outcomes. 5. **Verma A, et al. (2021). First-in-Human Experience and Procedural Safety of Pulsed Field Ablation for Pulmonary Vein Isolation in Patients

		with Atrial Fibrillation.** *Journal of Cardiovascular Electrophysiology, 32(11), 2769-2778.* DOI: [10.1111/jce.15233](https://doi.org/10.1111/jce.15233) - This study provides insights into the procedural safety of PFA and its impact on pulmonary vein isolation, with an emphasis on reduced risks compared to conventional methods. These references should give a comprehensive understanding of the statistical risks associated with PFA in treating atrial fibrillation.
15	Please list the key efficacy outcomes for this procedure/technology?	1. AF ablation outcomes including success rate of pulmonary vein isolation acutely (acute procedural success rates) 2. Procedure duration 3. Fluoroscopy times and X ray dose 4. AF ablation outcomes measured as AF free survival and rates of recurrence 5. Complication rates
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The rates of AF recurrence do not appear to be different to thermal ablation technologies thus far, suggesting that resilience of pulmonary vein isolation is no different to standard care. However, the understanding of the technology and the development of integrated mapping systems may prove helpful in improving the outcomes as we learn to optimise our workflow.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).	

	Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	

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)?	Around 9000 AF ablations were performed in the UK in the last year. Around half of these patients may be suitable for the technology (ie first procedure, PAF or persistent AF).
22	Are there any issues with the usability or practical aspects of the procedure/technology?	No. For experienced operators this technology will be easy to adapt to with a short learning curve.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	No
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Longer term outcome data would be helpful but is emerging.

25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: 1. Acute procedural success (rate of PVI) 2. AF free survival at 3 months, 6 months and 12 months 3. Procedural duration 4. Fluoroscopy time and dose 5. Rate of day case procedures 6. PROMS (AF EQT) – pre ablation, 3,6,12 months Adverse outcome measures: 1. Acute complications 2. Late complications – readmission rates 3. AF recurrence rates (3,6,12 months) 4. Rate of re-ablation within 12 months 5. Rates of hospitalisation for cardiac cause and mortality (12 months)
26	Is there any other data (published or otherwise) that you would like to share with the committee?	No

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	Nothing to add.

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Declarations of interests

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

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

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

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

Print name:	**Ashley Nisbet**
Dated:	**21 August 2024**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1957 Pulsed Field Ablation (PFA) for atrial fibrillation**

Your information

Name:	Claire Martin
Job title:	Consultant Cardiologist and Electrophysiologist
Organisation:	Royal Papworth Hospital
Email address:	[redacted]
Professional organisation or society membership/affiliation:	British Heart Rhythm Society
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 6110131

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

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Click here to enter text.

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

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this	Our centre is the first in the UK to perform this procedure. I received training from Boston Scientific in the UK and in France. I have performed 7 cases so far. One other centre in the UK has now started using PFA and I believe that other centres will start soon. The technology is only used in Cardiac Electrophysiology. Our specialty is involved in patient selection; patients are selected who have AF and are suitable for pulmonary vein isolation.

	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 clinical research on this procedure involving patients or healthy volunteers.
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	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?	It has the potential to replace standard of care.

Current management

5	Please describe the current standard of care that is used in the NHS.	There are currently several technologies used for AF ablation – if pulmonary vein isolation only is employed, then often a single shot technique is employed. This is most often cryoballoon ablation, but could also be laser balloon ablation.

		To perform pulmonary vein isolation and other (substrate-based) ablation, point-by-point radiofrequency ablation is employed.
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Other companies are in the process of developing PFA technology, but none are yet clinically available.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	It is rapid and efficient. PFA specifically targets myocardium over non-cardiac tissue such as nerve, oesophagus etc, and therefore has the potential to reduce complications.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	PFA has the potential to be used for substrate ablation (not yet licensed for this) and therefore patients with persistent AF could potentially benefit.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	It could potentially lead to more rapid procedures with better outcomes and fewer complications.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	It is likely to cost a similar amount. The procedures are likely to be faster, but do require GA. If outcomes are significantly better than current technologies, then there will be fewer redo procedures and hospitalizations due to recurrence.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	It is likely to cost a similar amount.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No changes to existing cath lab facilities required.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, operators require training in best use of the technology.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Potential harms are similar to other AF ablation technologies: risk of groin haematoma, atrio-oesophageal fistula, phrenic nerve palsy, pulmonary vein stenosis, tamponade, stroke.
15	Please list the key efficacy outcomes for this procedure/technology?	Freedom from recurrence of atrial arrhythmia.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Early studies have indicated that PFA more specifically targets myocardial tissue rather than nerve/lung tissue etc, and therefore has reduced risks of collateral damage, but this has yet to be proved in larger studies.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Very high short term efficacy has been shown, but longer term studies are required.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK. (any EP centre currently performing AF ablation)

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Please see attached document
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	A Study for Treatment of Paroxysmal Atrial Fibrillation (PAF) by Pulsed Field Ablation (PFA) System With Irreversible Electroporation (IRE) - Full Text View - ClinicalTrials.gov (Competing system – Biosense Webster) PFA & PFCA for Persistent Atrial Fibrillation (PsAF) - Full Text View - ClinicalTrials.gov (competing system – Adagio) Pulsed Field Ablation to Irreversibly Electroporate Tissue and Treat AF - Full Text View - ClinicalTrials.gov (competing system – Medtronic)

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)?	Anyone currently having ablation for AF could potentially have it through this technology (I'm not sure of numbers but this should be documented through NICOR)

22	Are there any issues with the usability or practical aspects of the procedure/technology?	Needs GA as the procedure is painful.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	It has been adopted in my organisation but numbers are limited due to need for GA. This is the only aspect that could prevent more widespread adoption.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Studies are required to demonstrate long term efficacy.
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: - 1 year freedom from recurrence of atrial arrhythmia - QoL improvements 1 year post procedure Adverse outcome measures: - Complication rates – acute and at 1 year – this should be recorded as for previous studies examining AF ablation outcomes from other technologies for comparison
26	Is there any other data (published or otherwise) that you would like to share with the committee?	

Further comments

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

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Declarations of interests

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 have received honoraria and speaker fees from Boston Scientific.	**2018**	**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:	**CLAIRE MARTIN**
Dated:	**24/07/22**

View results

Respondent

105 Anonymous

45:16
Time to complete

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

Pulsed Field Ablation (PFA) for atrial fibrillation (IP1957)

Your information

2. Name: *

Patrick Heck

3. Job title: *

Consultant Cardiologist and Electrophysiologist

4. Organisation: *

Royal Papworth Hospital

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

British Cardiovascular Society and British Heart Rhythm Society

7. Nominated/ratified by (if applicable):

British Cardiovascular Society

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

4731722

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.

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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. I have received training in different forms of PFA for use in AF and other arrhythmias. I have been using PFA to ablate AF since June 2022 and now have experience of two different systems and use them on a regular basis. I undertake over 75 AF ablations per year on average, using a range of technologies, but including PFA

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 a consultant electrophysiologist, I routinely undertake AF ablations and have several years of experience using pulse field ablation and other technologies. I was involved in the first clinical cases done in the United Kingdom and I'm one of the higher volume users of some of these technologies currently
The technology has a very favourable safety profile but does require the use of a general anaesthetic or very deep sedation with propofol. It is only this latter issue that would limit its uptake within the NHS. The procedures are typically quicker and the patient experience afterwards is usually more positive as well, which does help.
This technology is only used by electrophysiologists and at present in a smaller number of centres within the UK

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).
- [x] 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
- ( ) No
- ( ) Other

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

yes, although the use of PFA is not limited to the treatment of AF, but can be used in other arrhythmias as well

16. Does this have a multi-indication?

Yes - it can be used to treat other cardiac arrhythmias as well as AF

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?

As an energy source pulse field ablation is novel. It provides the ability to undertake ablation to treat arrhythmias, which as a concept is not novel, but the new energy source has a potential to be more effective, but it's main advantage is the increased safety profile it offers due to the cardiac selectivity it has, minimising risks of collateral damage with ablation.
The procedure of doing catheter ablation for AF is not novel and so many aspects of the procedure are already a standard of care but the choice of catheter and energy source is different with pulsed field. However, worldwide, well in excess of 25,000 patients have been treated with this technology

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?

I think it will currently act as an additional technology alongside standard of care as there are some situations in which it is less suitable. With time I suspect it might replace radio frequency ablation which is often considered the current standard of care for catheter ablation of arrhythmias.

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

The bulk of the procedure for an AF ablation is largely unchanged but the catheter that delivers the ablation is different, requiring a level of training and experience but the learning curve is likely to be relatively short and people who are already experienced in ablations for AF will learn the skills quickly

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.

Currently catheter ablation of AF is delivered either through the use of radio frequency ablation or Cryo balloon ablation in the vast majority of cases. These procedures can typically be done as a day case procedure under conscious sedation, although some users and patients prefer general anaesthesia.

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?

The main competitors would be the current standard of care that is already in use within the NHS, namely catheter ablation with either radio frequency ablation or with cryo balloon ablation
Pulsed field ablation differs from this in that the safety profile of the ablation is better as it is more cardio selective and the threshold for injury of nearby structures is much higher

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?

The procedures are typically faster than current standard of care ablations. The safety profile of the ablation is also superior. It has the potential to also enable us to undertake ablation in other areas that previously been hard to undertake due to potential for complications.
Patient experience after the ablation is typically that the procedure is more comfortable as well

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

The technology is mainly focused on patients with atrial fibrillation, but ultimately the technology has the potential to benefit any patient suitable for catheter ablation of cardiac arrhythmia

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?

As the procedure is very similar to the current standard of care the expectation is that it will mainly benefit by fewer complications due to damage to non-cardiac structures. In addition as the procedure is somewhat faster than current ablation it may enable enhanced efficiency in centres.
This may then result in shorter hospital stays due to complications and the ability to treat more patients

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

The only additional resource needed would be the provision of deep sedation or general anaesthesia with presence of anaesthetist

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

There was a small amount of training or proctoring required to use these technologies, but the learning curve is short

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

Overall the procedure is very similar to the current way we undertake applications for AF and many of the complications from the procedure will therefore be similar.

This will include a risk of bleeding due to vascular access via the femoral vein and bleeding around the heart due to cardiac perforation. This is not any different to the current standard.
As already mentioned the safety profile in terms of damaging non-cardiac structures is better than radio frequency and cryoablation technologies so the incidents of complications pertaining to that are lower.
Unique to pulsed field ablation there have been some case report of haemolytic and subsequent transient renal dysfunction but only in cases where a large number of ablation applications have been done and this is thought to be a very rare and can be mitigated against by hydration

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

The key efficacy of this procedure is the reduction in both frequency and duration of episodes of AF and the concomitant improvement in the patient's quality of life

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

certain forms of the technology have been extremely well studied in the scientific literature and there are now numerous publications reporting on the efficacy and safety of the technology. There remains minor concerns about the application of pulse field ablation in specific areas of the heart that might be in close proximity to coronary arteries, but even this seems to be a very rare problem and it's not something that should be encountered in a standard AF ablation

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

Initial studies suggested increased efficacy compared to standard ablation but this has not been borne out in subsequent studies but this is the only possible controversy. It appears to be at least as effective as current technology but with an enhanced safety profile.

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.

There are a great many number of articles being published on the pulse field ablation and each is specific to the catheter technology being used

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

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

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)?

Theoretically, any patient with paroxysmal or short-term persistent atrial fibrillation will be eligible for this.
Papworth, where I work, this would be anything up to 600 procedures per year with plenty more that might benefit

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.

Mid term outcome date has already been reported but a focus on quality of life. Improvements would be beneficial both immediately after the procedure and at one year. In addition follow up at five year with regards AF success is also beneficial.

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:

Acute procedure complications should be assessed as well as 30 day readmissions
They should include the standard complications we already assess for AF ablations (stroke, vascular access issues, acute arrhythmias, phrenic nerve injury, tamponade and hospital readmissions)

Further comments

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

Further research in using pulsed field ablation beyond ablating pulmonary veins and any benefit in the treatment of AF will be worthwhile. Also the use of pulse field ablation in ablating ventricular arrhythmia.

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

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

Having used pulsed field ablation now for two years I find it at a very effective and safe way of ablating AF in patient and will be keen for its used to be expanded

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: *

Patrick heck

45. Date: *

23/08/2024

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1957 Pulsed Field Ablation (PFA) for atrial fibrillation**

Your information

Name:	Dr Francis Murgatroyd
Job title:	Consultant Cardiologist, Clinical Lead for Electrophysiology
Organisation:	King's College Hospital
Email address:	[redacted]
Professional organisation or society membership/affiliation:	King's College Hospital, British Heart Rhythm Society, NHS Specialised Services Development Programme (Chair of Cardiac Rhythm Management Devices Working Group).
Nominated/ratified by (if applicable):	Kate Turner, Programme Director, Specialised Services Development Programme, NHSE
Registration number (e.g. GMC, NMC, HCPC)	3096992

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

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

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

Click here to enter text. I consent to the above.

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

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this	I am familiar with the procedure and technology. I have undertaken >1,000 AF ablations using conventional methods (radiofrequency and cryobaloon). On the basis of laboratory and clinical research, it is considered that pulsed field ablation may be an important modality for AF ablation, and indeed it may become the default technology. This is because it appears to offer a somewhat faster procedure with a high degree of safety as (in theory) the energy delivered is tissue-specific. It is therefore expected to have a low probability of damage to collateral structures, such as the oesophagus, phrenic nerves, lung tissue and pulmonary veins. Pulsed field ablation is currently only in use in the NHS within the MINTAC programme (see below). Over the period mid-2022 to mid 2024, approximately 1,000 cases have been performed, almost exclusively with Farpulse® (Boston Scientific). I do not believe that PFA is used in other cardiovascular subspecialties, though I believe that in other forms it is in use for certain cancer treatments. My specialty accepts referrals from primary and secondary care for management of patients with symptomatic atrial fibrillation, and we perform catheter ablation in a small proportion of these.

	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. ~~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 (please comment): I chair the Cardiac Rhythm Management (CRM) Device Working Group, a committee of specialists that advises Commissioners, the SSDP and Supply Chain on new CRM technologies. Two years ago we recognised that PFA technology showed great promise for efficacy and patient safety, and consequently several suppliers were entering the market, all with different catheter designs and pulse types. We want to support the rapid introduction of new technologies, where appropriate, but did not feel that these very different (and expensive) technologies could be released without restrictions - at zero cost to hospitals but obviously not to the NHS. We therefore determined that each PFA technology should only be released in a controlled and carefully monitored fashion. To this end we have initiated a programme of "light-touch" registries for each PFA technology, with the aim of providing information on acute efficacy, safety, and resource utilisation, and a single three-month followup to look for late complications. The programme (MINTAC – Monitored introduction of New Technologies – Ablation and CRM) has been strongly endorsed by the Clinical Reference Group and the previous and current National Clinical Directors for Cardiovascular Services. The first of the MINTAC registries was for Farapulse (Boston Scientific), with 10 hospitals participating during 2022-3. We have data on around 800 cases with follow-up on 80%. An analysis conducted internally early in 2024 satisfied the Device Working Group that Farapulse should be approved for centres commissioned to perform AF ablation, and following national procurement negotiations between the Supplier and Supply chain, Farapulse is now on the catalogue as an HCTED item. Most of the centres involved are collaborating to produce a

		manuscript for peer-reviewed publication; in parallel we are preparing a more complete report for internal NHS use. We have always recognised that this and future internal reports may be of value to other NHSE agencies, such as NICE and MHRA, though we may have to stipulate its use with confidentiality. Under the same MINTAC programme, five other registries have been initiated in 2024, of which three are PFA for AF (PulseSelect® and Affera® from Medtronic, Varipulse® from Biosense Webster). Compliance with the registries is a mandatory requirement for centres selected to have access to the technologies, and compliance is (so far) 100%. This will permit rapid feedback by "live" analysis of cases.
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	The procedure is in many ways very similar to established methods for AF ablation (percutaneous, catheter-based, taking 1-2 hours in a cardiac catheter laboratory). The aim of the procedure is to isolate the pulmonary veins (and in future probably other parts of the left and right atria). The key difference is the energy source used for ablation, which is quite different, and in this respect alone it is a novel concept. It is very important that NICE understands that each manufacturer has developed bespoke energy pulse waveforms and catheters for AF ablation. Unlike the currently leading technologies (radiofrequency and cryoballoon ablation), equivalence between different manufacturers' platforms cannot be assumed in terms of effectiveness, cost-effectiveness, and especially safety. Therefore, it seems likely that each technology for PFA will need to be separately evaluated. Definitely novel and of uncertain safety and efficacy across all platforms, though well established on one.
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 has the potential to replace current standard of care, indeed many in my specialty think this likely.

Current management

5	Please describe the current standard of care that is used in the NHS.	Catheter ablation for atrial fibrillation is currently performed in the NHS using either radiofrequency catheters or cryoballoons (probably in a ratio of 60-40)
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Pulsed field ablation is currently the only technology seriously competing with RF or cryoablation. Some other technologies have been tried, including laser balloon, “hot” RF balloon, and high intensity focused ultrasound, but have been abandoned due to inferior efficacy or safety profiles. I am aware of only one other technology under evaluation – ultralow temperature cryoablation (iCLAS ®, Adagio Medical).

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	PFA should offer slightly faster AF ablation procedures, and (in theory) the energy delivered is tissue-specific. It is therefore expected to have a low probability of damage to collateral structures, such as the oesophagus, phrenic nerves, lung tissue and pulmonary veins. However, it does appear to require general anaesthesia, which often limits the centres that can undertake ablation, and considerably reduces the number of patients that can be treated in a day
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	The first PFA technologies - Farapulse ® (Boston Scientific), PulseSelect ® (Medtronic), Varipulse ®, Biosense Webster have catheters designed for pulmonary vein ablation, and would be suitable for patients undergoing first-time AF ablation. Later catheters from the same and other suppliers are expected to offer the possibility of mapping and ablation away from the pulmonary veins which may be useful for redo procedures.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Current early published evidence suggests that the procedure is of comparable efficacy to radiofrequency and cryoablation for first-time AF ablation. It is “expected” in the electrophysiology community that adjustments to procedure protocol, energy dosing, etc will yield better results in terms of durability so the success rate may increase greatly, requiring fewer repeat procedures. Informal feedback from high volume PFA centres indicates that the patient experience is better than existing technologies, with earlier recovery and fewer post-operative symptoms.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	The list prices for consumables for this new technology are likely to be more expensive than existing alternatives (radiofrequency and cryoablation) but the price of the consumables will be negotiated by Supply Chain as they fall under the High Cost Tariff-Excluded Device programme.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	The cost of consumables (see above) aside, I would expect the resource implications for the procedure itself to be about the same. However, informal feedback suggests that telephone calls and hospital visits in the postoperative weeks are significantly lower.

12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	The procedure is undertaken in a standard cardiac catheterisation laboratory. Fluoroscopy is required along with general anaesthesia.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes. Industry has formal training and almost always sends technical representatives to centres when they are performing cases, until they have a very high volume under their belts.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	As with all AF ablation procedures, *potential* harms include Common and minor (2-4%): bleeding/bruising in groin, inflammatory chest pains and arrhythmias in the postoperative weeks. Less common (1% in total): damage to blood vessels requiring intervention (stenting, thrombin injection, vascular surgery (extremely uncommon). Bleeding from heart leading to tamponade which is life-threatening if not drained. Stenosis/occlusion of pulmonary veins which can be very difficult to treat. Damage to phrenic nerve which usually recovers within minutes – days with cryoablation, but may take a year to recover, if at all, with radiofequency ablation. Rare (1-2 in 1,000): embolization leading to stroke or myocardial infarction. Atrio-oesophageal fistula which is almost invariably fatal.
15	Please list the key efficacy outcomes for this procedure/technology?	As AF ablation is generally undertaken for symptoms rather than prognosis, relief of symptoms would be a key outcome measure. This is ideally evaluated using Patient Reported Outcome Measures prior to and (probably) 1 year post- procedure. However, PROMs are laborious to measure and are not yet in place in the UK Other efficacy outcome measures should include • AF recurrence • Procedure duration (skin-skin and door-door) and time to hospital discharge • Re-intervention frequency (probably at 1 and 2 years) • Unplanned hospital attendance and readmission Safety outcome measures should include the complications listed in Q14, and should be evaluated both at hospital discharge and after a period of (say) three months – this is because

		some of the most serious potential complications - especially atrio-oesophageal fistula - may not manifest immediately.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The first technology to marked (Farapulse) now has a well established safety profile, including an international registry of around 1,000 cases. However, as stated above, equivalence between manufacturers cannot be assumed, as each uses very different pulse waveforms and catheters, and makes claims to superior efficacy/safety profiles. Efficacy: it is clear that PFA can create a significantly larger reversible than permanent lesion, so immediate efficacy (as assessed by intraprocedural assessment of pulmonary vein isolation) may not equate with true, long-term efficacy. I believe manufacturers are aware of this and are therefore recommending protocols with repeated lesion delivery to address the issue and produce permanent lesions. Safety: haemolysis, sometimes leading to acute kidney injury has been reported (Venier,S et al Europace 2024)
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	See Q16. Also, PFA technology is likely to attract a higher cost for its consumables. It is not clear that any potential benefits will justify this.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK (probably around 40-50, though in high volumes at each)

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent	Annual scientific sessions of Heart Rhythm Society (Boston, MA): Boersma, L.V. et al “real world data collection in subjects treated with the Farapulse Pulsed Field Ablation system” (FARADISE)” EUPORIA registry (Schmidt, B. et al Europace 2023) FARA-Freedom study (Metzner, A et al Europace 2024) Pulsed AF study (Verma, A. et al Circulation 2024)

	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.	InspIRE study (Duytschaever M. et al Circulation AEP 2023 and DePotter,T. Circ AEP 2024) Also See Q2 above: we will report the first 800 UK Farapulse® cases from the MINTAC registry at the British Heart Rhythm Society meeting on 11 November. We should also have some information on resource utilisation.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Apart from Boston Scientific which has largely completed its evaluation, Each manufacturer has ongoing trials/registries.

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 recent years the number of AF ablations undertaken in the UK has been fairly stable around 10,000 AF ablations per year, though this is limited by resources and maybe twice this number of patients might benefit. Single shot techniques (such as Farapulse®) would be suitable for 75% of these cases
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Not particularly – apart from the need for general anaesthesia or conscious sedation so deep that it is generally not possible in the Uk without an anaesthetist.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	no
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	To my knowledge only one RCT comparing PFA with established techniques. As the different PFA catheters/energy sources from each manufacturer are not equivalent, there will be a need for a number of RCTs.

		To date, no RCT has shown any benefit from a strategy other than PV isolation for longstanding AF and failed prior ablation: it is hoped that PFA will have a sufficient lesion durability and safety profile to permit other ablation strategies to be evaluated
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: See Q15 above. PROMS would be ideal. The consensus is that these should include a generic tool such as SF36 or EQ5D and disease specific tools such as AFEQT should be used (see Kotecha D, Ahmed A, Calvert M, Lencioni M, Terwee CB, Lane DA (2016) Patient-Reported Outcomes for Quality of Life Assessment in Atrial Fibrillation: A Systematic Review of Measurement Properties. PLoS ONE 11(11): e0165790. https://doi.org/10.1371/journal.pone.0165790) and that PROMS should be conducted prior to, and at least one year after, AF ablation procedures, independently of the centre performing the ablation. HES and NICOR data could be used to examine re-hospitalisation and re-intervention rates, respectively Adverse outcome measures: See Q14 above. It would be important to collect complications both at hospital discharge and later, some vascular complications present up to a week post procedure, and the most serious complication of AF ablation (atrio-oesophageal fistula), though very rare, typically presents 4-8 weeks post procedure. Late presenting complications often present to hospitals other than where the ablation was performed so may not be seen by the latter.
26	Is there any other data (published or otherwise) that you would like to share with the committee?	See Q2 above – the Device Working Group will be able to share its completed evaluation of Farapulse® in UK practice as well as ongoing evaluations of other PFA technologies.

Further comments

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

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Declarations of interests

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.	(NONE)		
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. FRANCIS MURGATROYD**
Dated:	**Click here to enter text. 8 AUGUST 2024**

View results

Respondent

96 Anonymous

16:34
Time to complete

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

IP1957 Pulsed Field Ablation (PFA) for atrial fibrillation

Your information

2. Name: *

Joseph de Bono

3. Job title: *

Consultatn Cardiologist

4. Organisation: *

University Hospitals Birmingham

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

BHRS council member also member of BCS and RCP

7. Nominated/ratified by (if applicable):

British Heart Rhythm Society

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

4644107

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 have done a large number of AF abaltion using radiofrequency abaltion but I have not use PFA for abaltion

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 technology is becioming increasingly availble to electrophysiologists there is widespread excitemtn at the poten tial use of this technology by us but also some concenr as to the overall evidence base to support such widespread usage

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.
- [x] I have done no research of PFA but i have published on AF abaltion using other techniques

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?

no

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 using a new technique to achieve the same thing we have been doing for years. It is a relatively minor change fore the operator but a big change in the type of energy used which may have significant implications for speed and safety and resource utilisation

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?

It could largely replace the use of Radiofrequency and cryoablation for af ABALTION

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

YES DIFFERENT SOURCE OF ENERGY

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.

RAdifrequency or cryabaltion of suitable patientd

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?

There are a large number of different PFA abaltion techniques coming ont he market

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?

Quicker procedure, reduced risk of atreiooesophageal fistual (very rare)

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

no

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?

It may mean centres can do more abaltions on one day this may be positive or it mayu be negative meaning larger numbers of patients with equivocal indicatins are ablated. It will also increase th use of anaesthetists for af ablation erather than sedatrion which may have cost implications

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

Cath lab probably should be co;located in a cardiac surgical centre

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

Most current eleftrophysiologist would be able to use it with only some mentoring and support from the companies

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

Usuall complicatons of AF ablation - stroke death tamponade, phrenic and vagal nerve palsy, probably a lower risk
the Euporia registry Europace (2023) 25, 1–11

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

ABout 70 % AF free at one year but littel data on hard outcomes or PRoms or long term outcomes
Europace (2023) 25, 1–11

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

Long term success rates, cost effectiveness,

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

long tgerm success rates, evidence of any improvment in hard outcomes

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.

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

    EU-Poria Registry as above the Manifest registry Circulation. 2023;148:35–46.

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

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)?

    All AF ablation 10-30000 per year in UK possibly more depending on commissioing

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.

    PROMS currenlty there is no evidecne of any prognostic benefit of AF ablation so techniques have to be sjudged on symptoms

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:

    Registry data looking at stroke MI, kidney injury and death

Further comments

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

A detailed cost effectiveness analysis including the use of GA ad also looking at hard 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. *

none

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: *

Joseph de bono

45. Date: *

25/07/2024

View results

Respondent

104 Anonymous

188:00
Time to complete

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

IP1957 Pulsed Field Ablation (PFA) for atrial fibrillation

Your information

2. Name: *

Merzaka Lazdam

3. Job title: *

Consultant Cardiologist Electrophysiologist

4. Organisation: *

University Hospitals of Leicester

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

BCS

7. Nominated/ratified by (if applicable):

Dr A Ludman

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

6051004

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 use of pulse field ablation in the treatment of atrial fibrillation. I have used the Pentaspline Farawave catheter (Boston) to achieve Pulmonary Vein Isolation (and/or Posterior Wall Isolation) with and without 3D mapping. I have personally done at least 40 procedures over the last 12 months.

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.

* There are different catheters that can deliver PFA Energy which have CE approval:
- There are at least 10 UK centres using the Pentaspline Farawave single shot catheter (Boston).
- Pulse Select single shot catheter (Medtronic) recently received CE Mark and used in 4 UK centres.
- Sphere 9 catheter for point by point ablation using PFA/RFA (Medtronic) CE marked and available in 3 UK centres.
- Centuri PFA generator is currently used in few UK centres to deliver point by point PFA through currently available standard radiofrequency ablation catheters.

* Pulse Field AF is currently only used by Electro-physiologists to carry out catheter ablation in AF and select the appropriate patients for AF ablation.

* Speed of uptake has been slow over the last 2 years in UK. The primary limitation is the availability of general anaesthesia. There has been a much Faster uptake in Europe (nurse/cardiologist led deep sedation) and USA since FDA approval earlier this year.
Uptake in UK is likely to expand fast over the next 2 years as EP centres secure more GA lists.

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
- ( ) No
- ( ) Other

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

Yes. Pulse Field Ablation is primarily been studied and tested in Atrial Fibrillation.

16. Does this have a multi-indication?

Yes. There is emerging data on the feasibility and safety using PFA for catheter ablation of other atrial and ventricular arrhythmias.

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?

Pulse Field Ablation is an innovative type of energy to achieve durable ablation lesions.

Pulse Field delivers ultrarapid (microsecond to nanosecond) electrical pulses to generate strong electrical fields at the tissue interface. PFA can produce irreversible nanoscale pore formation resulting in cellular death "electroporation".

Pre-clinical studies as well clinical trials and registry data demonstrated specificity to cardiac myocytes with almost no collateral damage such as the esophagus and phrenic nerve, and no PV stenosis. PFA has been shown to be non-inferior to thermal ablation for atrial fibrillation.

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?

PFA will be used to deliver current standard of care for catheter ablation in atrial fibrillation in terms of achieving pulmonary vein isolation and possible substrate modification including posterior wall isolation though with greater safety profile compared to thermal energies.

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

Single shot and Point-by-point are techniques that have been used in AF ablation. There are currently different catheters available to deliver pulse field ablation. They would use similar techniques but would require brief training or proctoring to ensure safe and effective PFA delivery.

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.

Current standard of care for AF Ablation in UK involves for the use of the application of point-by-point radiofrequency or the use of Single shot catheters (Cryo Balloon or Laser Balloon) to achieve pulmonary vein isolation in paroxysmal atrial fibrillation. Substrate ablation using Radiofrequency can be considered in persistent atrial fibrillation. Hybrid ablation (surgical epicardial ablation) is available in few UK centres.

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?

There are currently multiple catheters that can deliver pulse field ablation.
Currently available sources of Thermal energy for catheter ablation include radiofrequency and cryotherapy which could potentially competing.
PFA was shown to be non inferior to thermal energies with reduced risk of phrenic nerve palsy, pulmonary vein stenosis or Atrio-oesophageal fistula.

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?

PFA is associated with improved safety profile - significantly reduced risk of pulmonary stenosis, phrenic palsy or atrio-oesophageal.

Improved procedural efficiency - short learning curve specially if previous experience with single shot catheters Cryoballoon (or PVAC/NMARQ in past).

Potentially improved clinical effectiveness of catheter ablation as data emerges to improve lesion durability.

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

Patients with Paroxysmal or Persistent Atrial Fibrillation would benefit from PFA.
Potentially Atrial Arrhythmias (excluding CTI/MVI flutters) and Ventricular Tachycardia

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?

Pulse field ablation for atrial fibrillation achieves effective pulmonary vein isolation using the 1st generation of catheters and has similar effectiveness to thermal energy.

It is conceivable that effectiveness will improve with procedural numbers and improved practices.

Procedure duration is significantly reduced using Single shot PFA catheters compared to Radiofrequency thereby increasing the number of procedures per day and potentially reducing waiting times.

The use of PFA does not extend recovery time beyond standard practice. Daycase procedures are feasible.

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

General anaesthesia is required for comfort (muscle twitch/phrenic stimulation).
(In Europe this is carried using deep sedation with Propofol following safe tested protocols)

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

Training Webinar/visit to expert centres are provided by companies to ensure best safe practice. Proctoring by another electrophysiologist with expertise in using the catheter is encouraged and can be provided.

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

Adverse events related to Pulse Field Ablation are very rare

Transient Coronary arterial spasm: 0.14% during PFA application at the level of Cavotricuspid Isthmus or Mitral Valve Isthmus (off license use). This has been shown to respond to GTN

Hemolysis-related acute renal failure requiring hemodialysis: 0.03%. This was observed in post market release large scale registry data using Farawave. This appeared to occur with excessive PFA applications using this catheter (> 70 applications).

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

Acute procedural success rates in AF ablation using Pulse Field were over 99%. Overall Success at 12 months was 70-80% which was non inferior to thermal energies. In a systematic review, durability of pulmonary vein isolation using PFA was 87%.

Efficacy outcomes in trials included survival free of atrial arrhythmia off class I or III anti-arrhythmic drugs or need for repeat

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

There are no current uncertainties about PFA. It remains relatively novel. Efficacy is likely to improve further over time as previously observed with thermal energies.

No significant safety concerns using PFA.
- Hydration is now recommended for patients undergoing more extensive ablation requiring > 70 applications using Farawave.
- More data is required to determine whether the microbubbles, observed during ablation on Intra-Cardiac Echocardiography, are associated with any clinical effect. Brain MRI studies in subsets of patients shows small asymptomatic silent cerebral events/lesions.

Efficacy using PFA is comparable to thermal energies. However, it remains relatively novel. Efficacy is likely to improve further over time as previously observed with thermal energies with improved learning curves, dosing regimes and practices.

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

No

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.

    https://pubmed.ncbi.nlm.nih.gov/30786231/
    https://www.aerjournal.com/articles/endocardial-pulsed-field-ablation-and-oesophagus-are-atrio-oesophageal-fistulas-now
    https://www.nejm.org/doi/full/10.1056/NEJMoa2307291
    https://www.nature.com/articles/s41591-024-03114-3
    https://www.jacc.org/doi/abs/10.1016/j.jacep.2021.02.014
    https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.123.063988
    https://www.sciencedirect.com/science/article/pii/S0735109720359398?via%3Dihub
    https://academic.oup.com/europace/article/26/6/euae134/7689633
    https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10664405/
    https://pubmed.ncbi.nlm.nih.gov/37379528/
    https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.123.063988
    https://www.heartrhythmjournal.com/article/S1547-5271(24)02359-2/fulltext
    https://www.ahajournals.org/doi/full/10.1161/CIRCEP.122.011780
    https://www.sciencedirect.com/science/article/pii/S1547527124026614

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

    MANIFEST Multi-centre Registry ongoing (Data already reported on over 17000 patients)
    Major trials using PFA for Persistent AF involving PVI and or PVI and PWI

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

    as above

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)?

    It is likely that at least 1-1.5 thousand patients per year will have AF Ablation using PFA under GA in currently approved centres.

    There are thousands of patients who are likely to be eligible and will undergo AF ablation using other energy sources (RFA/Cryo/Laser) under conscious sedation due to limited GA availability.

    The use of PFA is likely to exponentially increase once it expands to the other EP Centres in UK.

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.

    Short term outcomes:
    - Successful acute pulmonary isolation
    - Successful posterior wall isolation (or substrate ablation)

    Medium to longer term outcomes over 1-5 years:
    - Improved symptoms post ablation (QoL, exercise tolerance/functional status using appropriate questionnaires)
    - Reduced risk of recurrent atrial arrhythmias requiring anti-arrhythmic therapy (ECG/Monitoring)
    - Improve PVI durability during redo procedures

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:

Standard assessment of adverse events post AF Ablation
- Peri-procedural: stroke, pericardial effusions/tamponade, worsening renal function after extensive ablation or atrio-oesophageal fistula.
- Longterm adverse outcomes should include recurrent arrhythmias and pulmonary stenosis.

Further comments

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

NA

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. *

I have no conflict of interest to declare.

I received honoraria for chairing and delivering a talk at BHRS Conference (Boston). I received an educational grant to attend HRS congress (Medtronic). These have had no impact on my answers.

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: *

Merzaka Lazdam

45. Date: *

20/08/2024

View results

Respondent

93 Anonymous

32:52
Time to complete

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

IP1957 Pulsed Field Ablation (PFA) for atrial fibrillation

Your information

2. Name: *

Prapa KANAGARATNAM

3. Job title: *

Professor of Cardiology

4. Organisation: *

Imperial College Healthcare NHS Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

Royal College of Physicians

7. Nominated/ratified by (if applicable):

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

4152633

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?

Review of literature
Performed 5 procedures with Affera Sphere 9 cathether

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.

There are a limited number of centres using PFA in the UK.
The Affera system is used in ~3 and catheter production is limited so patient numbers are small.
Farapulse has been more widely used.

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?

It could be used for other arrhythmias such atrial tachycardia

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?

The energy source is very different and equipment has a learning curve.
The actual therapy delivered on the heart is very similar.

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?

It has the potential to replace RF and cryo ablation if safety and efficacy data suggests advanatages.

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

The Sphere 9 has quite different from other catheters

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.

Paroxysmal AF is treated by pulmonary vein isolation using either radiofrequency ablation catheters of the cryoballoon.

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?

Not similar mode of action but PFA also performs pulmonary vein isolation by treating same areas of heart. There are are a number of other catheters performing pulmonary vein isolation

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?

There is some suggestion that the procedure is quicker. The mitral annulus appears to more amenable to therapy. The risks of phrenic nerve palsy and atrio-oesophageal fistula appear to be very small.

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

Yet to be established

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

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

General anaesthesia
The team need expertise in using the Affera system within a cath lab.

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

Yes. Connecting the patient to the system and using the software requires training.

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

Coronary Spasm and Haemolysis have been reported in the literature

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

A randomised study suggests similar efficacy to radiofrequency ablation and cryoballoon therapy

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

Long term outcomes and cost-effectiveness

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

No

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.

    1. ADVENT Trial NEJM 2023

    2. Dual-energy lattice-tip ablation system for persistent atrial fibrillation: a randomized trial, NAture Medicine 2024
    Elad Anter, Moussa Mansour, Devi G. Nair, Dinesh Sharma, Tyler L. Taigen, Petr Neuzil, Erich L. Kiehl, Josef Kautzner, Jose Osorio, Stavros Mountantonakis, Andrea Natale, John D. Hummel, Anish K. Amin, Usman R. Siddiqui, Doron Harlev, Paul Hultz, Shufeng Liu, Birce Onal, Khaldoun G. Tarakji, Vivek Y. Reddy & SPHERE PER-AF Investigators

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

    Yes

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

    N/A

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)?

    10,000

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.

    2 Year freedom from repeat procedure
    2 Year freedom from anti-arrhythmic drugs

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:

    1 year freedom from stroke and death

Further comments

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

Each manufacturers technology for PFA is different and may need manufacturer specific guidance

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: *

Prapa KANAGARATNAM

45. Date: *

22/07/2024

View results

Respondent

103 Anonymous

62:28
Time to complete

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

Pulsed Field Ablation (PFA) for atrial fibrillation (IP1957)

Your information

2. Name: *

Richard Balasubramaniam

3. Job title: *

Consultant Cardiologist

4. Organisation: *

University Hospitals Dorset

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

British Heart Rhythm Society

7. Nominated/ratified by (if applicable):

NICE

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

4293642

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?

Very familiar. One of the highest volume operators in the country for this technology practising at one of the highest volume centres.

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.

It is used at 11 sites at a minimum currently (Farapulse). It is being developed by a number of companies and the speed of uptake is likely to be significant as this is what has been seen across Europe and internationally.

The procedure is not used in other specialties as such but the modality is.

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).
- [x] I have done clinical research on this procedure involving patients or healthy volunteers.
- [x] 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
- ( ) No
- ( ) Other

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

yes

16. Does this have a multi-indication?

no (if i understand that question correctly)

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 a major development in terms of safety and speed. It is using a completely different modality which is safer and quicker.

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?

It is likely to replace the existing standard of care in many but not all situations on grounds of speed and safety.

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

Not yet but many companies are tweaking the procedure to provide even more benefits to the patient.

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.

Most centres use radiofrequency ablation or cryoablation for AF ablation procedures

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?

None with a similar mode of action

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?

Safety and speed - efficacy appears to be similar (not yet definitively proven to be superior in terms of efficacy but this may happen in the future)

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

1st time AF ablation patients

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?

Yes - safer, quicker and hence more patients with AF could be treated leading to lesser AF admissions

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

General anaesthesia is advisable

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

It is good practice to observe at another centre prior to starting these procedures in one's own centre. Most current AF ablation practitioners will find the transition to PFA relatively straightforward procedurally

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

The adverse events are significantly reduced compared to current widely used AF ablation methods - there have been no instances at all of the most dangerous complication of atriooesophageal fistula at all using this technology. For the latest published evidence on this, please refer to the following publication in Nature Medicine:

https://www.nature.com/articles/s41591-024-03114-3

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

Freedom from AF, reduction in complications, symptomatic improvement for patient

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

The technology is relatively new so we do not have long term outcome data beyond a few years but the initial data is highly encouraging and there is no reason to feel longer term data should be any different vs current standard of care.

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

No

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.

https://www.hrsonline.org/news/press-releases-statements/hr2024-features-recent-pfa-developments?gad_source=1&gclid=Cj0KCQjwq_G1BhCSARIsACc7NxoAkC-e6ZM78q9zIXTHmsExuQYjuaQZ4n3EdomGY-u6gmI5yzw8MBYaAnfsEALw_wcB

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

https://www.nature.com/articles/s41591-024-03114-3

https://www.sciencedirect.com/science/article/pii/S2405500X21001961

https://www.nejm.org/doi/full/10.1056/NEJMoa2307291

https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.123.063988

https://www.nature.com/articles/s41591-024-03022-6

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

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)?

Difficult to answer as it would depend on availability but in our population of around 1 million, at least 200 could be put forward for AF ablation using PFA

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.

In accordance with current NHS England recommendations and PROMS data

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:

Safety data as collected by the Manifest trial (https://www.nature.com/articles/s41591-024-03114-3) - at time of implant, 3 months and 12 months later

(

Further comments

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

No further comments at this stage - as with all procedures, it is important to keep an accurate registry for patients undergoing this procedure with good follow up data

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: *

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

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

I have received honoraria to speak or been on conferences sponsored by Boston, Medtronic, Abbott and Biosense as well as presenting at BHRS events and at Heart Rhythm Congress, UK

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: *

Richard Balasubramaniam

45. Date: *

14/08/2024

View results

Respondent

99 Anonymous

92:20
Time to complete

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

Ross Hunter

Your information

2. Name: *

Ross Hunter

3. Job title: *

Professor of Cardiology, Clinical Director of Arrhythmia Services

4. Organisation: *

St Bartholomew's Hospital

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

BHRS

7. Nominated/ratified by (if applicable):

BHRS

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

GMC 6031316

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 very familiar with AF ablation. I am the Clinical Director for Arrhythmia Services at Barts Hospital which is the highest volume AF ablation unit in the country. According to NICOR I am also one of the highest volume AF ablators in the country.

I am also familiar with PFA technology. I have performed AF ablations using the Farapulse system (Boston Scientific) and the Varipulse system (Biosense Webster). I have also watched other systems in use. I a familiar with the data surrounding PFA and the different systems.

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.

I am currently using PFA technology for AF ablation. In answer to those specific points:
- The AF ablation procedure is widely performed in the NHS albeit mostly within specialist centres (57 centres according to NICOR). NICOR data shows that in the year 2022-23, 11 454 AF and related AT ablations were performed. All of these could potentially be done with PFA. In the NHS, catheter ablation procedures are mostly performed under local anaesthetic - I am not aware of good data for this but I would estimate that only 25% of cases are done with general anaesthesia, although this number is rising. PFA has been tried under deep sedation but this is not widely practiced and it is therefore largely dependent on general anaesthesia. I believe this will slow the uptake of PFA in the UK. I would estimate that 2 years from the release date that 20-30% of AF ablations will be performed using PFA, with further growth likely to perhaps 40-50% by 5 years.
- The procedure is not performed (and the technology not used) by clinicians in other specialties.
- The Arrhythmia specialty does not really refer patients for this procedure elsewhere or to other specialties. There are very few surgeons performing surgical AF ablation nationally using different techniques (not PFA) but this number is negligible.

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).
- [x] 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?

No

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 technology is used for catheter ablation of AF in a similar manner to other technologies. Data thus far suggests similar efficacy. It does allow for some flexibility for ablation that may improve outcomes fractionally but this remains to be seen and will be "evolution not revolution".

The main advantages that I can see are:
1. It is significantly faster than other technologies. An experienced operator would complete an AF ablation using PFA in 30-40 mins (Farapulse specifically, other manufacturers to be determined), compared to 40-60 using cryo, compared to 60-90 using radiofrequency ablation.
2. The potential for day case ablation is very high.
3. Patient experience is positive. There is little or no post operative pain, whereas there often is for RF and cryo.
4. There is likely a small safety advantage with PFA, although this is not proven yet as the complication rate is low with all technologies, so this will need a very large volume of patients to prove.

The main disadvantages are:
1. a likely higher price point.
2. dependency on general anaesthesia.

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?

PFA has the potential to become the new standard of care. However, it is dependent on general anaesthesia. Therefore some centres would likely not adopt this, or use it for only some cases. It would therefore exist alongside current technologies for use in catheter ablation procedures for the medium term, with a drift towards replacing conventional technologies for the most part over time.

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

No

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.

By far the most common technologies currently used for AF ablation are radiofrequency ablation and cryoballoon ablation.

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?

    No

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?

    1. Quicker procedures with a high likelihood of being day case procedures.
    2. Because of this, more procedures can be done and provision may increase/waiting lists reduce.
    3. Good patient experience in that very little post op pain compared to other technologies.
    4. Likely fractionally safer.

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

    Not really. All would benefit.

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?

    It is very quick, has little post op pain, and is excellent for day case procedures (ablation is often associated with an overnight stay). It would likely facilitate high volume services and reduce waiting times which in itself increases success rates. It remains unproven, but it likely has a fractionally lower complication rate and a fractionally higher success rate, although this difference is likely a small evolution.

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

    Only an increase in provision of general anaesthesia as it is not well tolerated under sedation.

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

    There is minimal training for anyone who is currently doing AF ablation procedures. It is very similar procedurally to using other technologies. Joining an operator experienced in PFA for a list is enough training. The company also facilitates this.

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

The adverse events with PFA are no different to that with all AF ablation technologies and relate mostly to the procedure rather than the technology as such. Problems include:
haematoma at the groin access site 1%, tamponade requiring a drain 1%, very serious problems including stroke, the need for cardiac or vascular surgery, or death are rare at approximately 2/1000 combined.

The risks of phrenic nerve palsy which occurs in 1% of cryoablations, and 2/1000 radiofrequency ablations do not seem to be a risk with PFA.

Also, the rare but awful complication of atrio-oesophageal fistula which has a mortality of 50%, has substantial morbidity and usually involves 1-2 months in hospital for those who survive, does not occur with PFA. This occurs for 1/1000 people having radiofrequency ablation and 1/10 000 having cryoablation.

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

There are limited data so far. The largest RCT to date showed a one year freedom from atrial arhrythmias following ablation with the Farapulse PFA system of 73%, which was the same as the comparator group undergoing conventional ablation. This is comparable to outcomes for the other PFA technologies demonstrated in smaller studies.

https://www.nejm.org/doi/full/10.1056/NEJMoa2307291

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

I don't think there are any uncertainties regarding non-inferiority compared to conventional AF ablation technologies in terms of safety and efficacy.

It remains to be seen whether PFA will be safer or have greater efficacy with further use.

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

no

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.

I don't know of anything sufficiently important or worth mentioning that will not be rapidly found on your literature search.

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

This is a very hot topic in catheter ablation on a world wide level. Most reputable AF ablation studies are registered on clinicaltrials.gov and there are many such studies and RCTs listed on there.

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

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)?

Although the number of patients with AF is enormous, a minority are put forward for catheter ablation. NICOR suggests there were 11 454 complex atrial ablation procedures performed in the year 2022-23, with a growth rate (excluding Covid period) of perhaps 2-5% per year. It is this pool pf patients who would really be eligible for this technology as opposed to others.

Given that the roll out of PFA would be limited by the fact that really it requires general anaesthesia for use, I think it would be used for perhaps a quarter of AF ablation procedures in place of existing technologies two years after UK release, and half of procedures five years after release, with a continuing but plateauing upward trend.

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.

1. procedure metrics are easily captured nationally via the compulsory NICOR dataset. A key benefit is the very short procedure times.
2. rates of day case discharge
3. patient experience. It is debatable what this is worth. My experience is that PFA is fantastic on this front and that patients wake up as if they have had nothing done. This could be demonstrated by looking at patient pain, symptoms and satisfaction.
4. Outcomes. Difficult to standardise without expensive ambulatory monitoring. However, new commissioning requirements mandate symptom scores be collected at baseline and 1 year post procedure. This could be used as a PROM for comparison to other technologies.

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:

1. safety end-points in terms of complication rates and readmission rates (usually up to 30 days).
2. Re-intervention rates, NICOR provide this at 1 and 2 years, so could use NICOR data to look at this.

Further comments

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

Only that this data collection is for PFA. However, there are many iterations of PFA rapidly hitting the market. These may not all be equal. Much of the experience thus far is with Farapulse which may sway the data being reviewed and the opinions fed back to NICE. Other PFA technologies could well be better or worse in different ways.

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
- [x] Indirect
- [ ] No interests to declare

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

I myself have no financial interests in PFA or any of the companies making PFA technologies. I am a director in a large department where others hold grants from companies making PFA technologies (although I am not currently in receipt of such grants). I myself have been involved in external evaluations of PFA technologies and limited market release in terms of using the PFA technologies in clinical practice. I myself was an inventor or STAR mapping and am a shareholder in Rhythm AI Limited which is a computer system used to map electrical activity in AF, although this is not an ablation technology as such and is unrelated to PFA.

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: *

R. Hunter

45. Date: *

07/08/2024

View results

Respondent

95 Anonymous

27:15
Time to complete

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

IP1957

Your information

2. Name: *

Steve Murray

3. Job title: *

Consultant Cardiologist & Electrophysiologist

4. Organisation: *

Newcastle upon Tyne NHS Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

GMC, BHRS, BCS

7. Nominated/ratified by (if applicable):

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

4099910

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 a user of the Glavanise Centauri system for PFA - which is "agnostic" to ablation catheter & mappign system. I am familiar with the Farapulse system from Boston Sci but I have not used it clinically. The Medtronic system - based on the old PVAC catheter - I have also not used, but in the past I was an international mentor/proctor for the PVAC catheter (this has been adapted to a PFA energy delivery system)

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.

PFA has been used as an energy modality for years in urology.
However delivery within cardiac ablation is relatively new to market, and largely limited to AF ablation. I have personal experience of using PFA for VT (ventricular tachycardia) ablation including epicardial ablation

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).
- [x] I have done clinical research on this procedure involving patients or healthy volunteers.
- [x] 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
- (•) The systems may be used for other arrhythmias - so perhaps consider expanding the ablation indcation?

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

AF ablation may also include atrial tachycardia & atrial flutter; as I mentioned previously, I have used it in VT ablation in the case of the Galvanise system

16. Does this have a multi-indication?

Possibly!

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?

Well the promise seems very innovative, but it is at the end of the day only another way to destroy cardiac tissue in a controlled way! (Ablation). The published data so far is perhaps not as fantastic as first promised! Many of the complications that were supposed to be impossible to cause have now been reported in industry sponsored studies!

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?

In some ways yes, but in other ways there are potential disadvantages, such as need for general anaesthetic; and of course it is more costly as its new!

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

Not really - only the modality of ebergy delivery

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.

Point to point radiofrequency ablation; balloon cryo ablation; small numbers of laser ablation.

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?

All the major medical device companies have PFA catheters in the pipeline; Boston Sci are "first to market" iwith their system, but the others are close behind

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?

Perhaps more durable and safer lesions - but again the promise has not necessarily been delivered to date in proper studies

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

Not above current procedures; perhaps persistent AF may be better treated but the data is so far lacking

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?

Only if it substantially increases the "first time success rate" - ie reduce redo procedures

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

Much more access to GA

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

Only a little - the procedure is essentially the same, just the energy used is different

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

Despite blood vessel and nerve damage being "impossible" with PFA as it is "tissue specific" in fact these have been reported in many studies - see ADVENT and the MANIFEST registry (Boston sponsored).
In our use we have been warned about R coronary spasm in flutter lines and the need for prophylactic nitrate, which is in direct contradiction to the promise!

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

Long term (>1 year) freedom of symptoms, freedom of AF (research definition = >30s)
Low complications - tamponade, vascular injury, phrenic and vagal nerve palsy, emboli and stroke

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

Cost and delivery in NHS setting with GA requirement versus cryo ablation (Boston themselves have published data comparing the two with minimal differences!)

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

As above

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.

    The major company papers are well publicised; our own first 25 with the Galvanise system was pubihed and presneted at BCS 2024 - Pesslie C et al, Heart 2024, 110;A113

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

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

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)?

    As many AF ablations per year could in theory be eligible - NICOR can update on this

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.

    The proposed NICOR CRM PROMS project would capture this 9planned but not enacted as yet); validated AF symptoms questionairres already exist

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:

Stroke, vascular injury, nerve palsy, embolus, recurrence of symptoms, hospitalisation, urgent healthcare review (out of hours, walk in centres, A&E attendances)

Further comments

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

The costs and resources needed to introduce this technology need to be factored in, as it may inadvertently lead to fewer cases being done due to GA requirements for not much more clinical efficacy

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. *

None

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: *

Steve Murray

45. Date: *

25/07/2024

View results

Respondent

113 Anonymous

17:49
Time to complete

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

IP1957

Your information

2. Name: *

tom wong

3. Job title: *

Consultant Cardiologist and Electrophysiologist

4. Organisation: *

Royal Brompton and Harefield Hospitals, Guy's and St Thomas' NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

GMC

7. Nominated/ratified by (if applicable):

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

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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.

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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 very familiar with this technology and have been using it in my clinical practice more than a year.

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.

    It is being used by over 30 centres in the UK (NHS and Private institutions). Electrophysiologist like myself performed this procedure and select patient to have this procedure.

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

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

Yes.

16. Does this have a multi-indication?

Yes

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?

PFA is very new in the field of electrophysiology. Novel indeed.

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?

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

The procedure is the same but the tool (PFA / non thermal ablation) is very new in this field.

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.

Thermal ablation to treat Atrial fibrillation.

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?

Thermal ablation to treat Atrial fibrillation. PFA is non thermal ablation.

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?

Safety profile is excellent with shorter procedure time.

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

Patient with symptomatic atrial fibrillation.

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?

    Yes. to improve safety and efficiency.

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

    No nee facility is required but only new equipment.

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

    Simple training to the physicians and supporting staff.

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

    Not appears to be any harm

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

Efficacy is the same as standard of care.

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

Long term outcome is not known.

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

Non

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.

    ADVENT (https://www.nejm.org/doi/full/10.1056/NEJMoa2307291)
    MANIFEST 17K (https://www.nature.com/articles/s41591 024 03114 3)
    Dual-energy lattice-tip ablation system for persistent atrial fibrillation: a randomized trial (https://www.nature.com/articles/s41591 024 03022 6)

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

    There are many

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

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)?

    >60% of patient who undergo AF ablation

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.

    Short, intermediate and long term outcomes are important.

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:

    Procedure related complications.

Further comments

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

    PFA opens a new era of catheter ablation.

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.

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- [x] No interests to declare

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

Non

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: *

tom wong

45. Date: *

22/12/2024