Engagement Report

Topic details

Title of policy or policy:	Catheter ablation for paroxysmal and persistent atrial fibrillation (adult)
Programme of Care:	Internal Medicine
Clinical Reference Group:	Cardiac Services
URN:	1903

1. Summary

This report summarises the responses NHS England received from engagement during the development of this policy proposition, and how this has been considered. The stakeholder testing generated feedback from 24 respondents and the public consultation feedback from 14 respondents. The stakeholder engagement identified 38 peer-reviewed studies and the consultation 44 articles or evidence sources were suggested for further review. The main themes of the engagement process were to clarify details within the inclusion and exclusion criteria of the policy. Each response was carefully considered by members of the Policy Working Group and minor changes have been made to the eligibility criteria and the policy proposition as a result.

A separate engagement report considers the feedback on the development of the shared decision making (SDM) tool and a patient reported outcome measure (PROMs) tool.

2. Background

Atrial fibrillation (AF) is the most common arrhythmia (heart rhythm disorder). Individuals can experience AF differently. Some individuals might have no symptoms, others have intermittent symptoms, and some individuals experiencing constant symptoms. Symptoms of AF include shortness of breath, lethargy (tiredness), chest pain, feeling dizzy or a feeling of the heart beating rapidly (known as palpitations).

Ablation is the targeted destruction of the tissue within the heart that causes the arrhythmia (heart rhythm disorder). 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. 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.

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 8/1/2020 to 22/1/2020. The comments were then shared with the Policy Working Group to enable full consideration of the 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 was completed following stakeholder testing.

The Programme of Care 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 was assured by the Patient Public Voice Advisory Group.

The policy proposition was amended in response to the stakeholder feedback and entered a four week public consultation between the 24/9/2020 till the 24/10/2020. The results were then shared with the Policy Working Group to enable full consideration of these comments and to support a decision on whether any changes to the proposition might be recommended.

Respondents were asked the following questions:

- Has all the relevant evidence been taken into account? -If you selected 'No', please give details
- Does the impact assessment fairly reflect the likely activity, budget and service impact? -If you selected 'No', what is considered to be inaccurate?
- Does the policy proposition accurately describe the current patient pathway that patients experience? - If you selected 'No', what is considered to be different?
- Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise as a result of the proposed changes that have been described?
- Are there any changes or additions you think need to be made to this document, and why?

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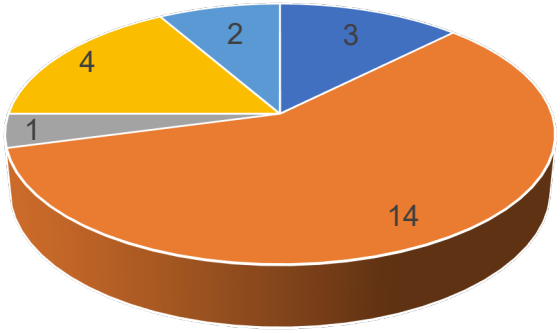
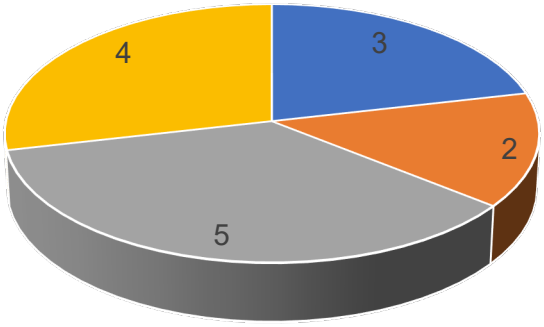
4. Engagement Results

Respondents in Stakeholder Testing (Total = 24)



- Individuals
- Hospitals/Trusts
- Academic collaborative
- AF related societies and charities – AICC, AF association, BHRS, BCCA

Respondents in the Consultation Process (Total =14)



- Patient/ Patient representative
- Service Provider
- Clinician
- Industry Representative

5. How has feedback been considered?

Responses to the engagement process have been reviewed by the Policy Working Group and the Internal Medicine Programme of Care (PoC). The following themes were raised during engagement:

Keys themes in feedback	NHS England Response
Relevant evidence	
14 respondents in the stakeholder testing submitted details of papers they believed to be relevant to the review and policy proposition. These evidence sources were mostly to suggest changes to the exclusion criteria contained within the policy and to provide additional information which stakeholders felt 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 after stakeholder testing. All studies reviewed did not fall within the 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

9 respondents provided additional evidence sources, including articles and relevant guidelines which they believed to be relevant to the policy proposition in the consultation process. This was mostly in response to questions regarding the exclusion criteria of the policy. Additional evidence was also provided regarding ablation techniques and the impact of differing ablation approaches on service delivery. Most respondents in the consultation process submitted details of more than one study. A full evidence summary report has been produced by the Public Health Lead for the stakeholder and consultation process. Some of the key trials and findings are summarised below.	effectiveness, safety and cost effectiveness. Stakeholders and those in the consultation process 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. 44 studies and evidence sources were identified in the consultation process. The evidence was reviewed by a specialist from Public Health England. Of the 44 evidence sources suggested, 8 were already identified within the evidence review process, 32 fell outside the PICO methodology for inclusion within the evidence review and 4 met the PICO search methodology for inclusion, but it was determined that their findings did not materially impact on the conclusions of the evidence review.
These 5 articles were suggested in both the stakeholder and the consultation process. • **CABANA trial results (Packer et. al. 2019 & Mark et. al. 2019)** – randomised controlled trial assessing whether catheter ablation is more effective than conventional medical therapy for improving outcomes in AF. Quality of life measures were also reported as a separate article, assessed through the AFEQT (AF effect on quality of life) questionnaire. • **Providencia et. al. 2016** – meta-analysis of studies comparing hypertrophic cardiomyopathy (HCM) versus non-HCM controls. The outcomes were freedom from AF/atrial tachycardia, and acute procedure-related complications. • **Kuck et. al. 2019-** a conference presentation, therefore the evidence falls outside the inclusion within the policy. • **Proietti et. al. 2015-** a systematic review to determine the progression of AF through an electronic database review.	The results from the CABANA trial were published after the evidence review was conducted. The findings of the trial determined that catheter ablation compared with medical therapy did not significantly reduce the primary composite outcome of death, disabling stroke, serious bleeding or cardiac arrest. The outcomes of the CABANA trial do not materially change the evidence review nor policy proposal eligibility criteria. The findings from Providencia et. al 2016, suggest that ablation is more effective in selected HCM patients. 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. This evidence does not materially change the inclusion/exclusion criteria of the policy. The study of Proietti et. al 2015 was excluded from the evidence review as it is not a comparison which includes the intervention of catheter ablation.
Hindricks et. al. 2020. European Society of Cardiology (ESC) guidelines	NHS England does not consider guidelines as evidence sources. The PWG considered the feedback and felt the

4 respondents in the consultation process highlighted the new ESC guidelines, which cover the full spectrum of patient diagnosis and management in AF.	consensus criteria on AF definitions should be added to the policy. The duration of anti-arrhythmia therapy and number of medications trialled were felt to be appropriate and were not altered. The development of the SDM and with the PROMs tools, facilitates patient informed choice. The results of the PROMs stakeholder assessment are published in a separate document.
Asad et. al. 2019-meta-analysis of RCTs to compare the primary outcome of all-cause mortality and secondary outcomes of cardiovascular hospitalisation and reoccurrence of atrial arrhythmia between catheter ablation and medical management approaches.	This evidence synthesis was published after the evidence review search and it includes primary evidence sources which are included within the evidence review. This does not materially change the conclusions within the included evidence review and the inclusion criteria for this sub-group populations.
Halder et. al. 2020- a randomised controlled trial of patients with long-standing AF to either surgical or catheter ablation. The primary outcome was freedom from AF and secondary outcomes of cost-effectiveness, adverse effects, improvement in patient symptoms and quality of life.	The current evidence review included evidence in the persistent AF group for surgical compared to catheter ablation includes a systematic review of 60 randomised control trials (RCT) (including 2 direct comparison RCT studies). These findings do not materially change the conclusions, within the evidence summary.
Impact on access caused by COVID-19	
9 respondents in the consultation process highlighted the impact that COVID-19 has placed on the health system and this may negatively impact equitable access, given that routine AF ablations had been deferred and some patients may now not be eligible for an ablation under the new policy proposition criteria.	NHS England appreciate the challenges that COVID-19 has placed on local health systems, but the policy will be enacted when routine and local services can resume.
Impact on access and equity for population groups	
Specific patient groups excluded or with restriction on receiving an ablation procedure such as those with HCM, atrial septal defect, mitral valve disease and those with a BMI>40 were highlighted within the stakeholder and also consultation process. Evidence sources were provided by stakeholders and consultation respondents to support viewpoints of population groups which they felt could be adversely affected by the policy.	The PWG have carefully considered the views put forward by stakeholders and within the consultation process. Please see below for details on individual inclusion/exclusion criteria. The evidence sources presented during the engagement process, fell outside the PICO methodology for inclusion within the policy.
Inclusion criteria	
Body Mass Index (BMI) – a number of respondents in both the consultation and	BMI is a strong indicator of procedural success and relapse of arrythmia, several

the stakeholder process thought that having an absolute BMI value between 35-40 with a requirement to lose > 10% of weight may negatively impact those with AF. Other respondents welcomed the requirement for an intensive weight management programme, wanting this to be extended to those excluded from ablation with a BMI of > 40. Within the consultation process there were 9 negative comments about the BMI inclusion criteria, 1 neutral comment and 2 supportive comments.	studies were put forward by respondents on this topic which supported this view. An Equality 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.
Antiarrhythmic 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. This was highlighted in both the stakeholder and consultation process. Some respondents highlighted the ESC guidelines to support their view. There were 8 comments on the use of antiarrhythmic drugs within the consultation process feedback.	The PWG determined the anti-arrhythmic trial from a consensus process and feel that a duration of 3 months is appropriate to trial 2 drugs and monitor for any adverse events. This is due to the risk and benefits of an ablative procedure compared to drug therapy. Inclusion criteria were modified after the stakeholder feedback. This determined that if '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. No further changes were made as a result of the consultation process.
Persistent AF– The definition of recurrence 'within' 12 months was challenged within the stakeholder assessment and a suggested consensus definition from the ESC guidelines was suggested in the consultation process. Some respondents within the stakeholder and also consultation process interpreted direct current cardioversion (DCCV) as mandatory prior to ablation in persistent AF. Within the consultation process, 3 comments discussed the requirement for a temporal link between the symptoms and rhythm change. Atrial diameter <55m as an absolute criteria was raised as potentially discriminatory to certain patients, especially those of short stature. The consultation feedback also highlighted that this univariant measure did not take into consideration other key factors	The definition of persistent AF has been amended to 'two or more episodes in the previous 24 months' as opposed to '12 months' after the stakeholder feedback with further clarification of 'sustained beyond 7 days, including episodes terminated by cardioversion after ≥ 7 days after the consultation feedback'. DCCV is not compulsory. Cardioversion could be either pharmacological or DCCV and the temporal link was to determine that interventions were resulting in symptomatic improvements for patients. The inclusion criteria requiring left atrial diameter <55mm has been modified to include left atrial volume <80ml as an alternative measurement after the stakeholder feedback, with no further alterations made as a result of the consultation feedback.

such as age, sex and also the consequences of remaining in AF e.g. in heart failure. In the consultation feedback, respondents highlighted the impact of a delay in ablation, citing that this could have increased adverse outcomes for patients and that the 2 year cut off could be impacted by the delay in treatment as a consequence of COVID-19.	The consultation feedback was considered, but as COVID-19 has impacted on all routine services, no additional changes were made as a result of this.
Repeat ablation criteria – in the stakeholder assessment this caused confusion 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 that an internal review would be sufficient. In the consultation feedback, 4 respondents suggested further detail as to the external review process, to reduce patient travel and delay in treatment. Respondents also highlighted that they felt this process would add additional clinical time on staff who were already challenged due to the workload generated by COVID-19.	A separate repeat ablation criteria section was included within the policy, from the stakeholder feedback, to aid clarity. Re-do procedures are commissioned if they meet the criteria. The need for 'documented' ongoing symptomatic episodes was removed as a result from the stakeholder feedback. 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 through 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. It was felt that this process would also remove procedural risk for those least likely to benefit.
Exclusion criteria	
Risk factors for ablation success - some respondents in the stakeholder feedback were keen to have more prescriptive criteria regarding risk factors for poor procedural success such as an exclusion for obstructive sleep apnoea patients. In the consultation process, clarity was added to the anticoagulation exclusion criteria.	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. The anticoagulation criteria were amended as a result of the consultation process, to include an absolute contraindication to anticoagulation and the use of a Left Atrial Appendage occlusion device was removed.
Hypertrophic cardiomyopathy – concern about the exclusion of HCM patients with persistent AF was mentioned in both the	This topic was carefully reviewed along with the commonly cited Providencia review (2016). The PWG felt that

stakeholder and consultation feedback. Within the consultation feedback, there were 9 responses on HCM populations.	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 New York Heart Association (NYHA) class between paroxysmal and persistent AF was highlighted in the stakeholder feedback. Within the consultation feedback the respondents highlighted 4 evidence sources to support their viewpoint that ablation had improved outcomes in those with heart failure.	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' in the stakeholder process. The PWG and the Public Health Expert considered the additional evidence presented as part of the consultation process and feel that the criteria are still valid, as it is only excluded in those patients classified as NHYA class 4 and this is due to the risk and benefits this patient population will derive from an ablative procedure.
Atrial septal defect (ASD) device – concern was raised by numerous stakeholders about excluding patients with percutaneous ASD closure devices.	Multiple studies were presented during the stakeholder 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. As a result of the stakeholder feedback, the ASD exclusion criteria have been amended and ASD patients fall within the 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'. No further amendments were made as a result of the consultation process.
Mitral valve disease - a respondent in the consultation process, suggested that those with mitral valve disease should be considered by the multi-disciplinary team, rather than an exclusion from ablation procedure.	The PWG reviewed this statement and felt that this exclusion was still appropriate as it relates to the success rates and longer-term benefits of an ablative procedure.
Other	
Data collection – multiple stakeholders and those in the consultation process 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.
Ablation technology/techniques - 14 respondents highlighted specific service delivery aspects which were impacted through the use of different ablative	The evidence sources were reviewed by the Public Health expert, but this was not a focus of the PICO criteria. The policy is focused on determining the inclusion and

techniques. Some respondents supplied evidence to support one ablative procedure over another.	exclusion criteria for ablation and not to determine individual differences between the types of ablation procedures. This would form part of a NICE Technology Appraisal process.
Formulation of the eligibility criteria- was highlighted as a concern in the stakeholder assessment	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 was also conducted and has informed the criteria.
Patient pathway- one consultation response discussed the draft patient pathway was poor quality and difficult to read.	The patient pathway has been removed from the policy.

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

The following changes based on the engagement responses have been made to the policy proposition:

From the stakeholder feedback:

1. The repeat ablation criteria have now been amalgamated under a separate 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 has 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 criteria 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.

From the consultation process:

1. Added and changed the definitions to match with the ECS consensus definitions :

   The European Society of Cardiology (ECS 2020) classifies AF as follows:
   - **first diagnosed: AF not diagnosed before, irrespective of its duration or the presence/severity of AF-related symptoms**
   - **paroxysmal AF: AF that terminates spontaneously or with intervention within 7 days**
   - **persistent AF: AF that is continuously sustained beyond 7 days, including episodes terminated by cardioversion after ≥ 7 days**
   - **permanent AF: AF that is accepted by the patient and clinician and no further attempts to restore/maintain sinus rhythm will be undertaken**

2. The **ESC reference** for these definitions has been added to the policy.

3. Amended the persistent AF definition to "**sustained beyond 7 days, including episodes terminated by cardioversion after ≥ 7 days**

4. Added clarity to the use of the external review to determine further interventional approach. Under exceptional circumstances a further ablation procedure can be considered but this needs to be reviewed and agreed by an **arrythmia** expert external to the centre, **which would be determined through the local network**

5. Reworded to assist with clarity "**an absolute contraindication to anticoagulation therapy or heparin**" and removed the reference to a LAA occlusion device.

6. Figure one, showing the patient pathway has been removed

7. Within the impact assessment, section B2.3 has been reworded to: "**performing procedures for which likely limited additional beneficial effect for patients**…."

8. Within the impact assessment the annual anticipated growth and the financial figures have been reviewed to ensure there is consistency across the sections.

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

There are no outstanding actions.