

## ORIGINAL PAPER

# A consultant-led anticoagulation review of all patients in one clinical commissioning group to prevent atrial fibrillation related stroke

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## Funding information

All four pharmaceutical manufacturers of DOACs were invited to co-fund the project and funding was secured from Daiichi-Sankyo. This funding was used for set-up costs of the service, staff salaries and reimbursement of physicians. None of the industry funding was paid directly to the physicians involved in the service, and support was not contingent on the prescription of DOACs through the service.

## Abstract

**Objective:** Ensuring patients with Atrial fibrillation (AF) are appropriately anticoagulated across NHS Bedfordshire Clinical Commissioning Group (BCCG) with the primary goal of reducing AF-related strokes.

**Methods:** With Inspira Health, BCCG adopted the Primary Care Atrial Fibrillation (PCAF) Service which is led by Consultant Cardiologists. PCAF uses retrospective clinical audit to identify patients who require prospective face-to-face review on the need for anticoagulation.

**Results:** 34 GP practices participated covering a 376 311 population (80% of BCCG). 12 573 patients' medical records were audited. The initial AF register was 7301 patients (AF prevalence 1.9%) and an additional 265 patients were identified through AF casefinder resulting in an AF prevalence of 2.0%. From 7566 patients with AF, 5831 were already on anticoagulants (77.1%), with 50.5% (n = 2947) on VKA medications and 49.5% (n = 2884) on direct oral anticoagulants (DOACs). Of the DOAC patients, 595 (20.6%) required dosage review or up to date blood tests. Case notes were reviewed for 1735 patients not on anticoagulation, with 901 (51.9%) patients deemed not eligible for anticoagulation. This left 834 (48.1%) patients who were eligible for, but not on, anticoagulation. A further 407 (13.8%) patients currently taking VKA medications were deemed sup-optimal with regards to INR control with TTR < 65%. In total 1241 patients were invited for review by a Consultant Cardiologist at their local GP practice, with an attendance rate of 90%. From all face to face and virtual consultations, 908 patients had anticoagulants prescribed, changed, management of INRs improved or were in the process of being anticoagulated at the time of follow-up. From this we would expect 36.3 AF related strokes prevented and a cost saving to the NHS of £470 200 per year.

**Conclusion:** Through comprehensive audit, BCCG have been able to ensure that patients with AF are appropriately anticoagulated in 80% of their catchment population. This has improved anticoagulation to prevent AF-related stroke.

## 1 | INTRODUCTION

Atrial fibrillation (AF) is the most common cardiac arrhythmia<sup>1</sup> and is known to cause one in four strokes.<sup>2-5</sup> Optimal treatment of AF results in a reduction in AF-related strokes which results in a reduction in mortality and morbidity and also, reduces the cost of stroke management to healthcare systems.<sup>6</sup>

To reduce the risk of AF-related stroke patients have historically been prescribed antiplatelet agents, in particular aspirin, and vitamin K antagonist (VKA) medications, usually warfarin. The beneficial effect of aspirin is minimal and is no longer recommended for AF related stroke reduction.<sup>7</sup> In contrast warfarin reduces the incidence of stroke in patients with AF by approximately two thirds.<sup>8,9</sup> However, anticoagulation with warfarin can be complex because of patient variation and multiple food and drug interactions affecting the bioavailability of the active drug. Because of VKA medications potential unpredictability, frequent blood tests are needed to monitor the effect of the drug to keep the anticoagulation within a narrow therapeutic window (international normalised ratio (INR) range between 2 and 3). This can prove challenging with the risk of INRs being too low and therefore offering little protection with regards to thromboembolic events or the INRs being too high and a risk of significant bleeding to patients.<sup>10</sup>

Alternative anticoagulants exist in the form of direct oral anticoagulants (DOACs), such as apixaban, dabigatran, edoxaban or rivaroxaban. DOACs have been shown to be at least as effective as VKA medications in reducing AF-related stroke with reduced risk of intra-cranial haemorrhage and similar bleeding profiles.<sup>11-20</sup> DOACs also have more consistent anticoagulant effects with few drug interactions and thus do not require monitoring of their anticoagulant effect reducing the need for regular blood testing.

Despite the range of anticoagulants available for use in patients with AF, Cowan and colleagues concluded that over one-third of high-risk patients remain untreated<sup>21</sup> and the National Institute for Health and Clinical Excellence (NICE) estimates that up to 45% of patients that should be anticoagulated are not.<sup>22</sup>

The importance of preventative treatments being offered to patients is identified within The NHS Long Term Plan which states 'Where 100 people with AF are identified and receive anticoagulation medication, an average of four strokes are averted, preventing serious disability or even death.'<sup>23</sup>

Our project focused on ensuring that patients with AF were appropriately anticoagulated across NHS Bedfordshire Clinical Commissioning Group (BCCG) with the primary goal of reducing AF-related strokes.

## 2 | METHODS

Working in partnership with Inspira Health, BCCG adopted the Primary Care Atrial Fibrillation (PCAF) Service model.<sup>24</sup> PCAF uses retrospective clinical audit to identify patients who require

### What's known

- Despite the range of anticoagulants available for use in patients with AF over one-third of high-risk patients remain untreated.
- The importance of preventative treatments being offered to patients is identified within The NHS Long Term Plan which states 'Where 100 people with AF are identified and receive anticoagulation medication, an average of four strokes are averted, preventing serious disability or even death.'

### What's new

- To our knowledge this is the largest geographical area covered in a systematic way to reduce AF-related stroke in the UK and meets a key component of the NHS Long Term Plan by addressing the need for effective preventative treatments in AF related stroke management.
- By working across the local health economy with a multidisciplinary team, it is possible to ensure effective anticoagulation in patients with atrial fibrillation.

prospective face to face review with Consultant Cardiologists to enable a decision on the need for anticoagulation.

### 2.1 | The PCAF service

#### 2.1.1 | PCAF service staff

The PCAF service involved three groups of staff:

1. Trained healthcare professionals with a nursing or allied health professional background (termed 'PCAF professionals').
2. Consultant Cardiologists from local hospitals.
3. Office administrative staff.

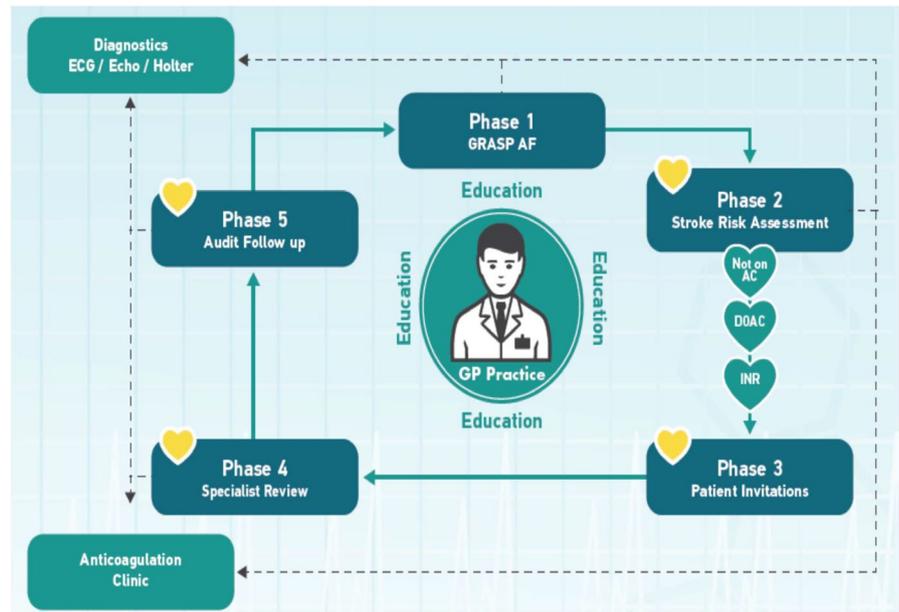
#### 2.1.2 | Practice enrolment

GP practices were informed of the service and invited to take part through the BCCG network and those practices interested in participating contacted the PCAF service staff.

#### 2.1.3 | Pathway

In each enrolled GP practice, the PCAF service was delivered via five phases, with an additional practice education programme (Figure 1). All work was carried out between September 2017 and November 2018.

**FIGURE 1** The Primary Care Atrial Fibrillation service audit cycle



### 2.1.4 | Phase 1

The case finder element of the Guidance on Risk Assessment in Stroke Prevention for Atrial Fibrillation (GRASP-AF) tool was used to search the records of all patients not currently listed on the practice's AF register in order to identify any further patients with a possible or probable diagnosis of AF. GRASP-AF is an automated electronic tool used widely in primary care in the UK. It is used to search electronic patient records to identify entries in the medical history that may potentially indicate a diagnosis of AF. This includes keywords as follows: AF resolved, probable/possible AF, CHA2DS2-VASc score calculated, irregular pulse, supraventricular tachycardia, history of AF, AF monitoring, heart rhythm therapy and/or anticoagulation therapy. Using this tool ensured that no high-risk patients were missed because they were not listed on the AF register. A PCAF professional then performed a comprehensive case note review of all identified patients, with the outcome being one of: (a) AF confirmed, or (b) patient does not have AF.

### 2.1.5 | Phase 2

The care management element of the GRASP-AF tool was then applied. This is an audit tool created in partnership with NHS Improving Quality that is used to risk-stratify patients and determine their current anticoagulation therapy.<sup>25</sup> This tool was used to audit all patients on the AF register, including those added following phase 1, to identify those at high-risk of stroke in whom anticoagulation is recommended or should be considered (CHA2DS2-VASc score  $\geq 1$ , excluding females with no additional risk factors) but who were not currently receiving anticoagulation therapy.<sup>26</sup>

The PCAF professional performed a comprehensive case note review of all identified patients, with the outcome being one of: (a) AF confirmed and patient eligible for a PCAF face-to-face review, (b) AF confirmed but only eligible for a 'virtual notes review' (applicable

to patients who were either housebound or were resident in a nursing home and were unable to attend the clinic), or (c) Patient not eligible to be invited for review in a PCAF clinic as anticoagulation therapy would not be indicated.

Patients not eligible for review was applicable to the following groups of patients:

1. Patients who had previously suffered an episode of AF but this had subsequently resolved (eg a single episode of AF following a surgical procedure or AF related to thyrotoxicosis which had since been successfully treated);
2. Patients with a current contraindication to anticoagulation (defined as on-going or recent untreated major bleeding, previous intracranial bleeding or a severe risk of bleeding);
3. Patients in whom, after a thorough review of their clinical records, it was found that there was no evidence that they had ever had AF.

In addition, all patients who were currently receiving VKA medications had their time-in-therapeutic-range (TTR) over the previous 6-month period calculated using an electronic TTR calculator; those who had a suboptimal TTR (defined as  $<65\%$  or two INR readings  $<1.5$ , two readings  $>5$  or one reading  $>8$  with no obvious reason) were also deemed to be at high risk and therefore eligible for review to assess the optimal anticoagulation strategy.<sup>27</sup>

All patients taking DOACs were reviewed to check correct doses were being prescribed as per NICE guidelines<sup>27</sup> and relevant Summary of Product Characteristics<sup>28-31</sup> and also to assess whether relevant blood tests were up to date.

### 2.1.6 | Phase 3

Two weeks before the scheduled PCAF clinic, an office administrator sent a letter to patients eligible for clinic review inviting them

to attend a PCAF appointment. Patients were then contacted by telephone 1 week prior to their appointment to explain the service and answer any queries, and again 1 day prior in order to minimise non-attendance ('call and recall' approach).

### 2.1.7 | Phase 4

A consultant cardiologist delivered PCAF anticoagulation assessment clinics within the patient's GP practice. The patient's current treatment was reviewed and, where appropriate, anticoagulation was prescribed in accordance with NICE guidelines. Other aspects of medical treatment for AF, such as rate or rhythm control therapies, were also reviewed where appropriate.

### 2.1.8 | Phase 5

Two months after PCAF Clinics, a PCAF professional would follow-up on recommendations made which includes: changes in medication, referral for further diagnostics and GP consultations regarding AF and anticoagulation. This review revealed the number of patients that commenced anticoagulation, changed from VKA to DOAC, declined recommendations, had AF ruled in/out following further diagnostics or had anticoagulation eligibility confirmed following other specialist opinion.

### 2.1.9 | Education

GPs, nurse clinicians, practice nurses and practice pharmacists were invited to take part in the consultant-led PCAF anticoagulation clinics, allowing opportunities for shared learning and discussion of individual cases.

This work was classified as Clinical Audit as it did not involve anything being done to patients beyond their normal clinical management and therefore did not require formal ethical approval. It aims to improve patient care through systematic review of care against explicit criteria and the implementation of change. We did not involve patients or the public in the design, conduct or reporting of our work.

## 2.2 | Statistical analysis

Continuous data are expressed as a total and mean average with range minimum to maximum. Categorical data are shown as absolute numbers and percentages and comparisons made with Chi-square tests (in all cases a  $P < .05$  was considered significant).

## 3 | RESULTS

BCCG have 48 GP practices with a population of 470 000. In total, 34 GP practices participated in the PCAF Service Review covering a

population of 376 311, which equates to 80% of the BCCG population. The average GP practice population size was 11 068 per practice (min 4511 – max 22 569).

In total, 12 573 patients' medical records were audited. The initial AF register size was 7301 patients with an AF prevalence of 1.9%. An additional 265 patients were identified through the AF casefinder search that had AF but not coded. This resulted in a total AF register size of 7566 and AF prevalence of 2.0%. The average AF register size was 222 per practice (min 62 – max 441).

From the 7566 patients with AF, 5831 were already on anticoagulants (77.1%), and of these 50.5% ( $n = 2947$ ) were on VKA medications and 49.5% ( $n = 2884$ ) were on DOACs.

Case notes were then reviewed for 1735 patients not on anticoagulation, with 901 (51.9%) patients judged not to be eligible for anticoagulation. This was because of either: anticoagulation not indicated (female gender the only risk factor), a contraindication to anticoagulation, an incorrect Read code for AF (commonly because of the application of an AF Read code at the time of investigation but not removed when AF not found) or resolution of AF (see Figure 2). This left 834 (48.1%) patients who were eligible for, but not on, anticoagulation.

A further 407 (13.8%) patients currently taking VKA medications were deemed sup-optimal with regards to INR control with  $TTR < 65\%$ . This gave a total of 1241 patients eligible for Consultant Cardiologist review.

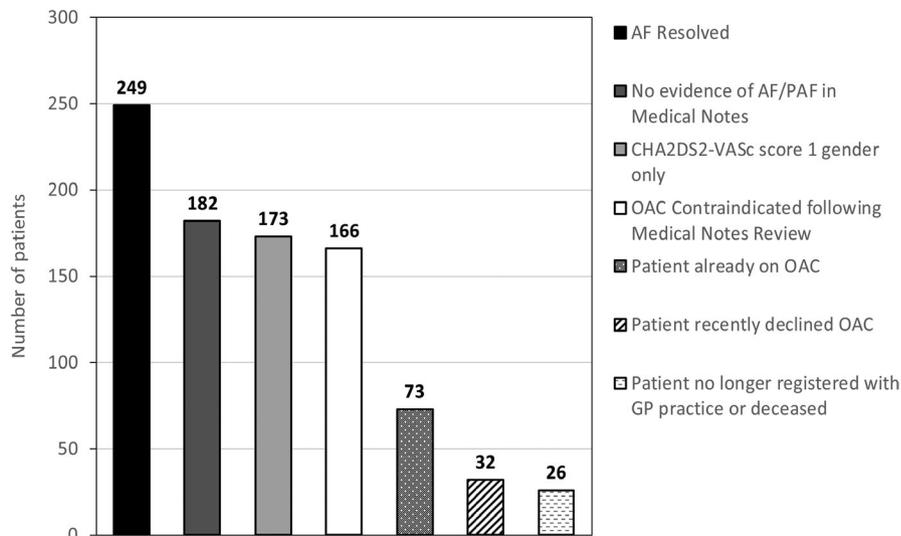
Of the 2884 patients taking DOACs, 595 (20.6%) patients required dosage review or up to date blood tests.

In total 1241 patients were eligible for review by a Consultant Cardiologist at their local GP practice and of these 821 attended from 912 invited in for a face to face consultation (attendance rate 90%). The outcomes of all face to face and virtual consultations were as follows: 933 recommended for anticoagulation (620 face to face and 313 virtual), 108 considered low-risk of stroke and therefore not anticoagulated, 78 required further diagnostics or other specialist opinion, 33 had contraindications for anticoagulation, 33 deemed not to have AF, 21 declined anticoagulation, 21 patients took information away to consider options and 14 patients were no longer registered with their GP practice or deceased (see Figure 3).

Two-months after each PCAF Clinic the outcomes from the Consultant Cardiologists' consultations was as follows: 359 were prescribed a DOAC (previously not anticoagulated), 229 changed from a VKA to a DOAC, 130 appropriately remained on VKA medications, 190 still required anticoagulation action to be completed, 78 declined anticoagulation, 35 had contraindications to anticoagulation, 174 patients not indicated for anticoagulation and 46 patients no longer registered with GP practice or deceased (see Table 1).

In total, 908 (73.2% of those reviewed) patients had anticoagulants prescribed, changed, management of INRs improved or were in the process of being anticoagulated at the time of follow-up. From this we would expect 36.3 AF related strokes prevented and a cost saving to the NHS of £470 200 per year; after taking into account the cost saving

**FIGURE 2** Reasons why patients were not eligible for anticoagulation review by a Consultant Cardiologist



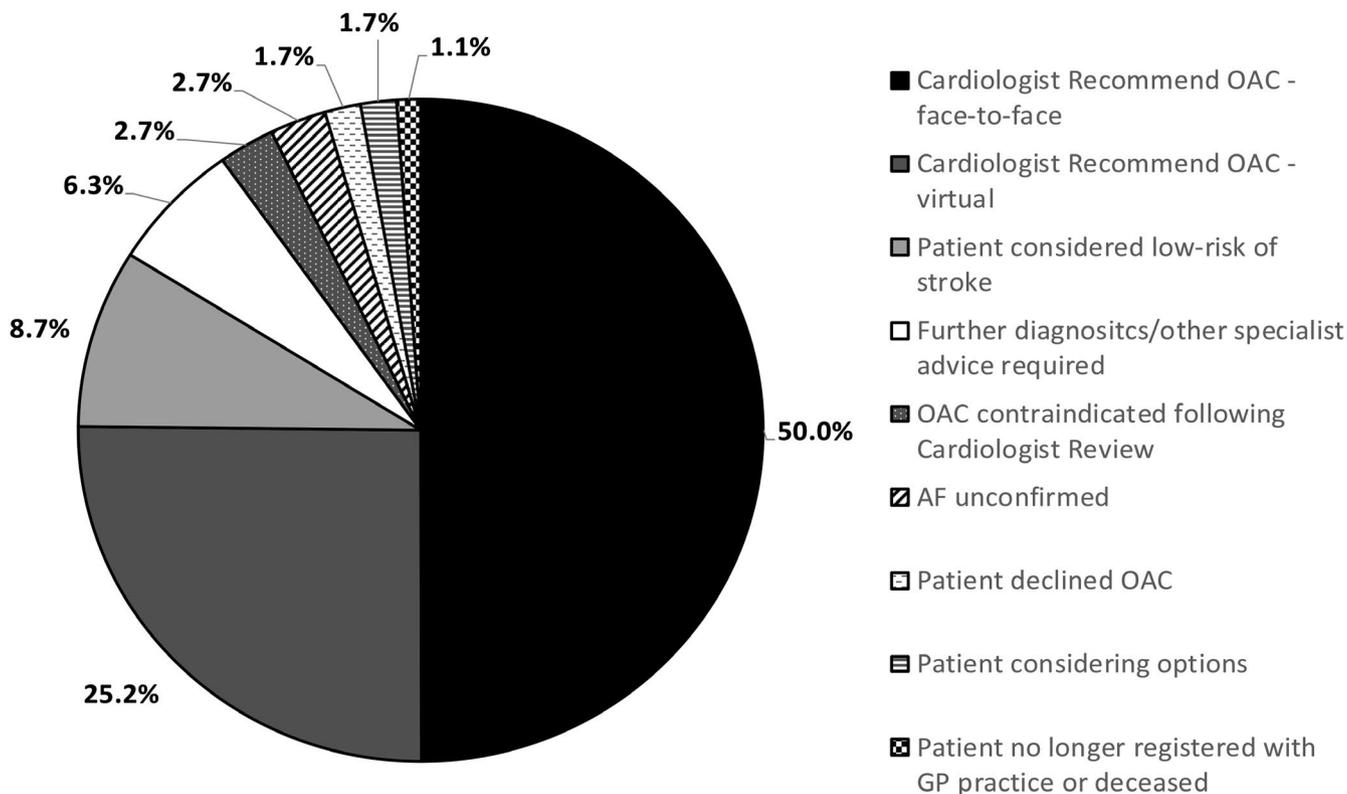
from avoided stroke admissions, the cost of new DOAC prescriptions and the potential cost of major bleeding risk (see Table 1). The number of expected deaths avoided is also estimated to be 21.6 per year based on a number needed to treat (NNT) of 42.

With the intervention of the PCAF service, the proportion of patients receiving anticoagulation increased significantly from 77.1% to 81.8% ( $P < .05$ ). In the patients on anticoagulants, 43.9% were on VKA medication (compared with 50.5% prior to the PCAF service,  $P < .05$ ), while 56.1% were on DOACs (compared with 49.5% prior to the PCAF service,  $P < .05$ ).

#### 4 | DISCUSSION

This paper reports on the work performed across the BCCG to ensure that patients with AF were appropriately anticoagulated. To our knowledge this is the largest geographical area covered in a systematic way to reduce AF-related stroke in the UK and meets a key component of the NHS Long Term Plan<sup>23</sup> by addressing the need for effective preventative treatments in AF related stroke management.

The proportion of AF patients who were anticoagulated increased significantly from 77.1% to 81.8% following this project.



**FIGURE 3** Recommendations from the Consultant Cardiologists' consultations

**TABLE 1** Outcomes from the Consultant Cardiologists' consultations after 2-mo follow-up

Outcome	Frequency (%)
Prescribed DOAC (previously not anticoagulated)	359 (28.9%)
Changed from Vitamin K Antagonist to DOAC	229 (18.5%)
Appropriately remain on Vitamin K Antagonist	130 (10.5%)
Still require anticoagulation action completing	190 (15.3%)
Declined anticoagulation	78 (6.3%)
Contraindicated from anticoagulation	35 (2.8%)
Not indicated for anticoagulation	174 (14%)
Patients no longer registered with GP practice or deceased	46 (3.7%)

Note: From this we would expect 36.3<sup>#</sup> AF related strokes prevented and a cost saving to the NHS of £470 200<sup>##</sup>

<sup>#</sup>AF related strokes prevented formula =  $908/25$  (NNT to prevent 1 stroke = 25).

<sup>##</sup>Cost saving formula =  $((\text{cost of stroke} = £24\,000 \times 36.3) - (\text{cost of average DOAC} = £650 \times 588) - (\text{cost of major bleed} = (£4000/100\,000) \times 470\,000))$ .

Additional Notes:

The 908 patients comes from those prescribed DOAC, changed from Vitamin K Antagonist to DOAC, appropriately remain on Vitamin K Antagonist and those still requiring anticoagulation action at the time of follow-up.

The 588 patients are those newly started on DOAC which comes from the 359 prescribed DOAC (previously not anticoagulated) and those changed from Vitamin K Antagonist to DOAC.

NNT to prevent 1 stroke see Reference.<sup>23</sup>

Cost of stroke see Reference.<sup>32</sup>

Cost of average DOAC provided by NHS Bedfordshire CCG.

Cost of major bleed see Reference.<sup>33</sup>

Also addressed by this project were the proportion of patients with sub-optimal TTRs taking VKA medications, with patients either being changed to DOACs or being educated on warfarin management to help improve TTRs. Patients with inappropriate DOAC doses or out of date blood tests were also highlighted and flagged accordingly for action by the GP practice.

Ninety percent of patients invited in for a face-to-face consultation attended. This high attendance rate was important in achieving the projects results. This was possible because of the call and recall method used and telephoning patients 1-week prior to the appointment and a further reminder the day before. The importance of telephone reminders has been noted in other studies.<sup>34,35</sup> It is also felt that the novel approach of having local hospital based Consultants attending patients local GP practices, bringing care closer to home, was an important factor in ensuring the highest number of patients attended face-to-face consultations.

The review of medical records found 265 patients who had AF were not appropriately coded. This is important in improving data quality and in helping GP practices ensure that submissions to the Quality and Outcomes Framework (QOF) are accurate for these patients. In reviewing medical records, it was also observed that because of patients underlying health conditions improving over time

and changes in clinical guidelines, patients previously recorded as 'contraindicated for anticoagulation' or as 'AF resolved' were now eligible for anticoagulation. This underpins the need for regular audit of patients with AF and that a historical recording of either a contraindication or resolution of AF may change with time.

We also observed that 78 patients eligible for anticoagulation declined it, equating to 7.9% of all eligible patients. Thus 92.1% of eligible patients in this study accepted the need for anticoagulation. Previous work<sup>36</sup> has shown that the uptake of anticoagulation is dependent on patient perceptions of the value of taking such medications and we believe that the PCAF service being a consultant-led service and the high attendance rate was a key factor in ensuring over 90% of eligible patients were anticoagulated appropriately.

The real value of this project is its primary goal to reduce AF-related strokes. An estimated 36.3 strokes have been prevented based on NNT 25<sup>23,37,38</sup> and with an estimated cost saving to BCCG health-care economy of £470 200 per year. This not only has a massive benefit in terms of quality of life for AF patients, but will significantly benefit patients' families as there is an associated reduction in poststroke care. The expected number of deaths saved is also estimated to be 21.6 per year based on NNT 42. There is of course a potential bleeding risk associated with anticoagulation treatments and NICE estimates this to be an increase in major bleeds of three per 100 000 people. This is estimated to be an increased cost of £4000 per 100 000 people.<sup>33</sup>

There is also significant clinical value in auditing DOAC doses to ensure that patients are being dosed appropriately. Using the incorrect DOAC dose is poor value for money; if the dose is too low fewer strokes will be avoided and if the dose is too high then patients are at higher risk of bleeding. Therefore, medicines optimisation is vital in ensuring DOAC dosing is right first time. Patient satisfaction has also been noted to be positive during the project with many patients appreciating the proactive approach taken by their local GP practices in the management of their AF and especially grateful with one to one consultations with Consultant Cardiologists. Improved working relationships between local Cardiologists and GPs has also been another added value from the project.

The PCAF service involves GP practice administrative and clinical staff, Consultant Cardiologists and PCAF trained Clinical Auditors. It is designed so that it can be used at individual or multiple GP practices or across other entire Clinical Commissioning Groups across the country. The model is designed to bring the expert knowledge of AF management to the GP practices and with GP or Pharmacist involvement in patient consultations, specialist training is provided with the intention of leaving each GP practice with the knowledge to improve AF management at the local healthcare setting. Clinicians are also engaged with quality and safety audits to identify each patient on a DOAC and check that the dose is correct and that the patients' renal function has recently been checked. Particular focus has been placed on ensuring that clinicians adopt creatinine clearance using the Cockcroft-Gault formula when prescribing the appropriate DOAC dose. In addition to this, we have worked with local Cardiologists to feedback on progress and have also shared the audit results with local haematologists; as initiation of anticoagulant also

occurs in secondary care. The results of the audit are also shared across the local Integrated Care System. Education of clinicians across BCCG is an important aspect of this project as is leaving a legacy to ensure anticoagulation is done correctly first time and for the right patients.

BCCG have a Cardiology Implementation Group which includes secondary care clinicians, nurses, managers, GPs, Public Health and Clinical Commissioning Group leads such as the Head of Medicines Optimisation. It was believed that this project is an area where we can make a difference across the local healthcare community. The 2015/2016 QOF data for BCCG showed that 22.2% patients (n = 1395) were not receiving anticoagulant therapy, despite being identified as high risk of stroke. The findings of this paper showed that in fact the percentage was marginally higher at 22.9% (n = 1735). It was also known from preliminary audit work that a significant proportion of patients were on the incorrect dose of DOAC compared with the licensed indications and a significant number of patients on warfarin were sub-optimally controlled. Focusing purely on the people on the AF register there was clearly potential to prevent a significant number of strokes. Across the CCG, GPs reported that they lacked confidence in treating and advising on anticoagulation for AF and there was a lack of resource in GP practices to run and manage AF patients identified through audit (eg GRASP-AF).

The work programme and business case was supported by the Cardiology Implementation Group and a lead Consultant Cardiologist was identified to sponsor the project alongside the Head of Medicines Optimisation and a GP with specialist interest in Cardiology. Consultant Cardiologists were encouraged to prescribe the most appropriate DOAC based on local and NICE guidelines.

Inspira Health conducted the PCAF audits for each individual GP practice and supported Consultant Cardiologists during the patient clinics. Audit results have then been shared with GP practices and across BCCG via GP study days. In addition to sharing audit results, Consultant Cardiologists have also taught at training sessions on AF at GP study days. Bringing specialist knowledge from secondary to primary care has helped build good working relationships across primary and secondary care.

This project highlights the importance of reviewing AF registers across the country and has numerous implications. A significant proportion of AF patients are potentially not on anticoagulation and 13.8% of patients managed with VKA medications, and 13.2% of patients on DOACS are sub-optimally anticoagulated. Using the PCAF model led to a high proportion of these patients being appropriately anticoagulated. It is hoped that the knowledge given by local consultant cardiologists delivering the face to face consultations in local GP practices will leave a legacy of good quality practice which will be confidently delivered by these practices in the future.

#### 4.1 | Limitations

This project is based on “real-world” medicine and has not been subjected to randomised control trial conditions. Our estimates of

stroke prevention and the reduction in potential deaths is not an observed finding but instead based on estimates from other studies examining the effects of anticoagulation.

## 5 | CONCLUSIONS

By working in partnership with Inspira Health and securing funding from industry, BCCG have been able to ensure that patients with AF are appropriately anticoagulated in 80% of their catchment population. This has enabled improved anticoagulation to prevent AF related stroke.

### CONFLICT OF INTEREST

NC, CH and ADG are members of Inspira Health and received funding from Daiichi-Sankyo for set-up costs and staff salaries. JPC received reimbursement from Inspira Health for delivering PCAF clinics. JPC has received travel bursaries and speaker fees from Daiichi Sankyo, Bayer and Pfizer.

### AUTHOR CONTRIBUTIONS

FG and JPC had the idea for the study. NC and CH were responsible for study design. ADG was responsible for data analysis. All authors contributed to preparation of the manuscript. JPC is guarantor for the study.

### ETHICAL APPROVAL

This work was classified as Clinical Audit as it did not involve anything being done to patients beyond their normal clinical management and therefore did not require formal ethical approval.

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