Engagement Report

Topic details

Title of policy or policy statement:	Percutaneous left atrial catheter ablation for the treatment of atrial fibrillation
Programme of Care:	Internal Medicine
Clinical Reference Group:	Cardiac services
URN:	1903

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered. There were 24 respondents in total, they mostly focused on the specific details of the eligibility criteria. Several peer-reviewed studies were also submitted by stakeholders for further review. Each response was carefully considered by members of the Policy Working Group and minor changes have been made to the eligibility criteria as a result.

2. Background

Atrial fibrillation (AF) is the most common arrhythmia (heart rhythm disorder). Some people with AF may have no symptoms at all whilst other people can have symptoms that come and go and yet others have constant symptoms. Symptoms of AF include shortness of breath, chest pain, feeling dizzy or a feeling of the heart beating rapidly (known as palpitations) and lethargy. AF significantly increases the risk of a stroke. AF-related strokes are more disabling and can prove fatal, more so than any other type of stroke. A blood clot can form in the heart when the heart is not beating in normal regular rhythm. If a clot breaks away from the heart and travels to the brain this may cause a stroke. AF can also cause heart failure in some people if their heart rate remains too fast for a long time. People with AF can be offered a range of medicines, known as anti-arrhythmic drugs, to try to restore and maintain a normal heart rhythm or to slow the heart rate down. These medicines may not always be successful or tolerated by people. In such cases, a procedure known as catheter ablation can be considered.

Ablation is the targeted destruction of the tissue within the heart that causes the arrhythmia (heart rhythm disorder). Ablation procedures are carried out in people that have non-permanent atrial fibrillation when medicines are not working or tolerated. Percutaneous left atrial catheter ablation is an ablation procedure that is carried out under sedation or a general anaesthetic. A small skin cut is made in the groin and thin tubes, known as catheters, are inserted into the femoral vein. These catheters are advanced into the upper chambers, the atria, of the heart under X-ray guidance. Certain parts of the left atrium are targeted with an energy source to isolate the areas that cause AF.

Catheter ablation is currently available on the NHS and there is evidence that supports its use in reducing the symptoms of AF. It is not clear how many times this procedure should be repeated if the symptoms return. NHS England has carefully reviewed the evidence to treat paroxysmal and persistent atrial fibrillation with catheter ablation. We have concluded that there is enough evidence to continue to make the treatment available at this time.

This policy proposition has been developed by a Policy Working Group made up of consultant cardiologists, a patient and public voice representative, a public health expert and senior managers from NHS England. (include overview)

3. Engagement

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The policy proposition was sent for stakeholder testing for 2 weeks from 18th January 2020. The comments have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the proposition might be recommended.

Respondents were asked the following questions:

- It is proposed that products will go for a period of public consultation. Please select the consultation level that you consider to be most appropriate:
    - changes that could reasonably be expected to be broadly supported by stakeholders - up to 4 weeks consultation
    - up to 12 weeks consultation to include some additional proactive engagement activities during the live consultation period
- Do you have a comment on any potential impact on the equity of access to left atrial ablation that may arise as a result of this policy?
- As this procedure is already routinely commissioned, do you have a comment on the general and specific inclusion criteria contained within the policy?
- Do you have a comment on the general and specific exclusion criteria contained within the policy?
- Do you have a comment on any potential impact this policy will have on current and future access to left atrial ablation for atrial fibrillation? Your comments could describe both perceived positive or negative impact(s).
- Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.
- Do you have any further comments on the proposed Policy document? If Yes, please describe below, in no more than 500 words, any further comments on the proposed changes to the document as part of this initial 'sense check'.

A 13Q assessment has been completed following stakeholder testing.

The Programme of Care has decided that there were complications or concerns raised during stakeholder testing about the potential for direct or indirect negative impacts on patients. Therefore, the proposition was subject to further public consultation. This decision has been assured by the Patient Public Voice Advisory Group.

4. Engagement Results

There were 24 respondents in total:

- 3 individuals
- 14 hospitals/Trusts
- 1 academic collaborative
- 4 AF related societies and charities – AICC, AF association, BHRS, BCCA
- 2 pharmaceutical companies

Feedback was generally positive, and many welcomed a national commissioning policy with eligibility criteria for AF ablation. Full responses can be found in the appendix.

5. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group and the Internal Medicine PoC. The following themes were raised during engagement:

Keys themes in feedback	NHS England Response
Relevant Evidence	
14 stakeholders submitted details of papers they believed to be relevant to the review and Policy Proposition – mostly in response to the questions regarding exclusion criteria contained within the Policy and regarding additional information that should have been considered in the evidence review. Most stakeholders submitted details of more than one study and several papers were suggested by more than one stakeholder.	38 studies were reviewed by a specialist from Public Health England. All studies reviewed did not fall within PICO search methodology. One study could not be sourced. Only RCTs were included in the evidence review. The methods of the rapid evidence review stipulate that subgroup results can be included in the review where presented in the evidence selected to examine clinical effectiveness, safety and cost effectiveness. Stakeholders identified factors that may influence the efficacy of catheter ablation, which whilst in scope of the PICO (subgroups that may benefit more), are not considered in the experimental studies included in the rapid evidence review.
CABANA trial – randomised controlled trial assessing whether catheter ablation	This large trial investigating AF ablation was published after the evidence review

is more effective than conventional medical therapy for improving outcomes in AF.	to inform this policy proposal was completed. Nonetheless, it was reviewed by the PWG at the stakeholder response phase. The outcomes of the CABANA trial do not materially change the evidence review nor policy proposal eligibility criteria.
Providencia et al, 2016 – meta-analysis of studies comparing hypertrophic cardiomyopathy (HCM) versus non-HCM controls. The outcomes of freedom from AF/atrial tachycardia, and acute procedure-related complications.	This study was commonly cited by stakeholders. This review suggests that ablation is more effective in selected HCM patients, especially those with paroxysmal AF and a small atrium and less effective in persistent AF. The policy proposal only excludes HCM patients with persistent AF, as highlighted in this study, these patients are less likely to have a 'successful' procedure and more likely to have repeat procedures.
Impact on equity of access	
Specific patients group denied access such as those with hypertrophic cardiomyopathy (HCM), atrial septal defect and those with a BMI>40	The PWG have carefully considered the views put forward by stakeholders, please see below for details on individual inclusion/exclusion criteria.
Inclusion criteria	
BMI – a number of respondents thought that having an absolute BMI cut-off may negatively impact those from low socioeconomic backgrounds. Others welcomed the requirement for an intensive weight management programme for some of these patients prior to being eligible for an ablation.	BMI is a strong indicator of procedural success and relapse of arrythmia, several studies were put forward by respondents on this topic which supported this view. An Equalities and Health Inequalities Assessment (EHIA) has been completed which aims to minimise adverse policy implications for those with a protected characteristic under the Equality Act 2010. Ensuring equal access to ablation for patients with a high BMI would negatively impact them as the risk to benefit ratio would be greater putting them at unnecessary risk.
Re-do criteria - caused confusion amongst stakeholders as it was often interpreted as 'no re-do procedures' being permitted. Some stakeholders felt mandating an external review for a patient who has already undergone a re-do procedure would cause unnecessary delay and	A separate re-do criteria section has now been included in the policy to aid clarity. Re-do procedures are commissioned if they meet these criteria. The re-do criteria has been amended to highlight that re-do procedures can be considered in patients with ongoing

that an internal review would be sufficient.	symptomatic episodes of atrial tachycardia as well as atrial fibrillation. The re-do criteria for paroxysmal AF have been amended to include atrial tachycardia, this means any ablation for atrial tachycardia will count towards the 2-ablation limit within the last 5 years. It is important to highlight that this is not an absolute limit as patients can have further ablation procedures under exceptional circumstances if reviewed and agreed by an expert external to the centre. The need for 'documented' ongoing symptomatic episodes was removed. The PWG agreed that some patients will know and understand their disease well and will not require 'documented' confirmation of episodes which may delay treatment. Mandating an external review was very carefully considered by the PWG and agreed via a formal consensus exercise. The PWG felt that the need for an external review at this stage of the patient pathway was appropriate to prevent unnecessary procedures and therefore reduce waiting times for patients most likely to benefit from an ablation and remove procedural risk for those least likely to benefit.
Antiarrythmic drugs – a minimum 3-month trial of at least 2 rate control agents was highlighted to be overburdensome for those who may not be able to tolerate pharmacological options.	A duration of 3 months is appropriate to trial 2 drugs and monitor for any adverse events.
Persistent AF– some respondents interpreted DCCV as mandatory prior to ablation in persistent AF. The definition of recurrence 'within' 12 months was also challenged. Atrial diameter <55m as an absolute criterion was raised as potentially discriminatory to certain patients, especially those of short stature.	DCCV is not compulsory but cardioversion is (pharmacological or DCCV). The definition of persistent AF has been amended to 'two or more episodes in the previous 24 months' as opposed to '12 months. The remaining definition is unaltered. The inclusion for requiring left atrial diameter <55mm has been modified to

Another point highlighted was that the suggestion of trialling a minimum of two agents assumes that rate control has not already been achieved by one agent, or no agents.	include left atrial volume <80ml as an alternative measurement. Inclusion criteria modified to 'patients should remain symptomatic and have evidence of attempted rate control with up to two agents (beta-blockers, rate-limiting calcium channel blockers or digoxin) for at least 3 months' instead of a minimum of two agents.
Exclusion criteria	
Risk factors for ablation success - Some respondents were keen to have more prescriptive criteria regarding risk factors for poor procedural success such as an exclusion for obstructive sleep apnoea patients.	This was considered carefully by the PWG, although there is emerging evidence on various patient factors which may reduce success of an ablation, the PWG felt it was not appropriate to exhaustively list these in this policy proposal, nor is it the purpose of this document.
Hypertrophic cardiomyopathy – concern about the exclusion of HCM patients with persistent AF	This topic was carefully reviewed along with the commonly cited Providencia review (2016). The PWG felt that excluding HCM patients with persistent AF is consistent with the evidence base, HCM patients with paroxysmal AF are eligible for an ablation.
Heart failure – the discrepancy between NYHA class between paroxysmal and persistent AF was highlighted.	The PWG agreed to change the exclusion criteria for paroxysmal AF from 'NYHA class III and IV when not in AF' to 'NYHA class IV when not in AF'.
Atrial septal defect device – concern was raised by numerous stakeholders about excluding patients with percutaneous ASD closure devices.	Multiple studies were presented during this phase which suggested that patients with an ASD device can benefit from an ablation and that there are skilled clinicians carrying out this technically difficult procedure. We have removed this as an exclusion criterion and have added it as an inclusion under appropriate circumstances, 'patients with percutaneous ASD closure devices who should only have an ablation in specialist Level 1 adult congenital heart disease centres who are experienced in dealing with such patients'.
Future access to ablation	
Disparity between ablation rates in England and other western European countries	We note the disparity in ablation rates per population in England compared to other Western European countries, however there is no concrete evidence

	on what the 'right' procedural rate is. We hope the introduction of this this policy will reduce unwanted variation within England.
Other	
Data collection – multiple stakeholders raised the important issue of collecting accurate data to inform the evidence base as well as highlight variability in provision.	NHS England is working with NICOR (National Institute for Cardiovascular Outcomes Research) to improve data collection as well as the quality of the data. All centres are mandated to submit data to NICOR.
Formulation of the eligibility criteria	The eligibility criteria have been informed by the evidence review, PWG expertise, a formal consensus exercise and also taken into account stakeholder responses. A further 4 weeks public consultation period is also planned.

6. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

The following change(s) based on the engagement responses has (have) been made to the policy proposition:

1. The re-do criteria have now been amalgamated under their own heading to aid clarity.
2. The need for 'documented' ongoing symptomatic episodes has been removed from the re-do criteria.
3. The re-do criteria has been amended to highlight that re-do procedures can be considered in patients with ongoing symptomatic episodes of **atrial tachycardia** as well as atrial fibrillation.
4. The re-do criteria for paroxysmal AF have been amended to **include atrial tachycardia**, this means any ablation for atrial tachycardia will count towards the 2-ablation limit within the last 5 years.
5. Patients with an atrial septal defect device removed as an exclusion criterion and added to the inclusion criteria under appropriate circumstances, **'patients with percutaneous ASD closure devices who should only have an ablation in specialist Level 1 adult congenital heart disease centres who are experienced in dealing with such patients**.
6. Definition of persistent AF has been amended to **'two or more episodes in the previous 24 months'** as opposed to '12 months. The remaining definition is unaltered.
7. The inclusion criteria left atrial diameter <55mm has been modified to include **left atrial volume <80ml** as an alternative measurement.
8. The HF exclusion criteria for paroxysmal AF has been modified from 'NYHA class III and IV when not in AF' to **'NYHA class IV when not in AF'**

9. Contraindication to long-term anticoagulation therapy modified to **‘Contraindication to anticoagulation therapy or heparin (in the absence of LAA occlusion device)’**.
10. Liver failure modified to **‘significant and permanent liver failure’**.
11. Persistent AF criteria for a period of rate control has been modified to ‘patients should remain symptomatic and have evidence of attempted rate control **with up to two agents** (beta-blockers, rate-limiting calcium channel blockers or digoxin) for at least 3 months’ instead of a minimum of two agents.

7. Are there any remaining concerns outstanding following the engagement process that have not been resolved in the final policy proposition?

No. Responses have been carefully considered and noted in line with the following categories:

- Level 1: Incorporated into draft document immediately to improve accuracy or clarity
- Level 2: Issue has already been considered by the CRG in its development and therefore draft document requires no further change