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# Primary Care Atrial Fibrillation Service: outcomes from consultant-led anticoagulation assessment clinics in the primary care setting in the UK

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## ABSTRACT

**Objective:** Stroke-risk in atrial fibrillation (AF) can be significantly reduced by appropriate thromboembolic prophylaxis. However, National Institute for Health and Care Excellence estimates suggest that up to half of eligible patients with AF are not anticoagulated, with severe consequences for stroke prevention. We aimed to determine the outcome of an innovative Primary Care AF (PCAF) service on anticoagulation uptake in a cohort of high-risk patients with AF in the UK.

**Methods:** The PCAF service is a novel cooperative pathway providing specialist resources within general practitioner (GP) practices. It utilises a four-phase protocol to identify high-risk patients with AF ($CHA_2DS_2$-VASc ≥1) who are suboptimally anticoagulated, and delivers Consultant-led anticoagulation assessment within the local GP practice. We assessed rates of anticoagulation in high-risk patients before and after PCAF service intervention, and determined compliance with newly-initiated anticoagulation at follow-up.

**Results:** The PCAF service was delivered in 56 GP practices (population 386 624; AF prevalence 2.1%) between June 2012 and June 2014. 1579 high-risk patients with AF with suboptimal anticoagulation (either not taking any anticoagulation or taking warfarin but with a low time-in-therapeutic-range) were invited for review, with 86% attending. Of 1063 eligible patients on no anticoagulation, 1020 (96%) agreed to start warfarin (459 (43%)) or a non-vitamin K antagonist oral anticoagulant (NOAC, 561 (53%)). The overall proportion of eligible patients receiving anticoagulation improved from 77% to 95% (p<0.0001). Additionally, 111/121 (92%) patients suboptimally treated with warfarin agreed to switch to a NOAC. Audit of eight practices after 195 (185–606) days showed that 90% of patients started on a new anticoagulant therapy had continued treatment. Based on data extrapolated from previous studies, around 30–35 strokes per year may have been prevented in these previously under-treated high-risk patients.

**Conclusions:** Systematic identification of patients with AF with high stroke-risk and consultation in PCAF consultant-led clinics effectively delivers oral anticoagulation to high-risk patients with AF in the community.

## Strengths and limitations of this study

- This study directly assessed the outcome of a novel approach of delivering consultant-led anticoagulation assessment clinics in general practitioner practices.
- The study was not performed as a controlled trial.
- Only a random sample of the patients was assessed to ascertain adherence to anticoagulation therapy.
- Our estimates on stroke prevention through the intervention are based on estimates of the effect of anticoagulation derived from other studies.

## INTRODUCTION

Atrial fibrillation (AF) is the cause of one in four strokes,[1–4] and approximately 5% of unselected patients admitted for acute stroke have previously undiagnosed AF.[5] Optimal prevention of AF-related strokes is of obvious interest to patients with AF, as well as avoiding the cost of stroke management to healthcare systems.[6] Oral anticoagulation (OAC) using vitamin K antagonists (most commonly warfarin) or non-vitamin K antagonist oral anticoagulant (NOAC) drugs can prevent approximately two-thirds of AF-related strokes.[7 8] NOAC therapy can be delivered with a simpler infrastructure in a cost-effective way,[9–11] and with a lower risk for bleeding, especially for intracranial haemorrhage.[8 12] Despite the clear benefits in high-risk patients with AF, OAC is underused in patients with AF: the National Institute for Health and Clinical Excellence (NICE) estimates that 42% of patients that should be anticoagulated are not,[13] and similar observations have been made in other countries.[14 15] The reasons for this are likely to be multifactorial, including concerns from general practitioners (GPs) and patients regarding

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bleeding risk, the need for regular International Normalised Ratio (INR) monitoring on vitamin K antagonists, unsystematic identification and management of patients with AF in need of OAC and lack of awareness of this need.

There are some data that hospital clinicians with specialist training in the management of AF will achieve higher anticoagulation rates in patients with AF than GPs or internists.[16] However, most patients with AF are not under specialist care in the National Health Service (NHS). The recently-released AF management guideline from NICE focuses on the need for improved rates of anticoagulation in patients with AF at elevated risk of stroke,[17] and a related NICE document 'How to Change Practice' promotes the concept of better integration between primary and secondary care.[18]

Foreseeing this healthcare priority, we instituted an innovative Primary Care Atrial Fibrillation (PCAF) Service in GP practices in Merseyside in the UK in June 2012. The PCAF service provides a hospital consultant-led service offering specialist expertise in the management of patients with AF at high stroke-risk within GP practices, and has now expanded to involve GP practices across England and Wales. We aimed to determine the outcomes of this service over the 2 years since its inception.

## METHODS

### The PCAF service

#### 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 or Consultant Stroke Physicians from local hospitals
3. Office administrative staff.

#### Practice enrolment

GP practices were informed of the availability of the service through direct systematic marketing or by approaching CCG Commissioning Managers and/or Medicines Management teams. As the service expanded, interest was expressed from GP practices based on recommendations from previously-enrolled practices.

#### Pathway

In each enrolled GP practice, the PCAF service was delivered via four phases, with an additional practice education programme (figure 1).

##### *Phase 1*

The PRIMIS+ AF Query Case Finder Set 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 (eg, 'irregular pulse' or 'digoxin therapy'). In phase 1 of the PCAF service, this 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. This was to ensure that no high-risk patients were missed by virtue of not currently being 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:

- AF confirmed;
- Patient does not have AF;
- Patient referred for further investigation to ascertain a diagnosis of AF.

If required, specialist support was provided by a PCAF Consultant Physician.

##### *Phase 2*

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.[19] 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 ($CHA_2DS_2$-VASc score ≥1, excluding females with no additional risk factors) but who were not currently receiving anticoagulation therapy.[20] The PCAF professional performed a comprehensive case note review of all identified patients, with the outcome being one of:

- AF confirmed and patient eligible for a PCAF face-to-face review;
- 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);
- Patient not eligible to be invited for review in a PCAF clinic as anticoagulation therapy would not be indicated. This 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 warfarin had their time-in-therapeutic-range (TTR) over the prior 6-month period calculated using an electronic TTR calculator; those who had a suboptimal TTR (defined as <65%) were also deemed to be at high risk

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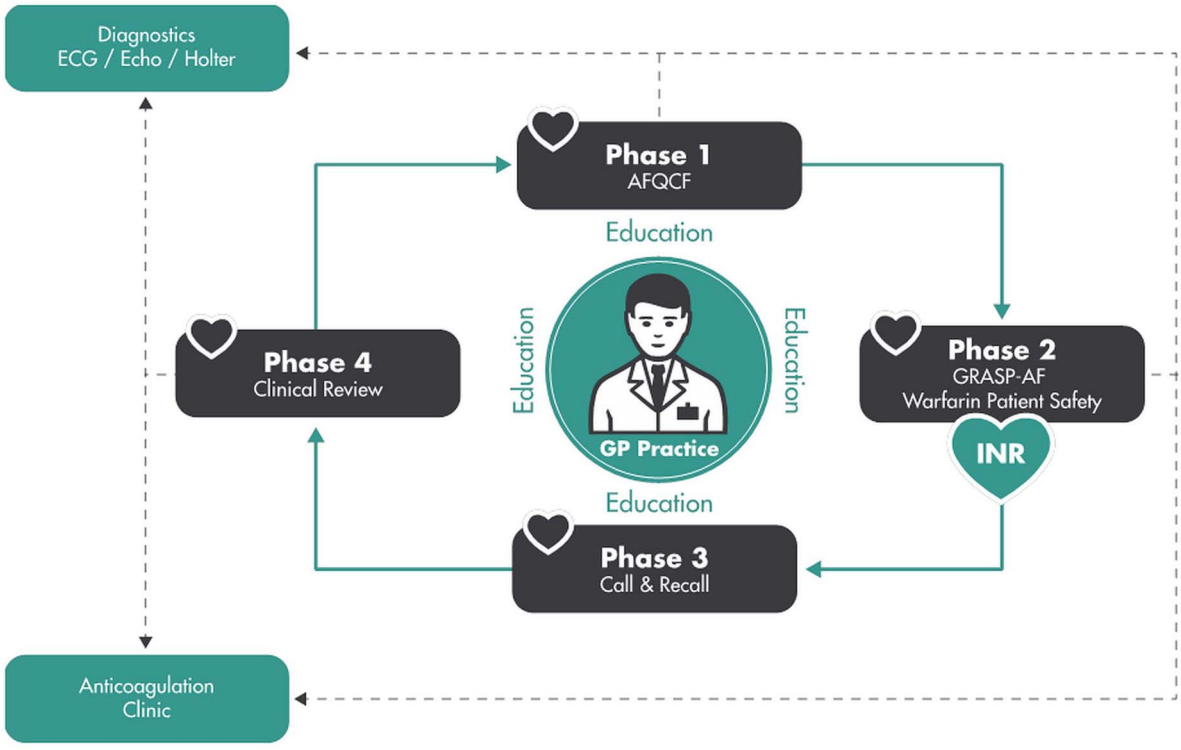



**Figure 1** Graphic showing the four phases of the Primary Care Atrial Fibrillation service pathway.

and therefore eligible for review to assess the optimal anticoagulation strategy.[17]

### *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. Literature detailing the reason for the clinic review and the risks and benefits of anticoagulation was also included with the invitation letter. 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).

### *Phase 4*

A consultant cardiologist or consultant stroke physician 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 and/or the local medicines management formulary. Other aspects of medical treatment for AF, such a rate or rhythm control therapies, were also reviewed where appropriate.

### 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. Additionally, staff members from enrolled practices had access to a consultant-led education programme. Practice staff attending this programme could count this towards their Continuing Professional Development/Continuing Medical Education targets for their annual appraisal but no other incentives for attendance were offered.

## Assessment of outcomes

The eventual outcome for each identified high-risk patients with AF in the PCAF pathway was recorded in the individual practices' network drive as well as on a central database. We assessed the uptake of anticoagulation in appropriate patients after intervention of the PCAF service compared to before. To assess on-going compliance with the prescribed treatment, case notes for patients who were prescribed a new or alternative anticoagulant agent were reviewed in a subset of GP practices in which the PCAF pathway had been completed at least 6 months prior. As per the definitions listed by the NHS Health Research Authority, this study was classified as a service evaluation rather than research and therefore did not require ethical review by a Research Ethics Committee.

### Statistical analysis

Continuous variables that are normally distributed are expressed as mean±SD, and variables that are not normally distributed are expressed as a median (IQR). Proportions were compared using the $\chi^2$ test. All tests

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were two-sided and p<0.05 was considered statistically significant.

## RESULTS

To date, the PCAF pathway has been implemented in 56 GP practices serving a population of 386 624 registered patients. For an average practice of 6000–7000 patients, it took approximately 12 h for a PCAF professional to utilise the search tools and perform a review of patient case notes, around 3 h for administrative staff to send invitation letters and contact patients by phone, and approximately 4 h for a physician (supported by a PCAF professional) to deliver the anticoagulation assessment clinic.

Outcomes from the four phases of the PCAF pathway are detailed below.

### Patients not on anticoagulation

#### Phase 1

For the 56 practices, clarification of the AF register resulted in a total population with AF of 7945 patients (prevalence 2.1%) (figure 2).

#### Phase 2

A total of 7487 (94%) of these patients had a $CHA_2DS_2$-VASc score of ≥1, of whom 4178 (56%; per-practice range 29%–78%) were already on anticoagulation. Case notes were then reviewed for 2914 patients not on anticoagulation, with 1335 (46%) patients judged not to be eligible for anticoagulation. This was due to either: anticoagulation not indicated (female gender the only risk factor), a contraindication to anticoagulation, an incorrect Read code for AF (commonly due to the application of an AF Read code at the time of investigation but not removed when AF not found) or resolution of AF. This left 1579 patients who were eligible for, but not on, anticoagulation.

#### Phase 3

These 1579 patients were invited to PCAF anticoagulation clinics using the 'call and recall' approach, of whom 1358 (86%) attended for review within 2 weeks of invitation. Only 221 (14%) patients did not attend for review, with 13 (1%) declining the invitation and 208 (13%) failing to attend.

#### Phase 4

Following review in clinic of the 1358 patients who attended, 1063 (78%) were confirmed to be eligible for anticoagulation. Of these patients, 84% had a $CHA_2DS_2$-VASc score of 2 or more, with the remaining 16% patients having a score of 1. Eighty-five per cent of these patients were also eligible using the criterion of a CHADS2 score ≥1, with 52% having a CHADS2 score ≥2. Antiplatelet therapy was being taken by 71% of patients at the time of review. Eleven per cent (n=117) of the 1063 patients not on anticoagulation had previously suffered a stroke or transient ischaemic attack (TIA).

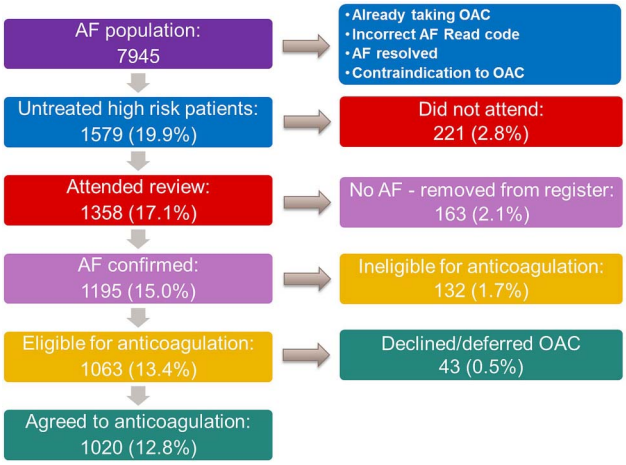



**Figure 2** CONSORT flow chart showing outcomes for patients not on anticoagulation identified through the PCAF service. AF, atrial fibrillation, OAC, oral anticoagulation; PCAF, Primary Care Atrial Fibrillation.

Following the consultation, 1020 (96%) patients agreed to start anticoagulation (warfarin in 43% and a NOAC in 53%). With regard to the 561 patients started on a NOAC, 12% of patients had previously tried but not tolerated warfarin, 21% had previously declined warfarin and 67% preferred a NOAC over warfarin. NOAC prescription was distributed among the three agents as follows: apixaban—17%, dabigatran—49% and rivaroxaban—34%.

Of the 43 (4%) patients that did not agree to start anticoagulation therapy at the time of their consultation, only 16 patients declined treatment, with the remaining 27 preferring to defer their decision pending further discussion with their GP.

Overall, taking into account all exclusions (patients deemed not to have AF and those ineligible for anticoagulation), the total number of patients eligible for anticoagulation registered to these 56 GP practices was 5471. With the intervention of the PCAF service, the proportion receiving anticoagulation improved from 77% (4187/5471) to 95% (5207/5471) (p<0.0001).

### Patients with a suboptimal TTR

A total of 4178 patients in the 56 GP practices were already anticoagulated with warfarin (figure 3). Case notes and INR records were reviewed for 3295 of these patients. A total of 387 (12%) patients with a suboptimal TTR (<65%) were identified and invited for review, of whom 83% attended. After clinical review, the majority of patients (62%) were advised to continue on warfarin. Reasons for this decision included: an improved TTR over recent readings, a clear reason for previous INR variability (such as previous courses of antibiotics), significant renal dysfunction contraindicating use of a NOAC, compliance issues that could be addressed at the

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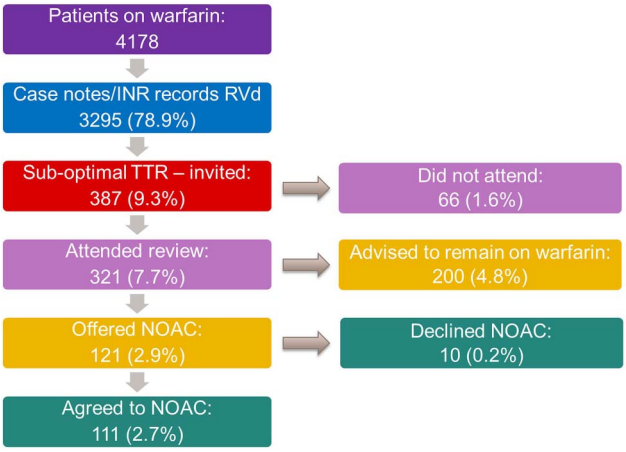



**Figure 3** CONSORT flow chart showing outcomes for patients on warfarin with a suboptimal TTR identified through the PCAF service. INR, International Normalised Ratio; PCAF, Primary Care Atrial Fibrillation; TTR, time-in-therapeutic range; NOAC, non-vitamin K antagonist oral anticoagulant.

clinic visit or concerns over non-compliance, in which case warfarin was felt more appropriate to a NOAC as compliance could continue to be assessed through INR monitoring. One hundred and twenty-one (38%) patients were offered a NOAC, with 111 (92%) agreeing to change therapy.

### Follow-up data

Eight random GP practices that had hosted the PCAF service at least 6 months previously were audited. A total of 87 patients initiated on a new anticoagulant agent were identified (median follow-up 195 (IQR 185–606) days). The characteristics of these patients (age 75 ±9 years, 60% male, median CHADS2 score 2 (1–3), median $CHA_2DS_2$-VASc score 3 (2–4)) were similar to those of the 1063 patients invited to PCAF clinics (age 74±10 years, 53% male, CHADS2 score 2 (1–3), $CHA_2DS_2$-VASc score 4 (2–6)). Twenty-five patients had been started on warfarin, 51 patients had been initiated on a NOAC as a first-line agent, and 11 patients had been switched from warfarin to a NOAC.

Of the 25 patients started on warfarin, 19 (76%) remained on this treatment at the time of the audit. One further patient had suffered recurrent deep vein thromboses on warfarin and had been switched by a consultant haematologist to a low-molecular-weight heparin, and therefore remained anticoagulated. Two patients had died during the follow-up period. In both cases, warfarin had been continued at the time of death and the deaths were unrelated to bleeding or stroke. Only 3 of the 25 patients requested to stop warfarin, resulting in an overall compliance rate of 88%.

For the 62 patients initiated on a NOAC, 50 (81%) remained on a NOAC. Three patients (all of whom had previously not been on any anticoagulation) had requested to switch to warfarin and remained anticoagulated. Three patients had died during follow-up; they had each remained on NOAC therapy up to the time of death and neither bleeding nor stroke were related to the cause of death. In one case, a new diagnosis of significant renal dysfunction was made (estimated glomerular filtration rate 35 mL/min) and NOAC therapy was stopped by the patient's GP. Five patients requested to stop anticoagulation, with three of these switching to an antiplatelet agent. Overall, the compliance rate with NOAC treatment was 85% (53/62), and with any anticoagulation therapy was 90% (56/62).

Taking both the warfarin and NOAC groups into account, 78 of 87 (90%) patients had continued anticoagulation following PCAF intervention, either the initial agent or an alternative.

## DISCUSSION

During the implementation of PCAF, we made several observations that can inform the future management of patients with AF: (1) there is a significant proportion of patients with AF at high risk of stroke in primary care that are not treated with OAC (23%), with a further group of patients inadequately anticoagulated with warfarin, and (2) a consultant-led anticoagulation service in the community will get the majority of these patients anticoagulated, including the facility for individual, patient-oriented anticoagulation decisions. Importantly, the PCAF intervention led to high compliance with newly-initiated anticoagulation. Taken together, PCAF has the potential to improve the utilisation of OAC, and to prevent strokes in high-risk patients with AF.

Evidence generated in the past decade underpins the use of OAC in the vast majority of patients with AF, that is, those with stroke risk factors (at least one, and certainly two of the $CHA_2DS_2$-VASc risk factors).[21 22] This was reflected in previous NICE guidance on AF, published in June 2006, that listed all but female gender of the $CHA_2DS_2$-VASc risk factors for use in stroke-risk stratification.[23] Hence, guidance applicable in the Merseyside region has effectively advocated anticoagulation use since 2006 in most patients who would now accrue a score of 1 or more under the $CHA_2DS_2$-VASc scoring system, though this has been substantially clarified in the latest guidance.[17] Despite this guidance, the PCAF programme identified 1063 high-risk patients without OAC, of whom 892 (84%) had a $CHA_2DS_2$-VASc score ≥2 and 171 (16%) had a $CHA_2DS_2$-VASc score of 1.[21 22]

Clinician-initiated health improvement reviews in primary care are known to commonly suffer from low attendance rates. However, the PCAF service was able to achieve an overall attendance rate of 85%. This is likely to be in part due to the 'call and recall' approach employed, with a letter invitation followed by phone call reminders 1 week and again 1 day prior to the appointment. Hence, this study corroborates prior studies showing that that attendance rates can be improved with telephone reminders.[24 25] In addition, it is possible that improved attendance may also have been related to the

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opportunity to see a specialist in the setting of their GP surgery.

Finally, the PCAF service has demonstrated a marked increase in the uptake of anticoagulation in high-risk patients with AF, including those who had previously been offered but refused anticoagulation. In some cases, the option of NOAC agents that do not require monitoring will have facilitated this decision, but past research has also shown that rates of uptake are dependent on patient perceptions of the value of anticoagulation.[26] We believe that the increased experience with managing anticoagulation in patients with AF, particularly with regard to NOACs, possessed by secondary care physicians in the fields of cardiology and stroke medicine helps to alter patients' perceptions in many cases towards acceptance and continuation of anticoagulation.

### Prevention of strokes by the PCAF service

The PCAF service predominantly identifies the at-risk primary prevention population, though a small proportion (11%) had suffered a previous stroke or TIA. In primary prevention patients, approximately 35 patients need to be treated with warfarin for a year to prevent one stroke, whereas, in patients with a prior stroke, the number needed to treat (NNT) is around 12.[7 27] Equivalent data are not available for the three available NOACs, but all have shown equivalent or superior efficacy compared to warfarin,[28–30] and modelling data have suggested a lower NNT compared to warfarin for each agent.[31] In this study, 1020 patients were newly anticoagulated due to the PCAF intervention, of whom 111 were secondary prevention patients. Compliance with therapy at follow-up was 90%, or approximately 918 patients. Furthermore, there were 111 patients who were previously on warfarin with a suboptimal TTR who have now started a NOAC. Based on the estimated efficacy, the intervention of the PCAF service may have prevented around 30–35 strokes per year in these 56 GP practices.

### The PCAF service as a model of care

In the traditional model of care, only a small proportion of patients typically gain access to specialist hospital-based resources. Within the field of AF, these are usually patients requiring input regarding rhythm management. At the same time, however, it is extremely difficult for primary care clinicians to not only be aware of developments in all areas of medicine, but also to have the knowledge and confidence to implement them. With specific regard to anticoagulation in patients with AF in primary care, familiarity with the $CHA_2DS_2$-VASc scoring system may not be universal, particularly as the CHADS2 score is still utilised for the Quality and Outcomes Framework (QOF). Additionally, primary care clinicians may have little or no experience with the NOAC agents, in part due to their relatively recent release and approval, and in part due to the limited number of conditions for which they are indicated.

The PCAF service took an innovative approach by bridging this boundary between primary and secondary care, providing specialist resources within the primary care setting. This strategy has two distinct advantages. First, patients currently managed solely within primary care are reviewed and, where appropriate, their anticoagulation treatment is optimised. Second, the educational legacy left within the GP practice following completion of the PCAF pathway enables such optimal treatment to be carried forward for future patients.

### Limitations

The PCAF intervention was not performed as a controlled trial, and our estimates on stroke prevention through the intervention are based on estimates of the effect of OAC derived from other studies. Furthermore, we only had resources to audit a random sample of the patients (8 GP practices) to ascertain adherence to anticoagulation therapy, and did not directly assess anticoagulation in all patients entered into PCAF.

## CONCLUSIONS

The PCAF service is an innovative care pathway bridging the boundary between primary and secondary care. Systematic identification of patients with AF with high stroke-risk and consultation in Consultant-led clinics through this service effectively delivers OAC to high-risk patients with AF in the community, with evidence of excellent continued compliance with treatment.

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**Contributors** MD was responsible for study design, data analysis and interpretation, drafting of the manuscript, final approval and is accountable for all aspects of the work. LP undertook study conception, drafting of the manuscript, final approval and is accountable for all aspects of the work. GJW was responsible for data interpretation, critical revision of the manuscript, final approval and is accountable for all aspects of the work. RMT was responsible for data acquisition and analysis, critical revision of the manuscript, final approval and is accountable for all aspects of the work. NC undertook study conception, critical revision of the manuscript, final approval and is accountable for all aspects of the work. JDM was responsible for study conception, critical revision of the manuscript, final approval and is accountable for all aspects of the work. PK was responsible for study design, drafting and critical revision of the manuscript, final approval and is accountable for all aspects of the work. DG undertook study conception and design, drafting and critical revision of the manuscript, final approval and is accountable for all aspects of the work. DG is the guarantor for the study.

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service, with demonstration of effective outcomes, the service is now funded primarily through commissioning by Clinical Commissioning Groups. This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

**Competing interests** Inspira Health Solutions Ltd., of which LP is a director and RMT/NC are employees, has received funding from Bayer Ltd, Boehringer Ingelheim Ltd and Pfizer Ltd to support the set-up of the PCAF service. MD has received physician fees from Inspira Health Solutions Ltd for delivering PCAF clinics. JDM has received speaker fees from Bayer Ltd, Boehringer Ingelheim Ltd and Pfizer Ltd and has received physician fees from Inspira Health Solutions Ltd for delivering PCAF clinics. PK has received consulting fees and honoraria from 3M Medica, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Daiichi-Sankyo, Johnson & Johnson, Medtronic, Merck, MSD, Pfizer, Sanofi, Servier and Takeda, and research grants from 3M Medica/MEDA Pharma, Bristol-Myers Squibb, Pfizer, Cardiovascular Therapeutics, Daiichi Sankyo, Sanofi Aventis, and St. Jude Medical. DG has received speaker fees from Bayer Ltd., Boehringer Ingelheim Ltd and Pfizer Ltd and has received physician fees from Inspira Health Solutions Ltd for delivering PCAF clinics; no other relationships or activities that could appear to have influenced the submitted work.

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